



BILLING CODE 6560-50-P

## 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.

**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 [*insert date of publication in the Federal Register*].

Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], 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> 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).

*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](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 *[insert date 60 days after date of publication in the **Federal Register**]*. 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>. 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 FFDCFA 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>.

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 December 8, 2017 **Federal Register** action, as well as the new indoxacarb tolerances can be found at <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 99.9<sup>th</sup> 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> 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*.

### *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 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]**

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

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

2. In § 180.564, add alphabetically the entries “Corn, pop, grain” and “Corn, pop, stover”

to the table in paragraph (a) to read as follows:

**§ 180.564 Indoxacarb; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

Commodity	Parts per million
* * *	* * *
Corn, pop, grain	0.02
Corn, pop, stover	15
* * *	* * *

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