



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2019-0273; FRL-10012-18]

Pydiflumetofen; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for the inadvertent residues of pydiflumetofen in or on animal feed, nongrass, group 18, hay; grass, forage, fodder and hay, group 17, except straw; and grass, forage, fodder and hay, group 17, straw. Syngenta Crop Protection, LLC 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-2019-0273, 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.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and 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: (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 FFDCFA 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-2019-0273 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-2019-0273, 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 June 7, 2019 (84 FR 26630) (FRL-9993-93), 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 9F8744) by Syngenta Crop Protection, LLC., P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.699 be amended by establishing tolerances for inadvertent residues of the fungicide, pydiflumetofen (3-(difluoromethyl)-*N*-methoxy-1-methyl-*N*-[1-methyl-2-(2,4,6 trichlorophenyl)ethyl]-1*H*-pyrazole-4-carboxamide) in or on rice, grain at 0.01 parts per million (ppm); non-grass animal feed (Crop Group 18), forage at 0.01 ppm; non-grass animal feed (Crop Group 18), hay at 0.03 ppm; grasses, forage at 0.15 ppm; grasses, hay at 0.50 ppm; grasses, straw at 0.04 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing. Based upon review of the data supporting the petition, EPA is establishing tolerances that vary slightly from what the petitioner requested, by using altered commodity definitions to reflect the Agency's preferred terminology and adjusted tolerance levels for several commodities. In addition, EPA is not establishing tolerances for residues of pydiflumetofen in or on rice, grain and non-grass animal feed (crop group 18), forage. The reasons for these changes are explained in Unit IV.D.

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

On August 12, 2019, EPA published in the *Federal Register* a final rule establishing a tolerance for residues of the fungicide pydiflumetofen in or on various commodities. *See* (84 FR 39761) (FRL-9997-09). EPA is incorporating by reference the aspects of that rulemaking that remain the same for this rulemaking: The toxicological profile and points of departure/levels of concern; the determination for reducing the children’s safety factor and conclusions about cumulative risk. The Agency conducted an updated risk assessment to evaluate exposure to

residues of pydiflumetofen from the reduced plant-back intervals on rice, grass grown for seed, non-grass animal feed crop group 18, and tobacco and concluded that the new use patterns would not impact previously assessed drinking water, dietary (food and drinking water), or residential, exposures to humans from the reduced plant-back intervals. Therefore, the Agency's conclusions of aggregate risk remain unchanged from the August 12, 2019 rulemaking and are also incorporated into this rulemaking.

Further information about EPA's risk assessment and determination of safety supporting the tolerances for inadvertent residues established in the August 12, 2019 *Federal Register* action, as well as the new pydiflumetofen tolerance can be found at <http://www.regulations.gov> in the document entitled, "Pydiflumetofen. Human Health Risk Assessment for New Foliar Uses on Berries, Low Growing, Crop Subgroup 13-07G; Brassica Head and Stem Crop Group 5-16; Brassica Leafy Greens Subgroup 4-16B; Bulb Vegetable Crop Subgroup 3-07A; Green Onion Crop Subgroup 3-07B; Bushberry Crop Subgroup 13-07B; Citrus Fruit Crop Group 10-10; Cottonseed Subgroup 20C; Edible-podded Legume Vegetables Subgroup 6A; Succulent Shelled Pea and Bean Subgroup 6B; Pome Fruit Crop Group 11-10; Root Vegetable Crop Subgroup 1A; Sorghum; Stone Fruit Crop Subgroups 12-12A, 12-12B, and 12-12C; Sunflower Subgroup 20B; Tree Nut Crop Group 14-12; Leaves of Root and Tuber Vegetable Crop Group 2; and New Seed Treatment Uses on Rapeseed Crop Subgroup 20A and Soybean; and Registration of a New Seed Treatment End-Use Product," dated July 22, 2019, in docket ID EPA-HQ-OPP-2018-0688.

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 pydiflumetofen residues. More detailed information on the subject action to establish tolerances in or on animal feed, nongrass, group 18,

hay; grass, forage, fodder and hay, group 17, except straw; and grass, forage, fodder and hay, group 17, straw can be found in the document entitled, “Pydiflumetofen. Human Health Risk Assessment for Amended Registrations to Allow 30-Day Minimum Plant-Back Interval (PBI) Restrictions for Rice, Grass Grown for Seed, Non-Grass Animal Feed Crop Group 18, and Tobacco and Petition for Inadvertent Tolerances in or on These Crops/Commodities.” at <http://www.regulations.gov>, under docket ID number EPA-HQ-OPP-2019-0273.

IV. Other Considerations

A. Analytical enforcement methodology

A multi-residue analytical method named Quick, Easy, Cheap, Effective, Rugged, and Safe (QuEChERS) is adequate as the enforcement method for plant commodities. QuEChERS as described in Eurofins validation study S14-05402. 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 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, FFDC section 408(b)(4) requires that EPA explain the reasons for departing from the Codex

level.

The Codex has not established MRLs for pydiflumetofen in or on any of the commodities under consideration.

C. Revisions to petitioned-for tolerances

The requested tolerance for “non-grass animal feed (Crop Group 18), hay” was modified to read “Animal feed, nongrass, group 18, hay” to be consistent with Agency naming practices. Requested tolerances for “grasses, forage,” “grasses, hay,” and “grasses, straw” were revised to read “Grass, forage, fodder and hay, group 17, except straw” and “Grass, forage, fodder and hay, group 17, straw” respectively, to be more consistent with the Agency’s preferred vocabulary and because EPA considers group 17 to be inclusive of a general request for tolerances on grasses.

Tolerances for inadvertent residues of pydiflumetofen were requested for non-grass animal feed (Crop Group 18), forage and rice, grain; however, the Agency is not setting tolerances because residues of pydiflumetofen in field accumulation in rotational crop trials were found at <0.01 ppm in or on these commodities, and the Agency does not believe that tolerances are needed, in accordance with the Agency’s guidance (OPPTS Guideline 860.1900).

The Agency is setting a tolerance in or on animal feed, nongrass, group 18, hay, of 0.04 ppm rather than at 0.03 ppm as requested based on clover hay data. The Agency is also setting a tolerance in or on grass, forage, fodder and hay, group 17, except straw of 0.7 ppm based on available data, which indicates that residues in or on grass forage and hay are within 5x, but residues on straw are much lower.

V. Conclusion

Therefore, tolerances are established for residues of pydiflumetofen in or on animal feed, nongrass, group 18, hay; grass, forage, fodder and hay, group 17, except straw; and grass, forage,

fodder and hay, group 17, straw.

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 for inadvertent residues 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 29, 2020.

Catherine Aubee,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA amends 40 CFR chapter I 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 § 180.699, revise paragraph (d) to read as follows:

§ 180.699 Pydiflumetofen; tolerances for residues.

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of pydiflumetofen, including its metabolites and degradates, in or on the commodities in table 2 to this paragraph (d). Compliance with the tolerance levels specified in table 2 to this paragraph (d) is to be determined by measuring only pydiflumetofen (3-(difluoromethyl)-N-methoxy-1-methyl-N-[1-methyl-2-(2,4,6-trichlorophenyl)ethyl]-1H-pyrazole-4-carboxamide) in or on the commodity:

Table 2 to Paragraph (d)

Commodity	Parts per million
Animal feed, nongrass, group 18, hay	0.04
Grass, forage, fodder and hay, group 17, except straw	0.7
Grass, forage, fodder and hay, group 17, straw	0.04