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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0347; FRL-8871-01-OCSPP]

Propamocarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes a tolerance for residues of

propamocarb in or on Vegetable, Brassica, head and stem, group 5-16.

The Interregional Project Number 4 (IR-4) requested this tolerance

under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 19, 2021. Objections and

requests for hearings must be received on or before December 20, 2021,

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-2020-0347, is available at [https://www.regulations.gov](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 is (202) 566-1744, and the telephone number for the OPP

Docket is (703) 305-5805.

Due to the public health emergency, the EPA Docket Center (EPA/DC)

and

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Reading Room is closed to visitors with limited exceptions. The staff

continues to provide remote customer service via email, phone, and

webform. For the latest status information on EPA/DC services and

docket access, visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Marietta Echeverria, Acting Director,

Registration Division (7505P), Office of Pesticide Programs,

Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington,

DC 20460-0001; main telephone number: (703) 305-7090; 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/title-40>.

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-2020-0347 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

December 20, 2021. 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-2020-0347, 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/dockets/contacts.html>.

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 September 10, 2020 (85 FR 55810) (FRL-

10013-78), 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

0E8832) by Interregional Project Number 4 (IR-4), Rutgers, The State

University of New Jersey, 500 College Road East, Suite 201W, Princeton,

NJ 08540. The petition requested that 40 CFR 180.499 be amended by

establishing a tolerance for residues of the fungicide propamocarb,

(propyl N-[3-(dimethylamino)propyl]carbamate), in or on Vegetable,

Brassica, head and stem, group 5-16 at 15 parts per million (ppm). That

document referenced a summary of the petition prepared by IR-4, the

petitioner, which is available in docket for this action, Docket ID

EPA-HQ-OPP-2020-0347, at [https://www.regulations.gov](https://www.regulations.gov/). Two comments were

received on the notice of filing. EPA's response to these comments is

discussed in Unit 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 in FFDCA section 408(b)(2)(D), 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 propamocarb including exposure

resulting from the tolerances established by this action. EPA's

assessment of exposures and risks associated with propamocarb follows.

In an effort to streamline its publications in the Federal

Register, EPA is not reprinting sections of the rule that would repeat

what has been previously published in tolerance rulemakings for the

same pesticide chemical. Where scientific information concerning a

particular pesticide chemical remains unchanged, the content of those

sections would not vary between tolerance rulemakings and republishing

the same sections is unnecessary and duplicative. 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 number of tolerance rulemakings for

propamocarb, in which EPA concluded, based on the available

information, that there is a reasonable certainty that no harm would

result from aggregate exposure to propamocarb and established

tolerances for residues of that chemical. EPA is incorporating

previously published sections from

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those rulemakings as described further in this rulemaking, as they

remain unchanged.

A. Toxicological Profile

For a summary of the Toxicological Profile of propamocarb, see Unit

III.A. of the December 5, 2019 rulemaking (84 FR 66616) (FRL-10000-33).

B. Toxicological Points of Departure/Levels of Concern

For a summary of the Toxicological Points of Departure/Levels of

Concern used for the risk assessment, see Unit III.B. of the February

7, 2017 rulemaking (82 FR 9519) (FRL-9957-68).

C. Exposure Assessment

Much of the exposure assessment remains the same, although the

dietary exposure and risk assessments for propamocarb were updated.

These updates are discussed in this section; for a description of the

rest of EPA's approach to and assumptions for the exposure assessment,

see Unit III.C. of the December 5, 2019 rulemaking.

EPA's dietary exposure assessments have been updated to include the

additional exposures for the new use of propamocarb on the commodities

in crop group 5-16. The assessment used the same assumptions as the

December 5, 2019 rule concerning tolerance-level residues, default and

empirical processing factors and 100% crop treated (PCT) for all

commodities in both the acute and chronic dietary exposure assessments.

Drinking water, non-occupational, and cumulative exposures.

Drinking water and non-occupational exposures are not impacted by the

new use, and thus have not changed since the last assessment. For a

summary of the dietary exposures from drinking water, see Unit III.C.2.

of the December 5, 2019 rulemaking. Propamocarb is registered for use

on golf course turf resulting in potential residential post-application

dermal exposure. During Registration Review, a dermal endpoint was not

selected; therefore, a quantitative residential dermal exposure

assessment was not necessary and was not conducted. EPA's conclusions

concerning cumulative risk remain unchanged from Unit III.C.4. of the

December 5, 2019 rulemaking.

Safety factor for infants and children. EPA continues to conclude

that there is reliable data showing that the safety of infants and

children would be adequately protected if the FQPA SF were reduced from

10X to 1X for all exposure scenarios. The reasons for that decision are

articulated in Unit III.D in the December 5, 2019 rulemaking.

Aggregate risks 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 the 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.

Acute dietary risks are below the Agency's level of concern of 100%

of the aPAD; they are 42% of the aPAD for all infants, the most highly

exposed subpopulation. Chronic dietary risks are below the Agency's

level of concern of 100% of the cPAD; they are 54% of the cPAD for

females 13 to 49 years old, the most highly exposed subpopulation.

A short-and intermediate-term oral adverse effect was identified;

however, propamocarb is not registered for any use patterns that would

result in either short- or intermediate-term oral residential exposure.

Short- and intermediate-term risk is assessed based on short- and

intermediate-term residential exposure plus chronic dietary exposure.

Because there is no short- or intermediate-term oral residential

exposure and chronic dietary exposure has already been assessed under

the appropriately protective cPAD (which is at least as protective as

the POD used to assess short- or intermediate-term risk), no further

assessment of short- or intermediate-term risk is necessary, and EPA

relies on the chronic dietary risk assessment for evaluating short- and

intermediate-term risk for propamocarb. Additionally, based on the lack

of evidence of carcinogenicity in two adequate rodent carcinogenicity

studies, propamocarb is not expected to pose a cancer risk to humans.

Therefore, based on the risk assessments and information described

above, EPA concludes there is a reasonable certainty that no harm will

result to the general population, or to infants and children, from

aggregate exposure to propamocarb residues. More detailed information

about the Agency's analysis can be found at [https://www.regulations.gov](https://www.regulations.gov/)

in the document titled ``Propamocarb Hydrochloride (HCl). Human Health

Risk Assessment for Proposed Uses in/on Vegetable, Brassica, Head and

Stem, group 5-16'' in docket ID number EPA-HQ-OPP-2020-0347.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method,

see Unit IV.A. of the December 5, 2019 rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S.

tolerances with international standards whenever possible, consistent

with U.S. food safety standards and agricultural practices. EPA

considers the international maximum residue limits (MRLs) established

by the Codex Alimentarius Commission (Codex), as required by FFDCA

section 408(b)(4). The Codex Alimentarius is a joint United Nations

Food and Agriculture Organization/World Health Organization food

standards program, and it is recognized as an international food safety

standards-setting organization in trade agreements to which the United

States is a party. EPA may establish a tolerance that is different from

a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain

the reasons for departing from the Codex level.

Codex MRLs for residues of propamocarb in/on cabbage, cauliflower,

and broccoli are 3 ppm, 2 ppm, and 1 ppm, respectively. As these levels

are significantly less than the recommended tolerance level of 15 ppm

for Vegetable, Brassica, head and stem, group 5-16, harmonization is

not possible because U.S. growers could have violative residues despite

legal use of propamocarb according to the label.

C. Response to Comments

Two comments were submitted to the docket in response to the

September 10, 2020 Notice of Filing. The first commenter stated that

there need to be regulations for residues of pesticide chemicals in/on

various commodities but expressed concern about the increasing use of

pesticides. The commenter urged EPA to fully evaluate the submitted

data as soon as possible to protect the U.S. public. Another commenter

expressed concerns regarding producers making products cheaper or using

pesticides for economic gain without considering human health. The

commenter stated that the government should have the ability to monitor

the chemicals put into food.

The Agency appreciates these comments and believes that the laws

applicable to pesticide tolerances address these concerns.

Specifically, the existing legal framework provided by

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section 408 of the FFDCA authorizes EPA to establish tolerances when it

determines that the tolerance is safe. As explained in this rule and in

the supporting human health risk assessment in docket ID number EPA-HQ-

OPP-2020-0347, EPA makes this determination based on an analysis of the

toxicology studies and then conducting detailed exposure and risk

assessments. The Agency's thorough process considers the validity,

completeness, and reliability of the available data as well as other

factors required by the FFDCA. For more information on the general

principles EPA uses in risk characterization and a complete description

of the risk assessment process, see <https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticide>.

V. Conclusion

Therefore, tolerances are established for residues of propamocarb,

(propyl N-[3-(dimethylamino)propyl]carbamate), in or on Vegetable,

Brassica, Head and Stem, Group 5-16 at 15 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in

response to petitions submitted to the Agency. The Office of Management

and Budget (OMB) has exempted these types of actions from review under

Executive Order 12866, entitled ``Regulatory Planning and Review'' (58

FR 51735, October 4, 1993). Because this action has been exempted from

review under Executive Order 12866, this action is not subject to

Executive Order 13211, entitled ``Actions Concerning Regulations That

Significantly Affect Energy Supply, Distribution, or Use'' (66 FR

28355, May 22, 2001), or to Executive Order 13045, entitled

``Protection of Children from Environmental Health Risks and Safety

Risks'' (62 FR 19885, April 23, 1997). This action does not contain any

information collections subject to OMB approval under the Paperwork

Reduction Act (PRA) (44 U.S.C. 3501 et seq.), nor does it require any

special considerations under Executive Order 12898, entitled ``Federal

Actions to Address Environmental Justice in Minority Populations and

Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis

of a petition under FFDCA section 408(d), such as the 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: October 8, 2021.

Marietta Echeverria,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending

40 CFR chapter I 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. 180.499, amend table 1 to paragraph (a) by adding in

alphabetical order the entry ``Vegetable, Brassica, Head and Stem,

Group 5-16'' to read as follows:

Sec. 180.499 Propamocarb; tolerances for residues.

(a) \* \* \*

Table 1 to Paragraph (a)

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Parts per

Commodity million

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Vegetable, Brassica, Head and Stem, Group 5-16.............. 15

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[FR Doc. 2021-22707 Filed 10-18-21; 8:45 am]

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