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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0384; FRL-9995-89]

Indoxacarb; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

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SUMMARY: This regulation establishes a tolerance for residues of the

insecticide indoxacarb in or on corn, pop, grain at 0.02 parts per

million (ppm) and corn, pop, stover at 15 ppm. FMC Corporation

requested this tolerance under the Federal Food, Drug, and Cosmetic Act

(FFDCA).

DATES: This regulation is effective May 26, 2020. Objections and

requests for hearings must be received on or before July 27, 2020, 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-2019-0384 is available at [http://www.regulations.gov](http://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. 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. Please review the visitor instructions and additional

information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael L. Goodis, Director,

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

Environmental Protection Agency, 1200 Pennsylvania Avenue 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).

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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 Government

Publishing Office's e-CFR site at <http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl>.

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-2019-0384 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

July 27, 2020. Addresses for mail and hand delivery of objections and

hearing requests are provided in 40 CFR 178.25(b). 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-2019-0384, by one of

the following methods:

Federal eRulemaking Portal: [http://www.regulations.gov](http://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 <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along

with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Summary of Petitioned-For Tolerance

In the Federal Register of February 25, 2020 (85 FR 10642) (FRL-

10000-85), EPA issued a document pursuant to FFDCA section 408(d)(3),

21 U.S.C. 346a(d)(3), announcing the filing of a revised pesticide

petition (PP 8F8708) by FMC Corporation, 2929 Walnut Street,

Philadelphia, PA 19104. The petition requested that 40 CFR 180.564 be

amended by establishing tolerances for residues of the insecticide

indoxacarb, [(S)-methyl 7-chloro-2,5-dihydro-2-[[(methoxycarbonyl)[4-

(trifluoromethoxy)-phenyl]amino]carbonyl]indeno[1,2e][1,3,4]oxadiazine-

4a(3H)-carboxylate], and its R-enantiomer [(R)-methyl 7 chloro-2,5-

dihydro-2[[(methoxycarbonyl)[4-(trifluoromethoxy)phenyl]

amino]carbonyl]indeno [1,2-e][1,3,4]oxadiazine-4a(3H)-carboxylate], in

or on corn, pop, grain at 0.02 parts per million (ppm) and corn, pop,

stover at 15 ppm. That document referenced a corrected summary of the

petition prepared by FMC Corporation, the registrant, which is

available in the docket, [http://www.regulations.gov](http://www.regulations.gov/).

EPA published this document in response to a comment received from

FMC Corporation in response to a previously published notice of filing

of August 2, 2019. In a comment submitted in response to that August 2,

2019 document, FMC Corporation noted that the August 2, 2019 notice

indicated that E.I. du Pont de Nemours had filed the petition and that

the incorrect petition summary was contained in the docket. EPA also

noticed that the originally submitted petition did not actually request

tolerances for residues of indoxacarb in or on popcorn commodities,

despite the intent to do so. As a result, FMC Corporation submitted a

revised petition, including a corrected summary of the petition, to

correct the original notice error. One public comment was received in

response to the corrected notice of filing. EPA's response to this

comment is discussed in Unit IV.C.

Based upon review of the data supporting the referenced petition,

EPA is establishing a tolerance for residues of indoxacarb in or on

corn, pop, grain and corn, pop, stover.

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 indoxacarb in or on corn, pop,

grain and corn, pop, stover.

In the Federal Register on December 8, 2017 (82 FR 57860) (FRL-

9970-39), EPA published a final rule establishing a tolerance for

residues of the insecticide indoxacarb in or on corn, field, forage;

corn, field, grain; and corn, field, stover based on the Agency's

determination that aggregate exposure to indoxacarb is safe for the

U.S. general population, including infants and children. Because the

toxicity profile for indoxacarb has not changed since that last rule

was published, EPA is incorporating the discussion of that profile

(Unit III.A.) and the identified toxicological endpoints (Unit III.B.)

as part of this rulemaking.

EPA's 2017 exposure assessment remains current in providing an up-

to-date assessment of indoxacarb, as that assessment included exposures

to indoxacarb in or on popcorn commodities as reflected in this

document. Based on the current and newly proposed uses of indoxacarb in

or on corn, pop, grain and corn, pop, stover, exposures can occur both

from dietary sources (food + water) and in residential settings. For

aggregate risk assessment, risk estimates resulting from food, drinking

water, and residential uses are combined. Acute, short-and

intermediate-term, and long-term (chronic) aggregate assessments were

performed for indoxacarb. Further information about EPA's risk

assessment and determination of safety supporting the tolerances

established in the

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December 8, 2017 Federal Register action, as well as the new indoxacarb

tolerances can be found at [http://www.regulations.gov](http://www.regulations.gov/) in the documents

entitled ``Indoxacarb: Human Health Risk Assessment for Indoxacarb to

Support the Proposed New Uses on Corn (Field, Pop, and Grown for

Seed),'' dated October 24, 2017 (docket ID EPA-HQ-OPP-2017-0095), and

``Indoxacarb. Section 3 Registration for the New Use of Indoxacarb on

Popcorn. Abbreviated Residue Chemistry Review,'' dated September 16,

2019 (docket ID EPA-HQ-OPP-2019-0384), respectively.

The acute dietary risk estimates determined for indoxacarb (food +

water) were found not to be of concern at the 99.9th exposure

percentile for the U.S. general population and all population subgroups

and are below the Agency's LOC (<100% of the acute population adjusted

dose (aPAD)). In addition, the chronic dietary risk estimates

determined for indoxacarb (food + water) were found not to be of

concern for the U.S. general population and all population subgroups

and are below the Agency's LOC (<100% of the chronic population

adjusted dose (cPAD)). As indicated in the supporting documents, the

acute and chronic dietary risks are below the Agency's level of

concern: 56% of the aPAD for children 1-2 years old, the group with the

highest exposure level; 35% of the cPAD for all infants (less than 1

year old), the group with the highest exposure level.

The acute aggregate assessment is based on food + drinking water

exposures only, because there are no acute residential exposures

expected. For the short-, intermediate- and long-term (chronic)

aggregates, the highest non-dietary exposure scenarios were selected as

being protective of all other potential exposure scenarios--these were

from spot treatments to carpets [coarse and pin stream] for short-term

exposures, and from spot-on treatments of dogs for intermediate- and

long-term exposures. There are no acute, short-term, intermediate-term,

or long-term (chronic) aggregate risk estimates of concern for adult or

child aggregate exposure to indoxacarb as a result of the current and

proposed uses (short-term aggregate margin of exposure (MOE) = 120;

intermediate-/long-term aggregate MOE = 260) because EPA considers MOEs

of less than 100 to be of concern for aggregate risk.

Therefore, based on the risk assessments and information described

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

result to the U.S. general population, or to infants and children, from

aggregate exposure to indoxacarb residues. More detailed information on

the subject action to establish tolerances in or on corn, pop, grain

and corn, pop, stover can be found at [http://www.regulations.gov](http://www.regulations.gov/) in the

document entitled ``Indoxacarb. Section 3 Registration for the New Use

of Indoxacarb on Popcorn. Abbreviated Residue Chemistry Review.'' This

document can be found in docket ID number EPA-HQ-OPP-2019-0384.

IV. Other Considerations

A. Analytical Enforcement Methodology

For the enforcement of tolerances established on crops, two High

Performance Liquid Chromatograph/Ultraviolet Detection (HPLC/UV)

methods, DuPont protocols AMR 2712-93 and DuPont-11978, are available

for use. The limits of quantitation (LOQs) for these methods range from

0.01 to 0.05 ppm for a variety of plant commodities. A third procedure,

Gas Chromatograph/Mass-Selective Detection (GC/MSD), DuPont method AMR

3493-95 Supplement No. 4, is also available for the confirmation of

residues in plants.

The method may be requested from: Chief, Analytical Chemistry

Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD

20755-5350; telephone number: (410) 305-2905; email address:

[residuemethods@epa.gov](mailto:residuemethods@epa.gov).

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 not

established MRLs in corn, pop, grain and corn, pop, stover for

indoxacarb.

C. Response to Comments

EPA received one public comment in response to the corrected notice

of filing, generally opposed to any indoxacarb residues in or on corn,

pop, grain and corn, pop, stover. Although the Agency recognizes that

some individuals believe that pesticides should be banned on

agricultural crops, the existing legal framework provided by section

408 of the FFDCA states that tolerances may be set when persons seeking

such tolerances or exemptions have demonstrated that the pesticide

meets the safety standard imposed by that statute. This comment appears

to be directed at the underlying statute and not EPA's implementation

of it; the comment provides no information relevant to the Agency's

safety determination.

V. Conclusion

Therefore, tolerances are established for residues of the

insecticide indoxacarb in or on corn, pop, grain at 0.02 parts per

million (ppm) and corn, pop, stover at 15 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), nor is it considered a

regulatory action under Executive Order 13771, entitled ``Reducing

Regulations and Controlling Regulatory Costs'' (82 FR 9339, February 3,

2017). 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

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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: May 7, 2020.

Michael L. Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

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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. 180.564, add alphabetically the entries ``Corn, pop,

grain'' and ``Corn, pop, stover'' to the table in paragraph (a) to read

as follows:

Sec. 180.564 Indoxacarb; tolerances for residues.

(a) \* \* \*

(1) \* \* \*

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Parts per

Commodity million

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\* \* \* \* \*

Corn, pop, grain........................................ 0.02

Corn, pop, stover....................................... 15

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[FR Doc. 2020-10483 Filed 5-22-20; 8:45 am]

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