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 <a href="https://www.regulations.gov">https://www.regulations.gov</a>.

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	
*	*	*	

<sup>1</sup> 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**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2025-0284, 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 (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?

In accordance with the Federal Food, Drug, and Cosmetic Act (FFDCA) sections 408(e) and 408(l)(6) of, 21 U.S.C. 346a(e) and 346a(1)(6), EPA is establishing a time-limited tolerance for residues of chlorantraniliprole, including its metabolites and degradates, in or on rice, grain at 15 parts per million (ppm). This time-limited tolerance expires on December 31, 2028.

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-2025-0284 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).

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-2025-0284, 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/where-send-comments-epa-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. Background and Statutory Findings

Section 408(1)(6) of FFDCA requires EPA to establish a time-limited tolerance or exemption from the requirement for a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. Such tolerances can be established without providing notice or period for public comment. EPA does not intend for its actions on FIFRA section 18 related time-limited tolerances to set binding precedents for the application of FFDCA section 408 and the safety standard to other tolerances and exemptions.

Section 408(e) of FFDCA allows EPA to establish a tolerance or an exemption from the requirement of a tolerance on its own initiative, *i.e.*, without having received any petition from an outside party.

FFDCA 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. . . .'

Section 18 of FIFRA authorizes EPA to exempt any Federal or State agency from any provision of FIFRA, if EPA determines that "emergency conditions exist which require such exemption." EPA has established regulations governing such emergency exemptions in 40 CFR part 166.

### III. Emergency Exemption for Chlorantraniliprole on Rice and FFDCA Tolerance

The Louisiana Department of Agriculture and Forestry (LDAF) has requested a specific emergency exemption for the use of foliar-applied chlorantraniliprole to control stem borer in rice. The applicant asserts that stem borer is a major pest in Louisiana rice, and that stem borer larvae feed internally in rice stems, causing severe economic damage. According to LDAF, there is a lack of adequate alternative controls that can be used in production systems where rice is rotated with crawfish. Without an effective control, Louisiana rice growers affected by uncontrolled stem borer face significant economic yield losses.

After having reviewed the submission, EPA determined that an emergency condition exists for this State, and that the criteria for approval of an emergency exemption are met. EPA has authorized a specific exemption under FIFRA section 18 for

the use of chlorantraniliprole on rice for control of stem borer in Louisiana.

As part of its evaluation of the emergency exemption application, EPA assessed the potential risks presented by residues of chlorantraniliprole in or on rice, grain. In doing so, EPA considered the safety standard in FFDCA section 408(b)(2), and EPA decided that the necessary tolerance under FFDCA section 408(l)(6) would be consistent with the safety standard and with FIFRA section 18. Consistent with the need to move quickly on the emergency exemption in order to address an urgent non-routine situation and to ensure that the resulting food is safe and lawful, EPA is issuing this tolerance without notice and opportunity for public comment as provided in FFDCA section 408(l)(6). Although this time-limited tolerance expires on December 31, 2028, under FFDCA section 408(l)(5), residues of the pesticide not in excess of the amount specified in the tolerance remaining in or on rice, grain after that date will not be unlawful, provided the pesticide was applied in a manner that was lawful under FIFRA, and the residues do not exceed a level that was authorized by this time-limited tolerance at the time of that application. EPA will take action to revoke the timelimited tolerance earlier if any experience with, scientific data on, or other relevant information on this pesticide indicate that the residues are not safe.

Because this time-limited tolerance is being approved under emergency conditions, EPA has not made any decisions about whether chlorantraniliprole meets FIFRA's registration requirements for use on rice or whether a permanent tolerance for this use would be appropriate. Under these circumstances, EPA does not believe that this time-limited tolerance decision serves as a basis for registration of chlorantraniliprole by a State for special local needs under FIFRA section 24(c). Nor does this tolerance by itself serve as the authority for persons in any State other than Louisiana to use this pesticide on rice FIFRA section 18 absent the issuance of an emergency exemption applicable within that State. For additional information regarding the emergency exemption for chlorantraniliprole, contact the Agency's Registration Division at the address provided under FOR FURTHER INFORMATION CONTACT.

# IV. 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 therein, 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 expected as a result of the use proposed by this emergency exemption request and the time-limited tolerance for residues of chlorantraniliprole on rice, grain at 15 ppm. EPA's assessment of exposures and risks associated with establishing the time-limited tolerance follows.

# A. 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 chlorantraniliprole, and its metabolite and degradates, used for human risk assessment, is discussed in Unit III of the final rule published in the **Federal Register** of February 7, 2014 (79 FR 7397) (FRL–9905–56).

### B. Exposure Assessment

1. Dietary exposure from food and feed uses. An acute dietary toxicity endpoint could not be identified based on the toxicology data currently available for chlorantraniliprole; therefore, an acute assessment was not conducted. To assess dietary exposure resulting from the proposed Section 18 use, EPA performed a chronic dietary analysis for chlorantraniliprole. In evaluating dietary exposure to chlorantraniliprole, EPA considered exposure under the time-limited tolerance established by this action as well as all existing chlorantraniliprole tolerances in 40 CFR 180.628. EPA assessed dietary exposures from chlorantraniliprole in food as follows:

i. Acute exposure. An acute dietary toxicity endpoint was not identified based on the toxicology data currently available for chlorantraniliprole; therefore, an acute assessment was not performed.

ii. Chronic exposure. In conducting the chronic (food and drinking water) dietary risk assessment for chlorantraniliprole, a dietary analysis was performed using tolerance-level residues and 100% crop treated (PCT) conservative assumptions. Default processing factors were also used.

iii. Cancer. EPA has classified chlorantraniliprole as "Not Likely to be Carcinogenic to Humans" based on weight of evidence of data. Therefore, a cancer assessment was not performed.

iv. Anticipated residue and percent crop treated (PCT) information. EPA did not use anticipated residues. However, tolerance level residues and 100% PCT were assumed for all food commodities in the dietary assessment for chlorantraniliprole.

v. Dietary exposure from drinking water. The Agency used screening level water exposure models: the Pesticide Root Zone Model (PRZM)-Exposure Analysis Modeling system EXAMS) and PRZM-Ground Water (GW) in the dietary exposure analysis and risk assessment for chlorantraniliprole. These simulation models take into

account data on the physical, chemical, and fate/transport characteristics of chlorantraniliprole. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at https://www.epa.gov/ pesticide-science-and-assessingpesticide-risks/models-pesticide-riskassessment#aquatic.

The highest modeled ground water EDWCs for chlorantraniliprole used in the dietary risk assessments were entered directly into the latest version of the Pesticides in Water Calculator (PWC 1.52). The highest surface water EDWCs for chlorantraniliprole used in the dietary risk assessments were generated using the Tier 1 Rice Model. EDWCs were calculated for groundwater and surface water based on the maximum annual application rate (0.132 lb ai/A/ Yr). The estimated drinking water contribution to chronic dietary exposure risks from drinking water were 647 parts per billion (ppb) for groundwater and 97 ppb for surface water. No acute dietary risk assessment was performed because an acute hazard was not identified. These modeled estimates of drinking water concentrations were directly entered into the dietary exposure model.

3. From non-dietary exposure. The term "residential exposure" is used in this document to refer to nonoccupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets).

Residential exposure to chlorantraniliprole is not expected based on the proposed use pattern on rice. However, chlorantraniliprole is currently registered for uses (i.e., residential or golf course turf, residential ornaments, and pre-and postconstruction termiticide use), where residential handler and post-application exposures are anticipated. No dermal, inhalation or oral PODs have been identified for short-term exposures to chlorantraniliprole. Therefore, no shortterm risk assessment has been conducted for the residential uses.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at: https://www.epa.gov/ pesticide-science-and-assessingpesticide-risks/standard-operatingprocedures-residential-pesticide.

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 chlorantraniliprole to share a common mechanism of toxicity with any other substances. In addition, chlorantraniliprole does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that chlorantraniliprole has a common mechanism of toxicity with other substances and concluded that it is not appropriate to conduct a cumulative exposure assessment. 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-andassessing-pesticide-risks/cumulativeassessment-risk-pesticides.

# C. Safety Factor for Infants and Children

1. In general. Section 408(b)(2)(C) of FFDCA 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 FQPA Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. Conclusion for chlorantraniliprole. EPA has determined that reliable data show that the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X for all population subgroups and chlorantraniliprole exposure scenarios. That decision is based on the following findings:

i. The toxicity database for chlorantraniliprole is (1) considered complete for evaluating and selecting toxicity endpoints and PODs, (2) dietary and residential exposure analyses are unlikely to underestimate exposure, and (3) there is no evidence of susceptibility or neurotoxicity in the database.

ii. No endpoints have been selected for acute oral, incidental oral, dermal, or inhalation routes of exposure; therefore, quantitative acute dietary, residential, and occupational human health assessments were not performed. However, an endpoint has been selected for chronic oral exposures and was quantitatively assessed. In general

chlorantraniliprole is non-toxic, as effects are non-adverse up to the limit dose in most studies (1,000 mg/kg/day for most studies, 2,000 mg/kg/day for acute neurotoxicity). Chlorantraniliprole is not considered developmentally toxic, genotoxic, neurotoxic, immunotoxic, or carcinogenic.

iii. In an 18-month oral (feeding) carcinogenicity study in mice, there is evidence of chronic dietary adverse effects following chlorantraniliprole exposure near the LOAEL limit dose of 935 mg/kg/day based on eosinophilic foci accompanied by hepatocellular hypertrophy and increased live weight in males only.

iv. There are no residual uncertainties identified in the exposure databases. Results of the chronic dietary analysis indicate that food and drinking water exposure are not of concern. This assessment was performed based on high-end assumptions such as 100% CT and tolerance-level residues, default processing factors, and modeled highend estimates of residues in drinking water, and is not expected to underestimate the exposure and risks posed by chlorantraniliprole. In addition, residential exposure to chlorantraniliprole is not expected based on the proposed use pattern on rice. Based upon the existing registered uses, residential exposures may occur during and following the application of products containing chlorantraniliprole. Also, non-occupational bystander spray drift exposures are possible. In an occupational setting, applicators may be exposed while handling the pesticide prior to and during application. There is potential for post-application exposure for workers re-entering treated areas. In the absence of any observed hazard from relevant exposures to chlorantraniliprole, occupational handler and post-application exposure assessments have not been performed.

# D. 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). 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

1. Acute risk. The acute aggregate risk assessment takes into account acute exposure estimates from dietary

consumption of food and drinking water. An acute endpoint for chlorantraniliprole was not identified based on the toxicology data currently available for chlorantraniliprole; therefore, an acute assessment was not performed.

- 2. Chronic risk. Chronic exposures are not expected for adults or children via residential exposure pathways from either the proposed use or existing registrations of chlorantraniliprole. Therefore, the chronic aggregate risk is equivalent to the chronic dietary risk estimates. The estimated chronic dietary exposure risks from food and water for chlorantraniliprole are below the LOC (<100% of the cPAD) for the US general population and all population subgroups. For chlorantraniliprole, EPA has concluded that chronic exposure from food and water will utilize 9.3% of the cPAD for Children 1-2 years old, the population group receiving the greatest exposure. For the overall U.S. population, chronic exposure from food and water will utilize 3.6% of the cPAD.
- 3. Short-term risk. Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water. Residential exposures are not expected for the proposed use; however, residential handler and post-application exposures are anticipated based on the registered use pattern of chlorantraniliprole. At this time, an endpoint has only been selected for chronic oral exposures; therefore, shortterm aggregate risk is equivalent to the chronic dietary exposures only and is not of concern. Chlorantraniliprole is not expected to pose a short-term risk because no short-term adverse effects were identified.
- 4. Intermediate-term risk.
  Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). At this time, an endpoint has only been selected for chronic oral exposures; therefore, intermediate-term aggregate risk is equivalent to the chronic dietary exposures only and is not of concern. Chlorantraniliprole is not expected to pose an intermediate-term risk because no intermediate-term adverse effects were identified.
- 5. Aggregate cancer risk for U.S. population. Chlorantraniliprole is classified as "Not Likely to Be Carcinogenic to Humans," therefore, a cancer aggregate assessment was not performed.
- 6. 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 chlorantraniliprole residues.

### V. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology is available for plants and livestock using liquid chromatography/ tandem mass spectrometer/mass spectrometer (LC/MS/MS) for analysis of chlorantraniliprole residues. The limit of quantitation (LOQ) is reported at 0.01 ppm for parent chlorantraniliprole. The LC/MS/MS method was adequately validated on a variety of matrices, and an acceptable Independent Laboratory Validation (ILV) study was submitted. The method for the determination of chlorantraniliprole in processed commodities is a LC/MS/MS method, DuPont-14314, which is a slightly modified version of DuPont-11374. The LOQ is reported at 0.010 ppm for chlorantraniliprole. The requirements for multiresidue methods data are fulfilled. Chlorantraniliprole is not recovered by the U.S. Food and Drug Administration's (FDA's) multiresidue methods.

#### 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 and Canada have established maximum residue limits (MRLs) for residues of chlorantraniliprole in/on rice. The recommended U.S. tolerance for the time-limited tolerance established by this action of 15 ppm chlorantraniliprole rice, grain is not harmonized with the Canadian MRL (0.15 ppm) nor the Codex MRL (0.4 ppm) for rice, grain because of

considerable differences in the use pattern, and EPA's regulations require adequate time-limited tolerances be in place in order to allow a pesticide use on food under an emergency exemption. Since EPA has determined that this time-limited tolerance is safe, EPA is establishing this time-limited tolerance despite the lack of harmonization with the related Codex MRL.

#### C. Effective and Expiration Date(s)

In general, a tolerance action is effective on the date of publication of the final rule in the Federal Register. For actions in the final rule that lower or revoke existing tolerances, EPA will set an expiration date for the existing tolerance of six months after the date of publication of the final rule in the Federal Register, in order to allow a reasonable interval for producers in exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

#### VI. Conclusion

Therefore, a time-limited tolerance is established for residues of chlorantraniliprole (CAS No. 50000–45–7) in or on food and feed commodity, rice, grain, at 15 ppm. This tolerance expires on December 31, 2028.

# VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at https://www.epa.gov/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 a time-limited tolerance or an exemption from the requirement of a tolerance for pesticide chemical residues in food that will result from the use of a pesticide under an emergency exemption granted by EPA under FIFRA section 18. The Office of Management and Budget 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 contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.* 

# D. Regulatory Flexibility Act (RFA)

Since tolerances and exemptions that are established in accordance with FFDCA sections 408(e) and 408(1)(6), 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. 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).

#### VIII. 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 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: November 3, 2025.

#### Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

For the reasons stated in the preamble, the EPA amends 40 CFR chapter I 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.

 $\blacksquare$  2. In § 180.628, add paragraph (b) and Table 2 to read as follows:

# § 180.628 Chlorantraniliprole; tolerances for residues.

(b) Section 18 emergency exemptions. A time-limited tolerance is established for residues of chlorantraniliprole, including its metabolites and

degradates, in or on the specified agricultural commodity in the table below. Compliance with the tolerance level specified in the following table is to be determined by measuring only chlorantraniliprole, 3-bromo-*N*-[4-chloro-2-methyl-6[(methylamino) carbonyl]phenyl]-1-(3-chloro-2-pyridinyl)-1*H*-pyrazole-5-carboxamide, in or on the specified agricultural commodity, resulting from use of the pesticide pursuant to FIFRA section 18 emergency exemption. The tolerance expires on the date specified in the table.

TABLE 2 TO PARAGRAPH (b)

Commodity	Parts per million	Expiration date
Rice, grain	15	12/31/2028

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# ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 180

[EPA-HQ-OPP-2025-0079; FRL-12955-01-OCSPP]

Castor Oil, Polymer With 2-Ethylhexanol, Maleic Anhydride and Soybean Oil, Sodium Salt in Pesticide Formulations: Tolerance Exemption

**AGENCY:** Environmental Protection

Agency (EPA). **ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of castor oil, polymer with 2-ethylhexanol, maleic anhydride and soybean oil, sodium salt (CAS No. 3057850-65-1) minimum number average molecular weight 4571; when used as an inert ingredient in a pesticide chemical formulation under 40 CFR 180.960. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Spring Regulatory Sciences on behalf of Ashland Specialty Ingredients G.P. submitted a petition to EPA requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of castor oil, polymer with 2-ethylhexanol, maleic anhydride and soybean oil, sodium salt on food or feed commodities when used in accordance with these exemptions.

**DATES:** This regulation is effective November 17, 2025. Objections and requests for hearings must be received