



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2024-0631; FRL 13060-01-OCSP]

Thiamethoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of thiamethoxam in or on pepper, black at 0.15 parts per million (ppm). Under the Federal Food, Drug, and Cosmetic Act (FFDCA), the American Spice Trade Association submitted a petition to EPA requesting that EPA establish a maximum permissible level for residues of this pesticide in or on this commodity.

DATES: This rule is effective on [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-2024-0631, is available at <https://www.regulations.gov>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Charles Smith, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; 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 might apply to them:

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

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

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

EPA is issuing this rulemaking under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a. FFDCA section 408(b)(2)(A)(i) allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." FFDCA section 408(b)(2)(A)(ii) defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings but does not include occupational exposure. FFDCA section 408(b)(2)(C) requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . ."

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. If you fail to file an objection to the final rule within the time period specified in the final rule, you will have waived the right to raise any issues resolved in the final rule. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2024-0217 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 July 3, 2025 (90 FR 29515 (FRL-12474-05-OCSPP)), EPA issued a document pursuant to FFDCa section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F9156) by the American Spice Trade Association. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide thiamethoxam in or on pepper, black at 0.1 ppm. That document referenced a summary of the petition that was prepared by the petitioner and is included in the docket. No comments were received in response to that notice of filing.

III. Final Tolerance Action

A. Aggregate Risk Assessment and Determination of Safety

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. Based upon review of the data supporting the petition and in accordance with its authority under FFDCa section 408(d)(4)(A)(i), EPA is establishing a tolerance that varies from what the petitioner sought. Specifically, EPA is establishing a tolerance of 0.15 ppm (versus the petitioned-for 0.1 ppm) because the monitoring data the tolerance is based upon demonstrate that a tolerance of 0.15 ppm is the appropriate level.

EPA has determined that it has sufficient data to assess the hazards of and to make a determination on aggregate exposure for thiamethoxam, including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with thiamethoxam is summarized in this unit.

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting

discussions previously published in other 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 this new rulemaking.

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

Tolerances for residues of thiamethoxam are listed in 40 CFR 180.565 and are expressed in terms of the combined residues of the insecticide thiamethoxam and its metabolites and degradates, including its metabolite CGA-322704. CGA-322704 is also the registered active ingredient clothianidin, for which tolerances are listed in 40 CFR 180.586. Clothianidin (hereinafter referred to as CGA-322704) has a complete toxicological database and appears to have effects in mammals that are different from those of thiamethoxam. A separate risk assessment that addresses risks from CGA-322704 residues resulting from the direct application of CGA-322704 (clothianidin), as well as risks from residues of CGA-322704 coming from thiamethoxam uses has been conducted, and there are no risk estimates of concern as a result of the proposed tolerance for thiamethoxam residues in or on black pepper.

Specific information on the risk assessments conducted in support of this action, including on the studies received and the nature of the adverse effects caused by thiamethoxam and CGA-322704, can be found in the documents titled “Thiamethoxam. Human Health Risk Assessment for Use on Imported Black Pepper” (hereinafter “Thiamethoxam Human Health Risk Assessment”) and “Clothianidin. Human Health Risk Assessment to Address Exposure Associated with a New Tolerance for Thiamethoxam in/on Imported Black Pepper” (hereinafter

“Clothianidin Human Health Risk Assessment”), which are available in the docket for this action.

B. *Toxicological Profile*

For a discussion of the toxicological profile of thiamethoxam, see Unit III.A. of the thiamethoxam tolerance rulemaking published in the *Federal Register* of February 15, 2017 (82 FR 10712) (FRL-9957-00).

C. *Toxicological Points of Departure/Levels of Concern*

For a summary of the toxicological points of departure (PODs)/levels of concern for thiamethoxam used for human health risk assessment, see Unit III.B. of the February 15, 2017, rulemaking (82 FR 10712) (FRL-9957-00).

D. *Exposure Assessment*

Much of the exposure assessment remains the same although updates have occurred to account for exposures from the petitioned-for tolerance. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, see Unit III.C. of the February 15, 2017, rulemaking (82 FR 10712) (FRL-9957-00).

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to thiamethoxam, EPA considered exposure under the petitioned-for tolerance as well as all existing thiamethoxam tolerances in 40 CFR 180.565. The assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02. EPA used 2005–2010 food consumption information from the United States Department of Agriculture’s National Health and Nutrition Examination Survey, What We Eat in America. EPA assessed dietary exposures from thiamethoxam in food as follows:

- i. *Acute exposure.* The acute assessment is based on tolerance-level residues and assumes 100 percent crop treated (PCT); the acute assessment is unrefined.
- ii. *Chronic exposure.* The chronic assessment is based on average residues from crop

field trials and assumes 100 PCT; the chronic assessment is moderately refined.

iii. *Cancer*. EPA has concluded that thiamethoxam is not likely to be carcinogenic to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information*. FFDCA section 408(b)(2)(E) authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require pursuant to FFDCA section 408(f)(1) that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of this tolerance.

EPA did not use PCT information in the dietary exposure assessment for thiamethoxam. 100 PCT was assumed for all food commodities.

2. *Dietary exposure from drinking water*. EPA has revised the thiamethoxam drinking water assessment since the February 15, 2017, rulemaking (82 FR 10712) (FRL-9957-00). Based on the Pesticide in Water Calculator's version 1.52, the estimated drinking water concentrations (EDWCs) of thiamethoxam in groundwater are 63 parts per billion (ppb) for acute exposures and 58 ppm for chronic exposures. Groundwater EDWCs were used in the dietary assessment for all sources of drinking water. 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>.

3. *From non-dietary exposure*. The term "residential exposure" is used in this document to refer to non-occupational, non-dietary exposure (e.g., from lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There are no new proposed

residential uses for thiamethoxam at this time. However, thiamethoxam is currently registered for the following uses that could result in residential handler and post-application short-term dermal, inhalation, and incidental oral exposures: turf (including residential lawns and golf courses), gardens and trees, and indoor environments (as a crack and crevice treatment). Worst-case residential exposure scenarios for adults and children were included in the aggregate risk estimates and were associated with post-application exposures from treated gardens, golf courses, and indoor spraying on carpets.

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.” In 2016, EPA’s Office of Pesticide Programs released a guidance document entitled “*Pesticide Cumulative Risk Assessment: Framework for Screening Analysis.*” The Agency has utilized this framework for thiamethoxam and determined that thiamethoxam along with clothianidin, acetamiprid, dinotefuran, imidacloprid, nithiazine, and thiacloprid form a candidate common mechanism group (CMG). This group of pesticides, referred to as neonicotinoids, is considered a candidate CMG because they share characteristics to support a testable hypothesis for a common mechanism of action for neonicotinoids. Following this determination, the Agency conducted an initial and updated screening-level cumulative risk assessment consistent with the 2016 guidance document, which indicated that cumulative risk estimates for neonicotinoids are below the Agency’s levels of concern. The Agency has determined that exposures from the petitioned-for tolerance are not anticipated to affect the overall results of the previous cumulative assessment. Therefore, there are no cumulative risks of concern, and the neonicotinoid cumulative assessment does not need to be updated for this action.

E. Safety Factor for Infants and Children

EPA continues to conclude that there are reliable data to support the reduction of the 10X

Food Quality Protection Act (FQPA) safety factor to 1X. See Unit III.D. of the February 15, 2017, rulemaking (82 FR 10712) (FRL-9957-00) for a discussion of the Agency's rationale for that determination.

F. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (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 margin of exposure (MOE) exists. Where different routes of exposure have different levels of concern, the Agency uses the aggregate risk index approach for calculating short-, intermediate-, and long-term aggregate risk estimates.

1. *Acute dietary risk.* The acute dietary risk estimates for thiamethoxam are not of concern. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute exposure to thiamethoxam from food and water is 13% of the aPAD for all infants (less than 1 year old), the population group receiving the greatest exposure.

2. *Chronic dietary risk.* The chronic dietary risk estimates for thiamethoxam are not of concern. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to thiamethoxam from food and water is 75% of the cPAD for children 1-2 years old, the population group receiving the greatest exposure.

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). Thiamethoxam 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 thiamethoxam. Using

the exposure assumptions described in this unit for short-term exposures, the MOEs for children (490 and 160) and adults (120) are greater than their respective LOCs of 100. As a result, the short-term aggregate risk estimates are not of concern for the general U.S. population or any population subgroup.

4. *Intermediate- and long-term risk.* Intermediate- and long-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). For thiamethoxam, residential exposures are not expected to occur for intermediate-term duration (1-6 months); therefore, intermediate- and long-term risk were not assessed.

5. *Aggregate cancer risk for U.S. population.* Thiamethoxam is classified as “Not likely to be carcinogenic to humans”; therefore, EPA does not expect thiamethoxam exposures to pose an aggregate cancer risk.

6. *Determination of safety.* Based on the risk assessments and information described above, 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 thiamethoxam residues. More detailed information on this action can be found in the Thimethoxam Human Health Risk Assessment and the Clothianidin Human Health Risk Assessment, which are available in the docket for this action.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate method, HPLC Method AG-675, is available to enforce the recommended tolerance. 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 U.S. 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.

Neither Codex nor Canada's Pest Management Regulatory Agency have established a MRL for thiamethoxam in or on black pepper. Therefore, there are no harmonization issues regarding the establishment of a tolerance without a U.S. registration on black pepper.

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 Sanitary and Phytosanitary Measures Agreement to adapt to the requirements.

V. Conclusion

Therefore, a tolerance is established for residues of thiamethoxam, in or on pepper, black at 0.15 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 a tolerance action 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.D.

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: December 17, 2025.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs

For the reasons set forth in the preamble, EPA is amending 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.

2. Amend § 180.565, by:

a. Adding the following commodity in alphabetical order to the table in paragraph (a):

“Pepper, Black”; and

b. Adding footnote 3 to the table in paragraph (a).

The additions read as follows:

§ 180.565 Thiamethoxam; tolerances for residues.

(a) * * *

Table 1 to Paragraph (a)

| Commodity | Parts per million |
|----------------------------|--------------------------|
| * * * * * | |
| Pepper, black ³ | 0.15 |
| * * * * * | |

¹ There are no U.S. registrations for these commodities as of February 15, 2017.

² There are no U.S. registrations for these commodities as of June 15, 2022.

³ There are no U.S. registrations for these commodities as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

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