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560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2025-0041; FRL-13401-01]

Isofetamid; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isofetamid in or on nut, tree, group 14–12, and almond, hulls. Under the Federal Food, Drug, and Cosmetic Act (FFDCA) ISK Biosciences Corporation submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on the identified commodities.

DATES: This regulation is effective [**INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER***]. Objections and requests for hearings must be received on or before [**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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-0041, is available at http://www.regulations.gov. Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *http://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.

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(c)(2)(A)(i) allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." FFDCA section 408(c)(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. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require 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.... " Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider, among other things, "available information concerning the cumulative effects of a particular pesticide's residues" and "other substances that have a common mechanism of toxicity."

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 the docket ID number EPA-HQ-OPP-2025-0041 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***].

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* "Order Urging Electronic Filing and Service," dated December 3, 2025, which can be found at *https://www.epa.gov/system/files/documents/2025-12/2025-12-03-order-urging-electronic-filing-and-service.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 July 3, 2025 (90 FR 29516) (FRL-12474-05-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 4F9151) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, OH 44027. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide isofetamid, in or on Tree nut, crop group 14-12 at 0.15 parts per million (ppm) and almond hulls at 15 ppm. The petition also requested to remove tolerances in 40 CFR part 180 for residues of the fungicide isofetamid including its metabolites and degradates in or on the raw agricultural commodities almonds at 0.01 ppm, almond hulls at 0.01 ppm. That document referenced a summary of the petition prepared by ISK Bioscience, 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 proposing a higher tolerance for Almond, hulls, based on the available data and the tolerance calculation

procedures of the Organization for Economic Cooperation and Development (OECD). The reason for these changes are explained in Unit IV.C.

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 isofetamid including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isofetamid is summarized in this Unit.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting sections that repeat what has been previously published for tolerance rulemakings of the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemaking, 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 several tolerance rulemakings for isofetamid in 2015, 2017, 2022 in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to isofetamid and established tolerances for residues of that chemical. EPA is incorporating previously published sections from the 2015 and 2017 rulemakings as described further in this rulemaking, as they remain unchanged.

Specific information on the risk assessment conducted in support of this action can be found in the document titled "*Isofetamid. Human Health Risk Assessment for a New Tolerance Registration of Isofetamid on Tree Nuts, Crop Group 14-12 and the*

Amended Tolerance on Almond Hulls" and the documents cited therein, which are available in the docket for this action at https://www.regulations.gov, docket ID number EPA-HQ-OPP-2025-0041.

B. Toxicological Profile

Specific information on the studies received and the nature of the adverse effects caused by isofetamid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://*www.regulations.gov in document Isofetamid. Human Health Risk Assessment for a New Tolerance Registration of Isofetamid on Tree Nuts, Crop Group 14-12 and the Amended Tolerance on Almond Hulls. at page 10 - 12 in docket ID number EPA-HQ-OPP-2025-0041.

C. Toxicological Points of Departure/Levels of Concern.

For a summary of the Toxicological Points of Departure/Levels of Concern for isofetamid used for human risk assessment, please reference Unit III.B. of the July 30, 2015, rulemaking (80 FR 45438) (FRL–9923–86).

D. Exposure Assessment

1. Dietary exposure from food and feed uses.

In evaluating dietary exposure to isofetamid, EPA considered exposure under the petitioned-for tolerances as well as all existing isofetamid tolerances in 40 CFR 180.681. EPA assessed dietary exposures from isofetamid 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. No such effects were identified in the toxicological studies for isofetamid therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. Chronic exposure.

In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 2005-2010 CSFII. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The unrefined chronic dietary exposure assessment used tolerance-level residues and assumed 100 percent crop treated (PCT) for all registered and proposed commodities. Default processing factors were used for all other proposed and registered processed commodities. Exposure to drinking water was incorporated directly into the dietary assessment. A cancer dietary assessment was not conducted because isofetamid is classified as ''not likely to be carcinogenic to humans."

2. Drinking water and non-occupational exposures.

The previously recommended estimated drinking water concentrations (EDWCs) are unchanged and are considered protective potential drinking water residue levels anticipated from the proposed tolerance updates. As stated in the July 30, 2015, rulemaking, the chronic dietary exposure and risk assessment incorporate the highest total EDWC of 110 parts per billion directly into this dietary assessment (80 FR 45438) (FRL–9923–86). The residential exposure assessment has not changed since the June 14, 2017, rulemaking (new residential uses. For a summary of the residential exposure 82 FR 27149) (FRL–9961–80) because there are no proposed analysis for isofetamid used for the human risk assessment, please reference Unit III.C.3. of the June 14, 2017, rulemaking.

3. Cumulative exposures.

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 isofetamid to share a common mechanism of toxicity with any other substances, and isofetamid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that isofetamid does not have a common mechanism of toxicity with other substances.

E. Safety Factor for Infants and Children.

1. *In general*. FFDCA section 408(b)(2)(C) 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*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA safety factor were reduced to 1X. That decision is based on the following findings:

EPA concludes that there are reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the July 30, 2015, rulemaking for a discussion of the Agency's rationale for that determination. (80 FR 45438) (FRL–9923–86).

F. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD

(cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

1. *Acute risk*. An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, isofetamid is not expected to pose an acute risk.

2. *Chronic risk*. Chronic Dietary risks of exposure for food and drinking water are below the level of concern (<100% chronic population-adjusted dose or cPAD) for the general U.S. population and all population subgroups. Isofetamid dietary exposure for food and drinking water is 1.1% of the cPAD for the general U.S. population and 3.9% of the cPAD for children 1-2 years old, the most highly exposed population subgroup. This unrefined chronic dietary exposure combined food and drinking water, and assumed 100% crop treated for all of the registered and proposed commodities.

A potential short-term adverse effect via the dietary and residential pathways of children 1 to <2 years old was identified; however, isofetamid is not registered for any use patterns that would result in short-term residential exposure. Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, Isofetamid is not expected to pose a cancer risk to humans.

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 isofetamid residues. More detailed information on this action can be found in the document titled “Isofetamid. Human Health Risk Assessment for a New Tolerance Registration of Isofetamid on Tree Nuts, Crop Group 14-12 and the

Amended Tolerance on Almond Hulls." in docket ID number EPA-HQ-OPP-2025-0041.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the July 30, 2015, rulemaking (80 FR 45438) (FRL–9923–86).

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 established MRLs for isofetamid in or on almonds at 0.01 ppm and almond hulls at 0.8 ppm. Neither Mexico nor Canada has MRLs established on tree nuts. These MRLs are different than the tolerances established for isofetamid in the United States because of differences in the proposed U.S. use sites. No changes to the use pattern of almond were assessed.

C. Revisions to Petitioned-For Tolerances

The Agency is increasing the tolerance on almond, hulls from the proposed tolerance of 15 ppm, to 20 ppm, based on the available use data and the OECD calculation procedures.

V. Conclusion

Therefore, tolerances are established for residues of isofetamid, in or on almond, hulls at 20 ppm, and in or on Nut, tree, group 14-12 at 0.15 ppm. The existing 0.01 ppm tolerance on almond is removed.

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 2026 *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: July 27, 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. In § 180.681, in paragraph (a) amend table 1 to paragraph (a) by

a. Removing the entry for “Almond”;

b. Revising the entry for “Almond, hulls”; and

c. Adding in alphabetical order the entry “Nut, tree, group 14-12”.

The revision and addition read as follows:

§ 180.681 Isofetamid; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)	
Commodity	Parts per million
Almond, hulls	20
* * * * * * *	
Nut, tree, group 14-12	0.15
* * * * * * *	

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