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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0520; FRL-10174-01-OCSPP]

Propamocarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes tolerances for residues of

propamocarb in or on onion, bulb, crop subgroup 3-07A; leek; and kale.

Bayer Crop Science LP requested these tolerances under the Federal

Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective September 30, 2022. Objections and

requests for hearings must be received on or before November 29, 2022

and must be filed in accordance with the instructions provided in 40

CFR part 178 (see also Unit I.C. of the SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket

identification (ID) number EPA-HQ-OPP-2021-0520, 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 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: Marietta Echeverria, Registration

Division (7505P), 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

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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-2021-0520 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

November 29, 2022. Addresses for mail and hand delivery of objections

and hearing requests are provided in 40 CFR 178.25(b), although the

Office of Administrative Law Judges encourages parties to file

electronically. See <https://www.epa.gov/sites/default/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf>.

 In addition to filing an objection or hearing request with the

Hearing Clerk as described in 40 CFR part 178, please submit a copy of

the filing (excluding any Confidential Business Information (CBI)) for

inclusion in the public docket. Information not marked confidential

pursuant to 40 CFR part 2 may be disclosed publicly by EPA without

prior notice. Submit the non-CBI copy of your objection or hearing

request, identified by docket ID number EPA-HQ-OPP-2021-0520, 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 December 21, 2021 (86 FR 72200) (FRL-

8792-06-OCSPP), 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 0E8891) by Bayer Crop Science LP, 800 N Lindbergh Blvd.,

St Louis, MO 263167. The petition requested that 40 CFR 180.499 be

amended by establishing tolerances for residues of the fungicide

propamocarb, in or on onion, bulb, crop subgroup 3-07A at 2 parts per

million (ppm); leek at 30 ppm; and kale at 20 ppm. That document

referenced a summary of the petition prepared by Bayer Crop Science LP,

the registrant, which is available in the docket, [https://www.regulations.gov](https://www.regulations.gov/). This supersedes the paragraph published in the

Federal Register on September 22, 2021 (86 FR 52624) (FRL-8792-03-

OCSPP). There were no comments received in response to either notice of

filing.

III. Aggregate Risk Assessment and Determination of Safety

A. Statutory Background

 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 those rulemakings as described

further in this rulemaking, as they remain unchanged.

B. 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).

C. 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).

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D. 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 to residues of propamocarb on imported commodities

of onion, bulb, crop subgroup 3-07A, leek and kale. 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

tolerances for imported commodities, 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. Because the

Agency has not identified a dermal endpoint, 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 Food Quality Protection

Act (FQPA) Safety Factor (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.

 Because no short-term or intermediate term adverse effect was

identified, propamocarb is not expected to pose a short-term or

intermediate-term risk.

 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.

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.

 The Codex has established MRLs for propamocarb in or on onion,

bulb, crop subgroup 3-07A at 2 ppm; leek at 30 ppm; and kale at 20 ppm.

The U.S. tolerances are harmonized with the relevant Codex MRLs.

V. Conclusion

 Therefore, tolerances are established for residues of propamocarb

in or on onion, bulb, crop subgroup 3-07A at 2 ppm; leek at 30 ppm; and

kale at 20 ppm.

VI. Statutory and Executive Order Reviews

 This action establishes tolerances 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

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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: September 15, 2022.

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 entries ``Kale'', ``Leek'', and ``Onion, bulb,

crop subgroup 3-07A'' and footnote 1 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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 \* \* \* \* \*

 Kale\1\................................................... 20

 \* \* \* \* \*

Leek \1\................................................... 30

Onion, bulb, crop subgroup 3-07A \1\....................... 2

 \* \* \* \* \*

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\1\ There are no U.S. registrations for these commodities as of

 September 30, 2022.

\* \* \* \* \*

[FR Doc. 2022-21186 Filed 9-29-22; 8:45 am]

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