



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2021-0641; FRL-13015-01-OCSP]

Isocloseram; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of isocloseram (CASRN 2061933-85-3) in or on multiple commodities which are identified and discussed later in this document. Under the Federal Food, Drug, and Cosmetic Act (FFDCA), Syngenta Crop Protection, LLC 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 [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 this document).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0641, is available online 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) 566-2427; 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).

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 the docket ID number EPA-HQ-OPP-2021-0641 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 "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 March 22, 2022 (87 FR 16133) (FRL-9410-11-OCSP), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1F8934) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide isocycloseram, in or on almond, hulls at 6 ppm; almond, oil at 1 ppm; almond, roasted at 0.5 ppm; apple, wet pomace at 1 ppm; barley, grain at 0.01 ppm; barley, hay at 0.01 ppm; barley, straw at 0.01 ppm; buckwheat, grain at 0.01 ppm; buckwheat, forage at 0.01 ppm; buckwheat, hay at 0.01 ppm; buckwheat, straw at 0.01 ppm; corn, field, grain at 0.01 ppm; corn, field, forage at 2 ppm; corn, field, stover at 1.5 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 1.5 ppm; cotton, gin byproducts at 10 ppm; cottonseed, subgroup 20C at 0.5 ppm; fruit, citrus, group 10–10 at 0.4 ppm; fruit, pome, group 11–10 at 0.4 ppm; fruit, stone, group 12–12 at 1 ppm; grain, cereal, forage, fodder and straw, group 16 at 0.01 ppm; nut, tree, group 14–12 at 0.15 ppm; oat, grain at 0.01 ppm; oat, forage at 0.01 ppm; oat, hay at 0.01 ppm; oat, straw at 0.01 ppm; onion, bulb, subgroup 3–07A at 0.01 ppm; onion, green, subgroup 3–07B at 0.9 ppm; orange, citrus oil at 190 ppm; orange, dried pulp at 9 ppm; orange, peel at 5 ppm; orange, wet pulp at 3 ppm; peas and bean, dried shelled, except soybean, subgroup 6C at 0.01 ppm; peanut, nutmeat at 0.01 ppm; pearl millet, grain at 0.01 ppm; pearl millet, forage at 0.01 ppm; pearl millet, hay at 0.01 ppm; pearl millet, straw at 0.01 ppm; peas, hay at 0.01 ppm; peas, vine at 0.01 ppm; plum, prunes at 4 ppm; proso millet, grain at 0.01 ppm; proso millet, forage at 0.01 ppm; proso millet, hay at 0.01 ppm; proso millet, straw at 0.01 ppm; rapeseed, subgroup 20A at 0.01 ppm; rye, grain at 0.01 ppm; rye, forage at 0.01 ppm; rye,

hay at 0.01 ppm; rye, straw at 0.01 ppm; soybean, seed at 0.15 ppm; soybean, hulls at 0.5 ppm; teosinte, grain at 0.01 ppm; teosinte, forage at 0.01 ppm; teosinte, hay at 0.01 ppm; teosinte, straw at 0.01 ppm; tomato, dried pomace at 35 ppm; tomato, sun-dried at 3 ppm; tomato, wet pomace at 10 ppm; triticale, grain at 0.01 ppm; triticale, forage at 0.01 ppm; triticale, straw at 0.01 ppm; vegetables, *brassica*, head and stem, group 5–16 at 4 ppm; vegetables, cucurbit, group 9 at 0.1 ppm; vegetables, fruiting, subgroup 8–10A at 0.5 ppm; vegetables, fruiting, subgroup 8–10B at 0.6 ppm; vegetables, leafy, group 4–16 at 9 ppm; vegetables, tuberous and corm, subgroup 1C at 0.01 ppm; wheat, grain at 0.01 ppm; wheat, forage at 0.01 ppm; wheat, hay at 0.01 ppm; wheat, straw at 0.01 ppm; cattle, fat at 0.03 ppm; cattle, kidney at 0.03 ppm; cattle, liver at 0.05 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.05 ppm; milk at 0.01 ppm; milk, cream at 0.01 ppm; goat, fat at 0.03 ppm; goat, kidney at 0.03 ppm; goat, liver at 0.05 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.05 ppm; horse, fat at 0.03 ppm; horse, kidney at 0.03 ppm; horse, liver at 0.05 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.05 ppm; sheep, fat at 0.03 ppm; sheep, kidney at 0.03 ppm; sheep, liver at 0.05 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.05 ppm; poultry (muscle, fat, offal) at 0.01 ppm; birds' egg at 0.01 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the in the docket, <https://www.regulations.gov>. No substantive public comments were received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the petitioned-for tolerance levels and commodity definitions for several commodities. The reasons 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 isocycloseram including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with isocycloseram is summarized in this unit.

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.

Isocycloseram is a new broad-spectrum insecticide. It belongs to the isoxazolines chemical class, which have an insecticidal mode of action based on allosteric modulation of the gamma aminobutyric acid (GABA) receptor. The toxicology database for isocycloseram is adequate for hazard characterization, toxicity endpoint selection, and Food Quality Protection Act Safety Factor (FQPA SF) consideration for registration in the U.S.

Rats are the most sensitive species in the database, and male rats are more sensitive than female rats. The testes, epididymides, and liver were the target organs of isocycloseram in oral toxicity studies in rats. Tubular degeneration of testes, and cellular debris and reduced sperm in the epididymides were observed in subchronic, chronic/carcinogenicity, and one-generation reproduction studies in rats. Additionally, hepatocyte vacuolation and/or inflammatory cell infiltrate were noted in the chronic/carcinogenicity and one-generation reproduction studies in rats. Toxicity in the rat was observed at lower dose levels with increased duration of exposure. In the 28-day dermal toxicity study in rats, no adverse effects were observed up to the limit dose. No adverse effects were observed in mice following subchronic and chronic exposure. Decreased body weight and poor clinical conditions (vomiting and slight body tremors) were observed in dogs after subchronic exposure.

There was no evidence of qualitative or quantitative life-stage susceptibility in the rat and rabbit developmental toxicity studies tested up to 15 mg/kg/day, and in one- and two-generation

rat reproduction studies tested up to 15 and 12 mg/kg/day respectively. There was no evidence of neurotoxicity in the acute and subchronic neurotoxicity studies up to the highest dose tested (1000 mg/kg for acute and 33 mg/kg/day for subchronic).

Isocycloseram is classified as “Not Likely to be Carcinogenic to Humans.” No treatment-related increase in tumors was observed in the carcinogenicity studies in rats and/or mice at doses that were considered adequate to assess carcinogenicity. Additionally, there was no evidence of mutagenicity *in vivo* or *in vitro*.

Isocycloseram and 26 metabolites/degradates were run through Derek Nexus (v6.1.0), and many of the metabolites produced similar alerts to the parent compound and expected to be equal or lesser mammalian toxicity to the parent. EPA conservatively assumed comparable toxicity for isocycloseram and relevant metabolites/degradates in the risk assessment.

Specific information on the studies received and the nature of the adverse effects caused by isocycloseram 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 <https://www.regulations.gov> in document Isocycloseram. Human Health Risk Assessment for the Section 3 Registration of the New Active Ingredient Isocycloseram on Treated Seeds, Agricultural Field Crops, Indoor/Outdoor Residential Areas, Residential/Commercial Turf, Greenhouse, Commercial/Industrial Areas, Industrial Structures, and Agricultural Structures (Isocycloseram Human Health Risk Assessment) can be found in docket ID number EPA-HQ-OPP-2021-0641.

C. Toxicological Points of Departure/Levels of Concern

Once a pesticide’s toxicological profile is determined, EPA identifies toxicological points of departure (PODs) 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 visit <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

Acute and cancer dietary risk assessments are not required since no appropriate toxicological effects attributable to a single exposure (dose) and no treatment-related increase in tumors, respectively, were observed in the available toxicity studies. The combined chronic toxicity/carcinogenicity study in the rat was selected for the chronic dietary endpoint for all populations with a NOAEL of 2 mg/kg/day. More detailed information on the toxicological endpoints for isocycloseram used for human risk assessment can be found in the Isocycloseram Human Health Risk Assessment in docket ID number EPA-HQ-OPP-2021-0641.

D. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isocycloseram, EPA considered exposure under the petitioned-for tolerances to be established in 40 CFR part 180. EPA incorporated exposure from isocycloseram's residues of concern in food and drinking water. EPA assessed dietary exposures from isocycloseram 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 isocycloseram; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the Dietary Exposure Evaluation Model - Food Commodity Intake Database (DEEM-FCID), Version 4.02, which incorporates 2005-2010 consumption data from 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 used tolerance-level residues (primary crops), calculated residues (livestock), and 100% crop treated (PCT) assumptions.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that isocycloseram 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 did not use anticipated residue and/or PCT information in the dietary assessment for isocycloseram. Tolerance-level residues for primary crops, calculated residues for livestock and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for isocycloseram in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of isocycloseram. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment>.

Based on the Pesticide Water Calculator (PWC Version 2.001), the estimated drinking water concentrations (EDWCs) of isocycloseram for chronic non-cancer assessments are estimated to be 9.9 ppb for surface water and 0.48 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value of 9.9 ppb was used to assess the contribution from drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., products registered for direct application to lawn and for garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Isocycloseram is proposed for the following uses that could result in residential exposures: lawns, indoor environments, gardens, and trees. EPA assessed the following residential exposure scenarios: Short term residential post-application exposure in children 1 to less than 2 years old (1 to <2) from incidental oral exposures resulting from indoor and lawns/turf applications. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-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.”

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 isocycloseram and any other substances. For the purposes of this action, therefore, EPA has not assumed that isocycloseram has 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/pesticide-cumulative-risk-assessment-framework>.

E. Safety Factor for Infants and Children

1. *In general.* FFDCFA 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 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. *Prenatal and postnatal sensitivity.* No evidence of qualitative or quantitative life-stage susceptibility in the rat and rabbit developmental toxicity studies and one- and two-generation rat reproduction studies up to the highest doses tested.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for isocycloseram is adequate for hazard characterization, toxicity endpoint selection, and FQPA SF consideration. EPA concluded that immunotoxicity and developmental neurotoxicity (DNT) studies could be waived and that dosing in the subchronic neurotoxicity (SCN) and rat and rabbit developmental toxicity and two-generation reproduction toxicity studies is adequate and additional studies are not required.

ii. There is no indication that isocycloseram is a neurotoxic chemical and there is no need for a DNT study or additional uncertainty factors (UFs) to account for neurotoxicity.

iii. There is no evidence that isocycloseram results in increased quantitative or qualitative lifestage susceptibility in rats and rabbits up to the highest dose tested. Although the rabbit and rat definitive developmental studies did not test up to the limit dose and there is a potential for susceptibility at higher doses, the concern is low based on the weight-of-evidence (WOE)

determination. The WOE indicates an overall low level of concern for lifestage sensitivity with no adverse effects observed in fetal compartments and that the animals were adequately challenged in dosing for all lifestages, and the selected PODs are protective of any potential effects that would be observed at a higher dose.

iv. There are no residual uncertainties identified in the exposure databases. The chronic dietary analysis incorporated 100 PCT and tolerance-level residues for primary crops and calculated residues for livestock and protective modeled water concentration estimates for potential exposure through drinking water. Residential post-application exposures are anticipated and were based on the 2012 Residential Standard Operating Procedures (SOPs) and chemical-specific turf transferrable residue (TTR) data. EPA does not believe that the non-dietary occupational exposures are underestimated because they are also based on conservative assumptions, including maximum application rates, and protective standard values for unit exposures and acreage treated/amount handled. Therefore, the dietary and residential exposure assessments do not underestimate exposures.

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). 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.

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, isocycloseram is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to isocycloseram from food and water will utilize 67% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure, and not of risk concern. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of isocycloseram is not expected.

3. *Short-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).

Isocycloseram is currently registered for uses that could result in short-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term residential exposures to isocycloseram.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in an aggregate MOE of 300 for food, water, and residential exposure to children 1-2 years old. Because EPA's level of concern for isocycloseram is an MOE below 100, these MOEs are not of concern.

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). Because no intermediate-term residential exposure is expected, an intermediate-term aggregate assessment was not conducted.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of any treatment-related increase in tumors in two adequate rodent carcinogenicity studies, isocycloseram is not expected to pose a cancer risk to humans.

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 isocycloseram residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (quick, easy, cheap, effective, rugged, and safe (QuEChERS)-based high-performance liquid chromatography with mass-spectrometric detection (HPLC-MS/MS) multi-residue method (EN 15662:2009)) are available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by 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 residues of isocycloseram in or on apple, wet pomace at 1 ppm; fruit, citrus, group 10-10, oil at 80 ppm; fruit, citrus, group 10-10, dried pulp at 3 ppm; and plum, prune, dried at 1.5 ppm. These MRLs are the same level as the tolerances being established for residues of isocycloseram in the United States.

The Codex has also established MRLs for residues of isocycloseram in or on cattle, meat at 0.02 ppm; goat, meat at 0.02 ppm; horse, meat at 0.02 ppm; milk at 0.05 ppm; poultry, meat at 0.02 ppm and sheep, meat at 0.02 ppm. These MRL levels are different than the tolerance levels

being established for isocycloseram in the United States. The United States has established tolerances for each of the above-listed commodities at 0.01 ppm to ensure no potential trade barriers with key importing partners of U.S. meat (Korea) and milk (Mexico, Indonesia, Vietnam) products.

C. Revisions to Petitioned-For Tolerances

The petitioner-requested commodity definitions for cattle, kidney; cattle, liver (cattle, meat byproducts); goat, kidney; goat liver (goat, meat byproducts); horse, kidney; horse, liver (horse, meat byproducts); sheep, kidney; and sheep, liver (sheep, meat byproducts); birds' eggs (egg); orange, citrus oil (fruit, citrus, group 10-10, oil); orange, peel (fruit, citrus, group 10-10, dried pulp); cream (milk, fat); pearl millet, forage (millet, pearl, forage); pearl millet, grain (millet, pearl, grain); pearl millet, hay (millet, pearl, hay); pearl millet, straw (millet, pearl, straw); proso millet, forage (millet, proso, forage); proso millet, grain (millet, proso, grain); proso millet, hay (millet, proso, hay); proso millet, straw (millet, proso, straw); peanut, nutmeat (peanut); poultry (muscle, fat, offal)(poultry, fat; poultry, meat; poultry, meat byproducts); plum, prunes (plum, prune, dried); tomato, sun dried (tomato, dried); Vegetables, Brassica, head and stem, group 5-16 (vegetable, *brassica*, head and stem, group 5-16); vegetables, fruiting, subgroup 8-10A; pea, hay and pea, vines (vegetable, legume, forage and hay, except soybean, subgroup 7-22A); vegetables, cucurbit, group 9 (vegetable, cucurbit, group 9); vegetables, fruiting, subgroup 8-10A and vegetables, fruiting subgroup 8-10B (vegetable, fruiting, group 8-10); vegetables, leafy, group 4-16 (vegetable, leafy, group 4-16); peas and bean, dried shelled, except soybean, subgroup 6C (vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E and vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F); vegetables, tuberous and corm, subgroup 1C (vegetable, tuberous and corm, subgroup 1C) are updated to Agency-preferred vocabulary (in parentheses, above) for consistency across chemicals.

Pursuant to 40 CFR 180.40(g), because there is a greater than 5x difference in residues for the representative crops, pecan and almond, the petitioner-requested tolerance for residues on

nut, tree, group 14-12, will not be established. Rather, EPA is establishing tolerances for residues on individual nut commodities that are based on translation from the available residue data on almond or pecan and their shared taxonomic classification, plant morphology, growing season, and agricultural practices. Using the residue data on almond, which shows residues at 0.2 ppm, EPA is establishing tolerances at 0.2 ppm on almond; almond, tropical; beechnut; bunya; candlenut; chestnut; chinquapin; ginkgo; nut, pine; pequi; pine, brazilian; pistachio; and yellowhorn. Using the residue data on pecan, which shows residues at 0.01 ppm, EPA is establishing tolerances at 0.01 ppm on African nut-tree; bur oak; butternut; cashew; chestnut, guiana; coconut; hazelnut; heartnut; monkey-pot; nut, brazil; nut, cajou; nut, coquito; nut, dika; nut, hickory; nut, macadamia; nut, mongongo; nut, pachira; nut, sapucaia; peanut; pecan; walnut, black; and walnut, English.

The petitioner-requested tolerance levels for cattle, fat; goat, fat; horse, fat; and sheep, fat are modified from 0.03 ppm to 0.05 ppm based on anticipated residues in ruminant commodities derived from the Langmuir model. The petitioner-requested tolerance levels for cattle, meat byproducts; goat, meat byproducts; horse, meat byproducts; and sheep, meat byproducts are modified from 0.05 ppm to 0.02 ppm based on the Langmuir model. The petitioner-requested tolerance levels were also modified for fruit, citrus, group 10-10 from 0.4 ppm to 0.5 ppm; vegetable, cucurbit, group 9 from 0.1 ppm to 0.15 ppm and for vegetable, leafy, group 4-16 from 9 ppm to 10 ppm based on the Organization for Economic Co-operation and Development (OECD) tolerance calculator. The petitioner-requested tolerance levels were also modified for tomato, dried from 3 ppm to 2 ppm; plum, prune, dried from 4 ppm to 1.5 ppm and fruit, citrus, group 10-10, oil from 190 ppm to 80 ppm to harmonize with Codex. Tolerances are established for grain, aspirated fractions at 15 ppm and milk, fat at 0.3 ppm based on calculated residues.

The petitioner-requested tolerances for residues on almond, oil; almond, roasted; orange, peel; are not established since anticipated residues are covered by the raw agricultural commodity or crop group tolerances. The petitioner requested tolerances for residues on tomato,

dried pomace; and tomato, wet pomace, which are not significant livestock feed items. These tolerances are not established since the aforementioned commodities are not routinely traded on the commodities exchange markets, and anticipated residues will not significantly increase livestock dietary exposure.

Additionally, although the petition requested that EPA establish a crop subgroup tolerance for rapeseed, subgroup 20A, after submission, the petitioner requested that EPA establish a tolerance just for rapeseed, seed at 0.01 ppm, instead of subgroup 20A. Accordingly, EPA is establishing only the individual commodity tolerance at this time because the label will be limited to the single crop, rather than allowing use on all commodities in the subgroup. As a result, the broader subgroup is unnecessary at this time.

V. Conclusion

Therefore, tolerances are established for residues of isocycloseram in or on African nut-tree at 0.01 ppm; almond at 0.2 ppm; almond, hulls at 6 ppm; almond, tropical at 0.2 ppm; apple, wet pomace at 1 ppm; barley, grain at 0.01 ppm; barley, hay at 0.01 ppm; barley, straw at 0.01 ppm; beechnut at 0.2 ppm; buckwheat, forage at 0.01 ppm; buckwheat, grain at 0.01 ppm; buckwheat, hay at 0.01 ppm; buckwheat, straw at 0.01 ppm; bunya at 0.2 ppm; bur oak at 0.01 ppm; butternut at 0.01 ppm; candlenut at 0.2 ppm; cashew at 0.01 ppm; cattle, fat at 0.05 ppm; cattle, meat at 0.01 ppm; cattle, meat byproducts at 0.02 ppm; chestnut at 0.2 ppm; chestnut, guiana at 0.01 ppm; chinquapin at 0.2 ppm; coconut at 0.01 ppm; corn, field, forage at 2 ppm; corn, field, grain at 0.01 ppm; corn, field, stover at 1.5 ppm; corn, pop, grain at 0.01 ppm; corn, pop, stover at 1.5 ppm; cotton, gin byproducts at 10 ppm; cottonseed, subgroup 20C at 0.5 ppm; egg at 0.01 ppm; fruit, citrus, group 10–10 at 0.5 ppm; fruit, citrus, group 10–10, dried pulp at 3 ppm; fruit, citrus, group 10–10, oil at 80 ppm; fruit, pome, group 11–10 at 0.4 ppm; fruit, stone, group 12–12 at 1 ppm; ginkgo at 0.2 ppm; goat, fat at 0.05 ppm; goat, meat at 0.01 ppm; goat, meat byproducts at 0.02 ppm; grain, aspirated fractions at 15 ppm; hazelnut at 0.01 ppm; heartnut at 0.01; horse, fat at 0.05 ppm; horse, meat at 0.01 ppm; horse, meat byproducts at 0.02

ppm; horse-chestnut, Japanese at 0.01 ppm; milk at 0.01 ppm; milk, fat at 0.3 ppm; millet, pearl, forage at 0.01 ppm; millet, pearl, grain at 0.01 ppm; millet, pearl, hay at 0.01 ppm; millet, pearl, straw at 0.01 ppm; millet, proso, forage at 0.01 ppm; millet, proso, grain at 0.01 ppm; millet, proso, hay at 0.01 ppm; millet, proso, straw at 0.01 ppm; monkey-pot at 0.01 ppm; nut, brazil at 0.01 ppm; nut, cajou at 0.01 ppm; nut, coquito at 0.01 ppm; nut, dika at 0.01 ppm; nut, hickory at 0.01 ppm; nut, macadamia at 0.01 ppm; nut, mongongo at 0.01 ppm; nut, monkey puzzle at 0.2 ppm; nut, okari at 0.2 ppm; nut, pachira at 0.01 ppm; nut, peach palm at 0.2 ppm; nut, pili at 0.2 ppm; nut, pine at 0.2 ppm; nut, sapucaia at 0.01 ppm; oat, forage at 0.01 ppm; oat, grain at 0.01 ppm; oat, hay at 0.01 ppm; oat, straw at 0.01 ppm; onion, bulb, subgroup 3–07A at 0.01 ppm; onion, green, subgroup 3–07B at 0.9 ppm; peanut at 0.01 ppm; pecan at 0.01 ppm; pequi at 0.2 ppm; pine, brazilian at 0.2 ppm; pistachio at 0.2 ppm; plum, prune, dried at 1.5 ppm; poultry, fat at 0.01 ppm; poultry, meat at 0.01 ppm; poultry, meat byproducts at 0.01 ppm; rapeseed, seed at 0.01 ppm; rye, forage at 0.01 ppm; rye, grain at 0.01 ppm; rye, hay at 0.01 ppm; rye, straw at 0.01 ppm; sheep, fat at 0.05 ppm; sheep, meat at 0.01 ppm; sheep, meat byproducts at 0.02 ppm; soybean, hulls at 0.5 ppm; soybean, seed at 0.15 ppm; teosinte, forage at 0.01 ppm; teosinte, grain at 0.01 ppm; teosinte, hay at 0.01 ppm; teosinte, straw at 0.01 ppm; tomato, dried at 2 ppm; triticale, forage at 0.01 ppm; triticale, grain at 0.01 ppm; triticale, straw at 0.01 ppm; vegetables, *brassica*, head and stem, group 5–16 at 4 ppm; vegetable, cucurbit, group 9 at 0.15 ppm; vegetable, foliage of legume, except soybean subgroup 7-22A at 0.01 ppm; vegetable, fruiting, group 8–10 at 0.6 ppm; vegetable, leafy, group 4–16 at 10 ppm; vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E at 0.01 ppm; vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F at 0.01 ppm; vegetable, tuberous and corm, subgroup 1C at 0.01 ppm; walnut, black at 0.01 ppm; walnut, English at 0.01 ppm, wheat, forage at 0.01 ppm; wheat, grain at 0.01 ppm; wheat, hay at 0.01 ppm; wheat, straw at 0.01 ppm; and yellowhorn 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/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: November 18, 2025.

Edward Messina,

Director, 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. Add § 180.730 to subpart C to read as follows:

§ 180.730 Isocycloseram; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide isocycloseram, including its metabolites and degradates, in or on the commodities in the table below.

Compliance with the tolerance levels specified below is to be determined by measuring only isocycloseram, 4-[5-(3,5-dichloro-4-fluorophenyl)-5-(trifluoromethyl)-4,5-dihydro-1,2-oxazol-3-yl]-N-(2-ethyl-3-oxo-1,2-oxazolidin-4-yl)-2-methylbenzamide, in or on the following commodities:

Table 1 to Paragraph (a)

Commodity	Parts per million
African nut-tree	0.01
Almond	0.2
Almond, hulls	6
Almond, tropical	0.2
Apple, wet pomace	1
Barley, grain	0.01
Barley, hay	0.01
Barley, straw	0.01
Beechnut	0.2
Buckwheat, forage	0.01
Buckwheat, grain	0.01
Buckwheat, hay	0.01

Buckwheat, straw	0.01
Bunya	0.2
Bur oak	0.01
Butternut	0.01
Candlenut	0.2
Cashew	0.01
Cattle, fat	0.05
Cattle, meat	0.01
Cattle, meat byproducts	0.02
Chestnut	0.2
Chestnut, guiana	0.01
Chinquapin	0.2
Coconut	0.01
Corn, field, forage	2
Corn, field, grain	0.01
Corn, field, stover	1.5
Corn, pop, grain	0.01
Corn, pop, stover	1.5
Cotton, gin byproducts	10
Cottonseed subgroup 20C	0.5
Egg	0.01
Fruit, citrus, group 10-10	0.5
Fruit, citrus, group 10-10, dried pulp	3
Fruit, citrus, group 10-10, oil	80
Fruit, pome, group 11-10	0.4
Fruit, stone, group 12-12	1
Ginkgo	0.2
Goat, fat	0.05

Goat, meat	0.01
Goat, meat byproducts	0.02
Grain, aspirated fractions	15
Hazelnut	0.01
Heartnut	0.01
Horse, fat	0.05
Horse, meat	0.01
Horse, meat byproducts	0.02
Horse-chestnut, japanese	0.01
Milk	0.01
Milk, fat	0.3
Millet, pearl, forage	0.01
Millet, pearl, grain	0.01
Millet, pearl, hay	0.01
Millet, pearl, straw	0.01
Millet, proso, forage	0.01
Millet, proso, grain	0.01
Millet, proso, hay	0.01
Millet, proso, straw	0.01
Monkey-pot	0.01
Nut, brazil	0.01
Nut, cajou	0.01
Nut, coquito	0.01
Nut, dika	0.01
Nut, hickory	0.01
Nut, macadamia	0.01
Nut, mongongo	0.01
Nut, monkey puzzle	0.2

Nut, okari	0.2
Nut, pachira	0.01
Nut, peach palm	0.2
Nut, pili	0.2
Nut, pine	0.2
Nut, sapucaia	0.01
Oat, forage	0.01
Oat, grain	0.01
Oat, hay	0.01
Oat, straw	0.01
Onion, bulb, subgroup 3-07A	0.01
Onion, green, subgroup 3-07B	0.9
Peanut	0.01
Pecan	0.01
Pequi	0.2
Pine, brazilian	0.2
Pistachio	0.2
Plum, prune, dried	1.5
Poultry, fat	0.01
Poultry, meat	0.01
Poultry, meat byproducts	0.01
Rapeseed, seed	0.01
Rye, forage	0.01
Rye, grain	0.01
Rye, hay	0.01
Rye, straw	0.01
Sheep, fat	0.05
Sheep, meat	0.01

Sheep, meat byproducts	0.02
Soybean, hulls	0.5
Soybean, seed	0.15
Teosinte, forage	0.01
Teosinte, grain	0.01
Teosinte, hay	0.01
Teosinte, straw	0.01
Tomato, dried	2
Triticale, forage	0.01
Triticale, grain	0.01
Triticale, straw	0.01
Vegetable, <i>brassica</i> , head and stem, group 5-16	4
Vegetable, cucurbit, group 9	0.15
Vegetable, foliage of legume, except soybean, subgroup 7-22A	0.01
Vegetable, fruiting, group 8-10	0.6
Vegetable, leafy, group 4-16	10
Vegetable, legume, pulse, bean, dried shelled, except soybean, subgroup 6-22E	0.01
Vegetable, legume, pulse, pea, dried shelled, subgroup 6-22F	0.01
Vegetable, tuberous and corm, subgroup 1C	0.01
Walnut, black	0.01
Walnut, english	0.01
Wheat, forage	0.01
Wheat, grain	0.01
Wheat, hay	0.01

Wheat, straw	0.01
Yellowhorn	0.2

(b) [Reserved]

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