

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2022-0576; FRL-11129-01-OCSPP]

### Imazapic; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of imazapic in or on rice, bran and rice, grain. BASF requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective August 7, 2023. Objections and requests for hearings must be received on or before October 6, 2023, 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-2022-0576, is available at <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. Please review the visitor instructions and additional information about the docket available at <https://www.epa.gov/dockets>.

**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; 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/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-2022-0576 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 October 6, 2023. 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-2022-0576, by one of the following methods:

- **Federal eRulemaking Portal:** <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/where-send-comments-epa-dockets>.

[www.epa.gov/dockets/where-send-comments-epa-dockets](https://www.epa.gov/dockets/where-send-comments-epa-dockets).

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 23, 2022 (87 FR 58047) (FRL-9410-05-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 2E9008) by BASF Corporation, 26 Davis Drive, Research Triangle Park, NC 27709-3528. The petition requested that 40 CFR part 180.490 be amended by establishing tolerances for residues of the herbicide imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid), in or on rice, bran at 0.2 parts per million (ppm), and rice, grain at 0.05 ppm. That document referenced a summary of the petition prepared by BASF Corporation, the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

#### 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 imazapic

including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with imazapic follows.

#### A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Endpoints were previously selected for imazapic; however, the toxicological database was reevaluated as part of Registration Review. The no-observed adverse-effect level (NOAEL) and lowest-observed adverse-effect level (LOAEL) for the chronic oral toxicity study in dogs were updated to reflect current practices in hazard evaluation. The NOAEL is now 501 and 534 mg/kg/day in males and females, respectively. The LOAEL is now 1,141 and 1,092 in males and females, respectively, based on decreased body weight, increased incidence of salivation and emesis, changes in hematological parameters, red blood cell morphology findings, changes in clinical chemistry parameters, gross pathology in the bone marrow, and histopathological findings. Adverse effects in the database were only noted in two studies at doses that are not considered relevant for human health risk assessment (>500 mg/kg/day). Therefore, no endpoints were selected for imazapic and a quantitative assessment is not needed.

Specific information on the studies received and the nature of the adverse effects caused by imazapic as well as the NOAEL and LOAEL from the toxicity studies can be found at <https://www.regulations.gov> in document titled "Imazapic Human Health Risk Assessment to Support the Establishment of a Tolerance without U.S. Registration in/on Rice" (hereafter "Imazapic Human Health Risk Assessment" on pages 11–13 in docket ID number EPA-HQ-OPP-2022-0576).

#### B. Toxicological Points of Departure/ Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment.

PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

Since no effects were seen in any guideline toxicity studies at doses relevant for human health risk assessment, no toxicological PODs were selected for imazapic.

#### C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to imazapic, EPA considered exposure under the petitioned-for tolerances as well as all existing imazapic tolerances in 40 CFR 180.490. There is likely to be dietary exposure to imazapic from its use as a pesticide on imported and domestic food. Should exposure occur, however, minimal to no risk is expected for the general U.S. population, including infants and children, due to the low toxicity of imazapic.

2. *Dietary exposure from drinking water.* While there is no additional exposures expected from imazapic tolerances for rice because it is for import only, there is likely to be dietary exposure to imazapic in drinking water from its registered uses as a pesticide on domestic crops. Should exposure occur, however, minimal to no risk is expected for the general U.S. population, including infants and children, due to the low toxicity of imazapic.

3. *From non-dietary exposure.* The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Imazapic is registered for domestic uses that could result in residential exposure, including residential spot-treatment for

weed control on/in walkways, driveways and gravel pathways. In a residential setting, residential adult handlers may be exposed while handling imazapic and both adults and children may be exposed following outdoor applications. Due to the low toxicity of imazapic, quantitative exposure assessments are not required. Residential exposure to imazapic is not expected to increase with this tolerance because this tolerance is for import only. EPA concludes with reasonable certainty that non-occupational exposures to imazapic do not pose a significant human health risk.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity." 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 imazapic and any other substances and imazapic does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that imazapic, imazapic, and imazethapyr have a common mechanism of toxicity with other substances. Further information regarding EPA Pesticide Commulative Risk Assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework>.

#### D. Safety Factor for Infants and Children

1. *In general.* 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 (FQPA) Safety Factor (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.

2. *Conclusion.* In the available guideline studies, imazapic exhibited

very low toxicity in mammalian systems, and no effects were seen at doses relevant for human health risk assessment. The database for imazapic is complete. No additional toxicological studies are currently required, and no additional safety factors to protect children are needed.

*E. Determination of Safety*

Taking into account the available data for imazapic, EPA has concluded that given the low toxicity of this substance, no risks of concern are expected. Therefore, 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 imazapic.

**IV. Other Considerations**

*A. Analytical Enforcement Methodology*

Adequate enforcement methodology (capillary electrophoresis CE methods (CE method M 3114 and CE method M 2379)) is available for tolerance enforcement. Residues are confirmed by liquid chromatography (LC)/mass spectrometry (MS) analysis.

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 has established an MRL for residues of imazapic in or on rice, grain at 0.05 ppm which is the same level as the tolerance being established for imazapic in or on rice, grain in the United States. Codex has not established an MRL for imazapic in or on rice, bran.

**V. Conclusion**

Therefore, tolerances are established for residues of imazapic, (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid) in or on rice, bran at 0.2 ppm and rice, grain at 0.05 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 tolerances 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: July 25, 2023.

**Charles Smith,**

*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**

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

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

■ 2. Amend § 180.490 by adding paragraph (a)(3) to read as follows:

**§ 180.490 Imazapic; tolerances for residues.**

(a) \* \* \*

(3) Tolerances are established for residues of the herbicide imazapic, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified is to be determined by measuring only imazapic (2-[4,5-dihydro-4-methyl-4-(1-methylethyl)-5-oxo-1H-imidazol-2-yl]-5-methyl-3-pyridinecarboxylic acid).

TABLE 3 TO PARAGRAPH (a)(3)

| Commodity         | Parts per million |
|-------------------|-------------------|
| Rice, bran .....  | 0.2               |
| Rice, grain ..... | 0.05              |

\* \* \* \* \*

[FR Doc. 2023-16613 Filed 8-4-23; 8:45 am]

**BILLING CODE 6560-50-P**