



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0045; FRL-10008-92]

Indaziflam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of indaziflam in or on multiple commodities which are identified and discussed later in this document. Bayer CropScience requested these tolerances 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-2020-0045, 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 20460-0001. 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.

Please note that due to the public health emergency the EPA Docket Center (EPA/DC) and Reading Room was closed to public visitors on March 31, 2020. Our EPA/DC staff will continue to provide customer service via email, phone, and webform. For further information on EPA/DC services, docket contact information and the current status of the EPA/DC and Reading Room, please visit <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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.

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.

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-2020-0045 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).

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-2020-0045, 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 April 15, 2020 (85 FR 20910) (FRL-10006-54), 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 8F8725) by Bayer CropScience 2 T.W. Alexander Drive, Research Triangle Park, NC 27709. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of indaziflam (*N*-[(1*R*,2*S*)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine) in or on grass, forage, fodder and hay, group 17, forage at 30 parts per million (ppm); grass, forage, fodder and hay, group 17, hay at 10 ppm; sugarcane, cane at 0.01 ppm; cattle, goat, horse, and sheep fat at 0.07 ppm; cattle, goat, horse, and sheep meat at 0.01 ppm; cattle, goat, horse, and sheep meat byproducts at 0.2 ppm; milk at 0.01 ppm; and milk, fat at 0.25 ppm. That document referenced a summary of the petition prepared by Bayer CropScience, the registrant, which is available in the docket, <http://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 indaziflam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with indaziflam follows.

On October 10, 2019, EPA published in the **Federal Register** a final rule establishing tolerances for residues of indaziflam in or on the tropical and subtropical fruit (edible peel) group 23 and tropical and subtropical fruit (inedible peel) group 24 based on the Agency's conclusion that aggregate exposure to indaziflam is safe for the general population, including infants and children. *See* 84 FR 54510 (FRL-9999-70). That document contains a summary of the toxicological profile and points of departure, assumptions for exposure assessment, and the Agency's determination regarding the children's safety factor, which have not changed.

EPA's dietary exposure assessments have been updated to include the additional exposure from use of indaziflam on grass forage, grass hay, and sugarcane cane, and from exposure to residues in edible ruminant commodities, *i.e.*, reliance on tolerance-level residues for all crops, maximum anticipated residues for all edible ruminant commodities, and an assumption of 100 percent crop treated (PCT). EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposure in drinking water and from residential sources,

although those latter exposures are not impacted by the new uses on grass forage, grass hay, and sugarcane cane and thus have not changed since the last assessment. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the October 10, 2019 **Federal Register** action, as well as the new indaziflam tolerances, can be found at <http://www.regulations.gov> in the document titled "Indaziflam - Aggregate Human Health Risk Assessment of the Proposed New Use on Lowbush Blueberry, and Crop Group Expansions to Tropical and Subtropical Fruit, Edible Peel, Group 23 and Tropical and Subtropical Fruit, Inedible Peel, Group 24." dated September 11, 2019 in docket ID EPA-HQ-OPP-2018-0561 and the document titled, "Indaziflam. Human Health Risk Assessment in Support of the Proposed New Uses on Grasses, Sugarcane, Wildlife Management, and Rights-of-Way" dated April 17, 2020 in docket ID number EPA-HQ-OPP-2020-0045.

Acute dietary risks are below the Agency's level of concern: 20% of the acute population adjusted dose (aPAD) at the 95th percentile of exposure for all infants less than 1 year old, the population subgroup with the highest exposure estimate. Chronic dietary risks are below the Agency's level of concern: 20% of the chronic population adjusted dose (cPAD) for children 1 to 2 years old, the population subgroup with the highest exposure estimate. The updated combined short-term food, water, and residential exposure estimates result in aggregate margins of exposure (MOEs) above the level of concern (LOC) of 100 for all scenarios assessed and are not of concern.

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 indaziflam residues. More detailed information on the subject action to establish tolerances in or on the grass forage, grass hay, sugarcane cane,

and edible ruminant commodities can be found in the document entitled, “Indaziflam. Human Health Risk Assessment in Support of the Proposed New Uses on Grasses, Sugarcane, Wildlife Management, and Rights-of-Way” by going to <http://www.regulations.gov>. The referenced document is available in the docket established by this action, which is described under ADDRESSES. Locate and click on the hyperlink for docket ID number EPA-HQ-OPP-2020-0045.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate residue analytical methods for enforcing tolerances for indaziflam residues of concern in/on the registered plant and livestock commodities. Method DH-003-P07-02 is an adequate high-performance liquid chromatography with tandem mass spectrometry (LC-MS/MS) tolerance enforcement method for indaziflam and 1-fluoroethyl diaminotriazine (FDAT) in crops. Method DH-009-A18-01 is an adequate LC-MS/MS tolerance enforcement method for the determination of indaziflam residues in livestock commodities.

These methods 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 FFDC 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 any MRLs for indaziflam.

V. Conclusion

Therefore, tolerances are established for residues of indaziflam, *N*-[(1*R*,2*S*)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates in or on grass, forage, fodder and hay, group 17, forage at 30 ppm; grass, forage, fodder and hay, group 17, hay at 10 ppm; and sugarcane, cane at 0.01 ppm. Compliance with the tolerance levels specified above is to be determined by measuring only indaziflam and FDAT, 6-[(1*R*)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of indaziflam, in or on the commodity.

Tolerances are also established for residues of indaziflam, *N*-[(1*R*,2*S*)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates in or on cattle, fat at 0.7 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.2 ppm; goat, fat at 0.07 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.2 ppm; horse, fat at 0.07 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.2 ppm; milk at 0.01 ppm; milk, fat at 0.25 ppm; sheep, fat at 0.07 ppm; sheep, meat at 0.01 ppm; and sheep, meat byproducts at 0.2 ppm. Compliance with the tolerance levels specified above is to be determined by measuring only indaziflam in or on the commodity.

Lastly, the existing tolerance in paragraph (a) for “Sugarcane, refined sugar” is removed

as unnecessary and the tolerances under paragraph (b), Section 18 emergency exemptions for “Grass, forage, fodder, and hay, group 17 forage”, and “Grass, forage, fodder, and hay, group 17, hay” are removed as unnecessary due to the establishment of the above tolerances.

VI. Statutory and Executive Order Reviews

This action establishes and modifies 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 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: May 26, 2020.

Michael 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 § 180.653:

- a. Redesignate paragraph (a) as (a)(1), revise newly redesignated paragraph (a)(1) introductory text and redesignate the table as Table 1 to paragraph (a)(1);
- b. In the table in newly redesignated paragraph (a)(1) remove the entry for “Sugarcane, refined sugar” and add alphabetically entries for “Grass, forage, fodder and hay, group 17, forage”; “Grass, forage, fodder and hay, group 17, hay”; and “Sugarcane, cane”;
- c. Add paragraph (a)(2); and
- d. Remove and reserve paragraph (b).

The additions and revisions read as follows:

§ 180.653 Indaziflam; tolerances for residues.

(a) *General* (1) Tolerances are established for residues of the herbicide indaziflam, *N*-[(1*R*,2*S*)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only indaziflam and FDAT, 6-[(1*R*)-1-fluoroethyl]-1,3,5-triazine-2,4-diamine, calculated as the stoichiometric equivalent of indaziflam, in or on the commodity.

Table 1 to paragraph (a)(1)

Commodity	Parts per million
* * * *	* * *
Grass, forage, fodder and hay, group 17, forage	30
Grass, forage, fodder and hay, group 17, hay	10

* * * * *	
Sugarcane, cane	0.01

(2) Tolerances are established for residues of the herbicide indaziflam, *N*-[(1*R*,2*S*)-2,3-dihydro-2,6-dimethyl-1*H*-inden-1-yl]-6-(1-fluoroethyl)-1,3,5-triazine-2,4-diamine, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only indaziflam in or on the commodity.

Table 2 to paragraph (a)(2)

Commodity	Parts per million
Cattle, fat	0.07
Cattle, meat	0.01
Cattle, meat byproducts	0.2
Goat, fat	0.07
Goat, meat	0.01
Goat, meat byproducts	0.2
Horse, fat	0.07
Horse, meat	0.01
Horse, meat byproducts	0.2
Milk	0.01
Milk, fat	0.25
Sheep, fat	0.07
Sheep, meat	0.01
Sheep, meat byproducts	0.2

(b) [Reserved]

* * * * *