major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and (c) does not have significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises to compete with foreign-based enterprises. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to constitute a major rule.

Unfunded Mandates Reform Act

This rule does not impose an unfunded mandate on State, local, or Tribal governments, or the private sector of more than $100 million per year. The rule does not have a significant or unique effect on State, local, or Tribal governments or the private sector. This determination is based on an analysis of the corresponding Federal regulations, which were determined not to impose an unfunded mandate. Therefore, a statement containing the information required by the Unfunded Mandates Reform Act (2 U.S.C. 1531 *et seq.*) is not required.

List of Subjects in 30 CFR Part 935

Intergovernmental relations, Surface mining, Underground mining.

Ben Owens,

Acting Regional Director, Interior Regions 1 & 2.

For the reasons set out in the preamble, 30 CFR part 935 is amended as set forth below:

PART 935—OHIO

■ 1. The authority citation for part 935 continues to read as follows:

Authority: 30 U.S.C. 1201 *et seq.*

■ 2. Section 935.15 is amended in the table by adding a new entry in chronological order by ''Date of final publication'' to read as follows:

§ 935.15 Approval of Ohio regulatory program amendments.

* * * * *

Original amendment submission date	Date of final publication	Citation/description
		OAC 1501:13–4–03(B)(1), (B)(4).
* * * * *	*	*
January 8, 2021	November 17, 2025.	

[FR Doc. 2025–20019 Filed 11–14–25; 8:45 am]

BILLING CODE 4310–05–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0319; FRL–12959–01–OCSPP]

Fluazinam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazinam (CASRN 79622–59–6) in or on pear, Asian. 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 on in or on the identified commodity.

DATES: This regulation is effective on November 17, 2025. Objections and requests for hearings must be received on or before before January 16, 2026 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–2023–0319, is available at *https://www.regulations.gov.* Additional information about dockets generally, along with instructions for visiting the docket in person, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Charles Smith, Director, Registration Division (RD) (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. 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).

If you have any questions regarding the applicablility 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. 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–2023–0319 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 January 16, 2026. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. 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–2023–0319, 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.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

II. Petitioned-For Tolerance

In the **Federal Register** of December 19, 2023 (88 FR 87733) (FRL–10579–11–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 3E9057) by ISK Biosciences Corporation, 7470 Auburn Rd., Suite A, Concord, Ohio 44077. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide fluazinam, (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on pear, Asian at 0.2 parts per million (ppm). That document referenced a summary of the petition prepared by ISK Biosciences 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.

Based upon review of the data supporting the petition, EPA has modified the commodity definition to be consistent with Agency nomenclature.

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

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections 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 three tolerance rulemakings for fluazinam (*i.e.,* November 7, 2012, rule (77 FR 66723) (FRL–9366–6), April 8, 2016, rule (81 FR 20545) (FRL–9942–99), and September 20, 2021 (86 FR 52077) (FRL–8664–01–OCSPP)), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to fluazinam and established tolerances for residues of that pesticide chemical. EPA is incorporating previously published sections from those rulemakings as described further in this rulemaking, as they remain unchanged.

B. Toxicological Profile

For a discussion of the Toxicological Profile of fluazinam, see Unit III.A. of the 2016 rulemaking establishing tolerances for residues of fluazinam in or on several commodities. The endpoint selection remains unchanged since that most recent comprehensive assessment. However, the hazard characterization was updated to clarify effects observed in the developmental neurotoxicity (DNT) study and how the doses at which they occurred compare to the doses selected for risk assessment. The guideline study database was re-evaluated to ensure that offspring were protected from effects which may occur after a single exposure in all studies, including at doses higher than the study no observed adverse effect level (NOAEL). There were effects observed in the developmental neurotoxicity study at doses similar to those used for the general population acute dietary point of departure (POD). Upon review, it was determined that the effects in question were either not attributable to a single exposure or were not appropriate to assess for the general population. The effects that are potentially relevant to an in utero acute exposure are adequately protected for by the POD selected for the females 13–49 assessment.

C. Toxicological Points of Departure/Levels of Concern

A summary of the toxicological points of departure/levels of concern used for the human health risk assessment, see Unit III.B. of the 2012 rulemaking establishing tolerances for residues of fluazinam in or on several commodities.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary

exposure to fluazinam, EPA considered exposure under the petitioned-for tolerance as well as all existing fluazinam tolerances in 40 CFR 180.574. EPA assessed dietary exposures from fluazinam 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. Such effects were identified for fluazinam.

In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02, which uses the 2005–2010 food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA utilized tolerance-level residues and 100 percent crop treated (PCT) for all commodities, default processing factors, and Estimated Drinking Water Concentrations (EDWCs), when appropriate.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA used the food consumption data from the USDA's 2005–2010 NHANES/WWEIA and DEEM–FCID; version 4.02. As to residue levels in food, EPA utilized a combination of tolerance-level residues, average field trial residues, mean residue values from the USDA Pesticide Data Program (PDP) monitoring data, empirical processing factors and/or default processing factors, and average PCT estimates, when appropriate.

iii. *Cancer.* Based on the toxicological profile in Unit III.A of the 2016 rulemaking, EPA has concluded that fluazinam does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA's estimated PCTs for existing uses are unchanged from the 2021 rulemaking establishing tolerances for residues of fluazinam in or on several commodities and can be found in Unit III of that rulemaking.

2. *Dietary exposure from drinking water.* For more discussion of the estimated drinking water concentrations for fluazinam, see Unit III. of the 2021 rulemaking.

3. *From non-dietary exposure.* See Unit III.C.3. of the 2016 rulemaking for a discussion of non-dietary exposure, which included residential exposures to golf course turf.

4. *Cumulative effects from substances with 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 fluazinam and any other substances, and fluazinam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that fluazinam has a common mechanism of toxicity with other substances.

E. Safety Factor for Infants and Children

EPA continues to conclude that there is reliable data to support the reduction of the Food Quality Protection Act (FQPA) safety factor. See Unit III.D. of the 2016 rulemaking for a discussion of the Agency's rationale for that determination.

F. Aggregate Risk 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). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short, intermediate, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

Acute dietary risks are below the Agency's level of concern of 100% of the aPAD: They are 33% of the aPAD for females 13 to 49 years old, the population subgroup with the highest risk estimate. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD, they are 99% of the cPAD for all infants, the population subgroup with the highest exposure estimate. The short-term aggregate risk assessments resulted in MOEs that are greater than the Agency's level of concern of 100 and therefore are not of concern. The MOEs are 500 for children 6 to less than 11 years old; 600 for youths 11 to less than 16 years old; and 550 for adults. Intermediate-term and long-term residential exposures are not expected.

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 fluazinam residues. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the document titled ''Fluazinam. Human Health Risk Assessment for a Proposed Tolerance without U.S. Registration on Pear, Oriental.'' in docket ID number EPA–HQ–OPP–2023–0319.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A of the 2016 rulemaking.

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 not established a MRL for fluazinam in or on pear, Asian.

V. Conclusion

Therefore, tolerances are established for residues of fluazinam (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on pear, Asian at 0.2 ppm.

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at *https://www.epa.gov/regulations/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 documented in the pesticide-specific registration review documents, located in each chemical docket at *https://www.regulations.gov.*

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: November 3, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, EPA is amending 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. Amend § 180.574 by:
■ a. In Table 1 to Paragraph (a)(1):
■ i. Adding in alphabetical order an entry for ''Pear, Asian''; and
■ ii. Revising footnote 1.

The addition and revision read as follows:

§ 180.574 Fluazinam; tolerance for residues.

(a) * * *
(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * * * *	
Pear, Asian [1]	0.2
* * * * * * *	

[1] There are no U.S. registrations.

* * * * *

[FR Doc. 2025–19917 Filed 11–14–25; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2025–0284; FRL–12973–01]

Chlorantraniliprole; Pesticide Tolerance for Emergency Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a time-limited tolerance for residues of chlorantraniliprole, including its metabolites and degradates, in or on rice, grain. This action is in response to EPA's granting of an emergency exemption under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) authorizing use of the pesticide on rice. This regulation establishes a maximum permissible level for residues of chlorantraniliprole. The time-limited tolerance expires on December 31, 2028.

DATES: This rule is effective November 17, 2025. Objections and requests for hearings must be received on or before January 16, 2026 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).