E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0433 and EPA-HQ-OPP-0833; FRL-13125-01-OCSPP]

Inpyrfluxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of inpyrfluxam in or on multiple commodities which are identified and discussed later in this document. Valent U.S.A., LLC 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) numbers EPA-HQ-OPP-2021-0433 and EPA-HQ-OPP-2021-0833 are available online at *https://www.regulations.gov*. Additional information about dockets generally, along with instructions for visiting the docket center in person, is available at *https://www.epa.gov /dockets*.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is EPA's authority for taking this action?*

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) 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." FFDCA section 408(b)(2)(A)(ii) 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. FFDCA section 408(b)(2)(C) 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 . . ."

C. *How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file

an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. 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-2021-0433 or EPA-HQ-OPP-2021-0833 in the subject line on the first page of your submission. This document addresses two related petitions for inpyrfluxam tolerance that were received by the Agency at different times and are docketed under EPA-HQ-OPP-2021-0433 and EPA-HQ-OPP-2021-0833. This final rule and all supporting documents will be uploaded to both dockets, EPA-HQ-OPP-2021-0433 and EPA-HQ-OPP-2021-0833. 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*]**.

The EPA's Office of Administrative Law Judges (OALJ), in which the Hearing Clerk is housed, urges parties to file and serve documents by electronic means only, notwithstanding any other particular requirements set forth in other procedural rules governing those proceedings. See "Revised Order Urging Electronic Filing and Service," dated June 22, 2023, which can be found at *https://www.epa.gov/system/files/documents/2023-06/2023-06-22%20-%20revised%20order%20urging%20electronic%20filing%20and%20service.pdf*. Although the EPA's regulations require submission via U.S. Mail or hand delivery, the EPA intends to treat submissions filed via electronic means as properly filed submissions; therefore, the EPA believes the preference for submission via electronic means will not be prejudicial. When submitting documents to the OALJ electronically, a person should utilize the OALJ e-filing system at *https://yosemite.epa.gov/oa/eab/eab-alj_upload.nsf*.

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 at *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. If you wish to include CBI in your request, please follow the applicable instructions at *https://www.epa.gov/dockets/commenting-epa-dockets#rules* and clearly mark the information that you claim to be CBI. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice.

II. Petitioned-For Tolerance

In the *Federal Register* of June 22, 2022 (87 FR 37287) (FRL-9410-02-OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 1F8922, PP 1F8924, and PP 1F8942) by Valent U.S.A. LLC, 4600 Norris Canyon Road, San Ramon, CA 94583. The petitions requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide inpyrfluxam, (3-(difluoromethyl)-N-[(3R)-2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide), in or on cotton, undelinted seed, at 0.01 parts per million (ppm) (PP 1F8922); cotton, gin byproducts (gin trash) at 0.02 ppm (PP 1F8922); wheat, forage at 0.01 ppm (PP 1F8924); wheat, grain at 0.01 ppm (PP 1F8924); wheat, hay at 1.5 ppm (PP 1F8924); wheat, straw at 0.3 ppm (PP 1F8924); and rapeseed, seed (crop subgroup 20A) at 0.01 ppm (PP 1F8942). That document referenced a summary of the three petitions prepared by Valent U.S.A. LLC, the registrant, which is available in the docket *http://www.regulations.gov* (docket ID numbers EPA-HQ-OPP-2021-0433 and EPA-HQ-OPP-2021-0833). There were no comments received in response to the June 22, 2022, notice of filing.

In the *Federal Register* of May 22, 2024 (89 FR 44954) (FRL-11682-04-OCSPP), EPA issued a notice that supersedes the June 22, 2022, notice of filing for PP 1F8942. This amended petition requests tolerances for residues of inpyrfluxam in or on rapeseed subgroup 20A at 0.01 ppm and “rapeseed, forage” at 0.02 ppm. One comment was received in response to the May 22, 2024, notice but was not germane to the petition.

EPA is not establishing a tolerance on “rapeseed, forage" as requested in PP 1F8942. The

reason for this change is explained in Unit IV.D.

III. Final Tolerance Action

A. *Aggregate Risk Assessment and Determination of Safety*

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

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections of the rule that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

EPA has previously published a tolerance rulemaking for inpyrfluxam in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to inpyrfluxam and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rule, as they remain unchanged.

B. *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.

Specific information on the studies received and the nature of the adverse effects caused

by inpyrfluxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in the final rule published in Unit III.A. of the *Federal Register* of August 26, 2020 (85 FR 52483) (FRL-10011-32).

C. *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*.

A summary of the toxicological endpoints for inpyrfluxam used for human risk assessment can be found at *http://www.regulations.gov* in the document "Inpyrfluxam. Human Health Risk Assessment for the Proposed New Use of Inpyrfluxam as a Seed Treatment on Canola and Rate Increase for Rapeseed Subgroup 20A." and "Inpyrfluxam. Human Health Risk Assessment for New Uses of Inpyrfluxam on Cottonseed and Wheat." (hereinafter "Inpyrfluxam Human Health Risk Assessment") on pages 16 and 18, respectively, in Docket ID numbers EPA-

HQ-OPP-2021-0433 and EPA-HQ-OPP-2021-0833.

D. *Exposure Assessment*

1. *Dietary exposure from food and feed uses.*

In evaluating dietary exposure to inpyrfluxam, EPA considered exposure under the petitioned-for tolerances as well as all existing inpyrfluxam tolerances in 40 CFR 180.712. EPA assessed dietary exposures from inpyrfluxam in food as follows:

i. *Acute exposure*. Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure.

The acute and chronic dietary assessment were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture (USDA) National Health and Nutrition Examination Survey, What We Eat in America. As to residue levels in food, the acute and chronic analyses incorporated anticipated residues to account for the metabolites of concern, 100 percent crop treated (PCT) estimates, default processing factors for processed commodities and empirical processing factors when available.

ii. *Cancer*. Based on the data summarized in Unit III.A., EPA has concluded that inpyrfluxam does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.*

The proposed uses do not result in an increase in the estimated residue levels in drinking water, so the estimated drinking water concentrations used in the August 26, 2020, final rule (85 FR 52483) (FRL-10011-32) are the same as those used in this assessment.

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). Inpyrfluxam is not registered for any specific use patterns that would result in residential exposure.

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."

EPA has not found inpyrfluxam to share a common mechanism of toxicity with any other substances, and inpyrfluxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that inpyrfluxam does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides*.

E. *Safety Factor for Infants and Children*

EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the August 26, 2020, rulemaking (85 FR 52483) (FRL-10011-32) for a discussion of the Agency's rationale for that determination.

F. *Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate PODs to ensure that an adequate

MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to inpyrfluxam will occupy 6.8% of the aPAD for all infants less than one year old, the population group receiving the greatest exposure.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to inpyrfluxam from food and water will utilize 2.4% of the cPAD for all infants less than one year old, the population group receiving the greatest exposure. There are no residential uses for inpyrfluxam.

3. *Short- and intermediate-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Short-term risk is assessed based on short-term residential exposure plus chronic dietary exposure. Because there is no short-term or intermediate residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short-term or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating the aggregate risk for inpyrfluxam.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, inpyrfluxam is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, 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 inpyrfluxam residues.

IV. Other Considerations

A. *Analytical Enforcement Methodology*

For a discussion of the available enforcement analytical methods, see Unit IV.A. of the August 26, 2020, rulemaking (85 FR 52483) (FRL-10011-32).

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 (MRL) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex 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.

Codex has not established MRLs for inpyrfluxam in/on cottonseed, rapeseed, or wheat.

C. *Revisions to Petitioned-For Tolerances*

Although the petition requested a tolerance for "rapeseed, forage", EPA has determined that the "rapeseed, forage" tolerance is not needed because the proposed pesticide product label prohibits livestock feeding and grazing of rapeseed forage (canola varieties only) treated with inpyrfluxam. The commodity definition for cotton, gin byproducts (gin trash) was also revised in conformity with EPA guidelines.

V. Conclusion

Therefore, tolerances are established for residues of inpyrfluxam, (3-(difluoromethyl)-N-[(3R)-2,3-dihydro-1,1,3-trimethyl-1H-inden-4-yl]-1-methyl-1H-pyrazole-4-carboxamide), in or on cotton, gin byproducts at 0.02 ppm; cotton, undelinted seed at 0.01 ppm; rapeseed subgroup 20A at 0.01 ppm; wheat, forage at 0.01 ppm; wheat, grain at 0.01 ppm; wheat, hay at 1.5 ppm; and wheat, straw at 0.3 ppm.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/laws-regulations/laws-and-executive-orders*.

A. *Executive Order 12866: Regulatory Planning and Review*

This action is exempt from review under Executive Order 12866 (58 FR 51735, October 4, 1993), because it establishes or modifies a pesticide tolerance or a tolerance exemption under FFDCA section 408 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.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

Executive Order 14192 (90 FR 9065, February 6, 2025) does not apply because actions that establish a tolerance under FFDCA section 408 are exempted from review under Executive Order 12866.

C. *Paperwork Reduction Act (PRA)*

This action does not impose an information collection burden under the PRA 44 U.S.C. 3501 *et seq.,* because it does not contain any information collection activities.

D. *Regulatory Flexibility Act (RFA)*

Since tolerance actions 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 RFA, 5 U.S.C. 601 *et seq.,* do not apply to this action.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate of $100 million or more (in 1995 dollars and adjusted annually for inflation) as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local, or Tribal governments or on the private sector.

F. *Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132

(64 FR 43255, August 10, 1999), because it will not have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government.

G. *Executive Order 13175: Consultation and Coordination with Indian Tribal Governments*

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000), because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal Government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal Government and Indian Tribes.

H. *Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because tolerance actions like this one are exempt from review under Executive Order 12866. However, EPA's 2021 *Policy on Children's Health* applies to this action. This rule finalizes tolerance actions under the FFDCA, which 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 ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is summarized in Unit III.E.

I. *Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355) (May 22, 2001) because it is not a significant regulatory action under Executive Order 12866.

J. *National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

K. *Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.,* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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: February 11, 2026.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons set forth in the preamble, 40 CFR chapter I is amended 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 § 180.712 paragraph (a)(1) in Table 1 to § 180.712 by adding the entries for "Cotton, gin byproducts", "Cotton, undelinted seed", "Rapeseed subgroup 20A", "Wheat, forage", "Wheat, grain", Wheat, hay", and "Wheat, straw", in alphabetical order, to read as follows:

§ 180.712 Inpyrfluxam; tolerances for residues.

(a)* * *

(1)* * *

Table 1 to § 180.712

Commodity	Parts per million
* * * * * * *	
Cotton, gin byproducts	0.02
Cotton, undelinted seed	0.01
* * * * * * *	
Rapeseed subgroup 20A	0.01
* * * * * * *	
Wheat, forage	0.01
Wheat, grain	0.01
Wheat, hay	1.5
Wheat, straw	0.3

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