



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2024-0217; 12852-01-OCSPP]

### Acetamiprid; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of acetamiprid in or on multiple spice commodities that are identified and discussed in this document. 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 these commodities.

**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-2024-0217, 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](mailto: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](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 1, 2024 (89 FR 54398 (FRL-11682-05-OCSP)), 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 3F9085) by the American Spice Trade Association. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the insecticide acetamiprid in or on pepper, black at 0.1 parts per million (ppm) and the following spices at 2.0 ppm: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black, seed; caraway, seed; celery, seed; chervil, seed; chinese nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin, seed; dill, seed; fennel, seed; fennel flower, seed; fenugreek, seed; grains of paradise, seed; guarana; honewort, seed; lovage, seed; mahaleb; malabar tamarind; milk thistle; mustard, black, seed; mustard, brown, seed; mustard, white, seed; nutmeg; poppy seed; sesame seed; and wattle seed. That document referenced a summary of the petition that was prepared by the petitioner and 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 tolerances that vary from what the petitioner sought. Specifically, EPA is establishing tolerance values that are consistent with Organization for Economic Cooperation and Development (OECD) rounding class practice. EPA

is also correcting commodity definitions for several commodities. The reasons for these changes are explained in Unit IV.C.

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

In an effort to streamline its publications in the *Federal Register*, EPA is not reprinting discussions that 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 rulemaking, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for this new rulemaking.

For acetamiprid, EPA previously published a tolerance rulemaking in the *Federal Register* of February 14, 2020 (85 FR 8433 (FRL-10004-12)), in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to acetamiprid and established tolerances for residues of that chemical. EPA is incorporating previously published sections from that rulemaking as described further in this rulemaking, as they remain unchanged. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by acetamiprid, can be found in the document titled “Acetamiprid. Human Health Risk Assessment for Proposed Tolerances for Residues, Without U.S. Registrations on Pepper, Black and Spices in Crop Group 26 that Overlap with the Codex Crop Subgroup of Spices, Seed” (hereinafter “Acetamiprid Human Health Risk Assessment”), which is available in the docket for this action.

#### B. *Toxicological Profile*

For a discussion of the toxicological profile of acetamiprid, see Unit III.A. in the final

rule of February 14, 2020.

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern (LOCs) 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://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/assessing-human-health-risk-pesticides>.

More detailed information on the toxicological endpoints for acetamiprid used for human health risk assessment can be found in the Acetamiprid Human Health Risk Assessment.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to acetamiprid, EPA considered exposure under the petitioned-for tolerances as well as all existing acetamiprid tolerances in 40 CFR 180.578. EPA assessed dietary exposures from acetamiprid in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified

in the toxicological studies for acetamiprid. In estimating acute dietary exposure, EPA used the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, the acute dietary exposure assessment used tolerance-level residues, 100 percent crop treated (PCT), and empirical and default processing factors.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment, EPA likewise used DEEM-FCID, Version 4.02, which incorporates 2005-2010 consumption data from USDA's NHANES/WWEIA. As to residue levels in food, the chronic dietary exposure assessment used tolerance-level residues except for milk and apple juice, for which EPA used Pesticide Data Program monitoring data; 100 PCT; and empirical and default processing factors. The chronic assessment also accounted for potential residues from the food handling establishment (FHE) use of acetamiprid. For commodities that would only have residues resulting from the FHE use, EPA used a residue value of one-half of the existing FHE tolerance and a PCT estimate of 4.65%.

iii. *Cancer.* EPA has concluded that acetamiprid 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 these tolerances.

FFDCA section 408(b)(2)(F) states that EPA may use data on the actual percent of food treated for assessing chronic dietary risk only if:

- *Condition a:* The data used are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain the pesticide residue.
- *Condition b:* The exposure estimate does not underestimate exposure for any significant subpopulation group.
- *Condition c:* Data are available on pesticide use and food consumption in a particular area and the exposure estimate does not understate exposure for the population in such area.

In addition, EPA must provide for periodic evaluation of any estimates used. To provide for the periodic evaluation of the estimate of PCT as required by FFDCA section 408(b)(2)(F), EPA may require registrants to submit data on PCT.

The acute and chronic assessments assumed 100 PCT for agricultural uses and the PCT estimate of 4.65% for the FHE use.

EPA estimates the percent of commodities treated in FHEs for uses of active ingredients based on the best available information. This includes survey information on pesticide usage related to the number of facilities being treated, product forms used (e.g., liquids and aerosols), and treatment schedule by FHE segments (e.g., warehouse, food processor, distributor, and restaurant). EPA also incorporated the best available information related to the transfer of commodities between various segments of FHEs and the percent of food consumed by location, either in the home or outside the home.

All information currently available has been considered and EPA has concluded that for any active ingredient, including acetamiprid, there is at most a 4.65% likelihood that a food commodity could contain potential residues resulting from one or more treatments while in the FHE channel of trade. Similar to estimates of agricultural use, this estimate should be

reconsidered in 5 years.

EPA believes that the three conditions discussed in Unit III.C.1.iv. have been met. With respect to Condition a, PCT estimates are derived from Federal and private market survey data, which are reliable and have a valid basis. EPA is reasonably certain that the percentage of the food treated is not likely to be an underestimation. As to Conditions b and c, regional consumption information and consumption information for significant subpopulations is taken into account through EPA's computer-based model for evaluating the exposure of significant subpopulations including several regional groups. Use of this consumption information in EPA's risk assessment process ensures that EPA's exposure estimate does not understate exposure for any significant subpopulation group and allows EPA to be reasonably certain that no regional population is exposed to residue levels higher than those estimated by the Agency. Other than the data available through national food consumption surveys, EPA does not have available reliable information on the regional consumption of food to which acetamiprid may be applied in a particular area.

*2. Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for acetamiprid in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of acetamiprid. 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 in Water Calculator and Provisional Cranberry Model, the estimated drinking water concentrations of acetamiprid for acute exposures are 88.1 parts per billion (ppb) in surface water and 211 ppb in ground water, and for chronic exposures are 12.7 ppb in surface water and 175 ppb in ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 211 ppb

was used to assess the contribution from drinking water. For the chronic dietary risk assessment, the water concentration of value 175 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., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). There are no new proposed residential uses for acetamiprid at this time. However, acetamiprid is currently registered for uses that could result in residential handler and post-application exposures, including gardens and trees, spot-on pet treatment, fly control, indoor crack/crevice, mattresses for bed bug control, and animal barns. For a summary of these exposures, see Unit III.C.3. in the final rule of February 14, 2020.

4. *Cumulative effects from substances with a common mechanism of toxicity.* FFDC section 408(b)(2)(D)(v) requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency considers “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 acetamiprid to share a common mechanism of toxicity with any other substances, and acetamiprid does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that acetamiprid does not have 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/cumulative-assessment-risk-pesticides>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* FFDC section 408(b)(2)(C) provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account

for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Evidence of qualitative susceptibility was observed in the 2-generation reproductive toxicity study, with the offspring effects (reductions in pup weights, reduction in litter size and viability, delays in weaning indices and the age to attain vaginal opening and preputial separation) considered more severe than the observed decrease in parental body weights. Qualitative susceptibility was also seen in the developmental neurotoxicity study with offspring effects (decreased pup weight, pre-weaning survival, and decreased startle response) occurring in the presence of marginal parental body weight decreases.

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 for all scenarios, with the exception of the assessment of inhalation exposure. The default FQPA 10X SF remains in place for assessing inhalation exposure due to the lack of a subchronic inhalation study. That decision is based on the following findings:

i. The toxicity database for acetamiprid is complete with the exception of a subchronic inhalation study.

ii. Acetamiprid produced signs of neurotoxicity in the high dose groups of the acute and developmental neurotoxicity studies in rats and the subchronic toxicity study in mice. However, no neurotoxic findings were reported in the subchronic neurotoxicity study in rats. Additionally, there are clear NOAELs identified for the neurotoxicity effects observed in the guideline studies. The doses and endpoints selected for risk assessment are protective and account for all adverse toxicological effects observed in the database.

iii. No quantitative or qualitative evidence of increased susceptibility of fetuses to *in utero* exposure to acetamiprid was observed in the developmental toxicity study in either rats or rabbits. Although increased qualitative susceptibility was seen in the reproduction toxicity and the DNT study, the degree of concern for the effects is low. There are clear NOAELs for the offspring effect and regulatory doses were selected to be protective of these effects. No other residual uncertainties were identified with respect to susceptibility. The endpoints and doses selected for acetamiprid are protective of adverse effects in both offspring and adults.

iv. There are no residual uncertainties identified in the exposure databases. The acute dietary food exposure assessment was performed based on 100 PCT and tolerance-level residues, and the chronic dietary exposure assessment was slightly refined using 100 PCT and tolerance-level residues for most agricultural commodities, with a PCT estimate of 4.65% used for commodities that would only have residues resulting from the FHE use. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to acetamiprid in drinking water. EPA used similarly conservative assumptions to assess post-application exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by acetamiprid.

#### *E. 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 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 margin of exposure (MOE) exists. Where different routes of exposure have different levels of concern, the Agency uses the aggregate risk index (ARI) approach for calculating short-, intermediate-, and long-term aggregate risk estimates.

1. *Acute dietary risk.* The acute dietary risk estimates for acetamiprid are not of concern. Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute exposure to acetamiprid from food and water is 75% of the aPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

2. *Chronic dietary risk.* The chronic dietary risk estimates for acetamiprid are not of concern. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to acetamiprid from food and water is 31% of the cPAD for all infants <1 year 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).

Acetamiprid 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 acetamiprid.

Using the exposure assumptions described in this unit for short-term exposures, EPA used the ARI approach for calculating the exposure estimates. Estimates greater than or equal to 1.0 are not of concern. For all lifestyles, the ARIs are greater than the target ARI of 1.0, and are not of concern. The ARIs ranged from 1.4 to 5.3. Children 1 to < 2 years old exposed to bed bug treatments indoors resulted in the lowest aggregate ARI of 1.4.

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).

An intermediate-term adverse effect was identified, and intermediate-term exposure is expected; however, since the same endpoint and POD were selected for short- and intermediate term durations, short-term exposure and risk estimates are considered protective of potential intermediate-term exposure and risk.

5. *Long-term risk.* For both adults and children, worst-case long-term scenarios reflect post-application exposure to pets treated with spot-on products. The long-term aggregate risk estimates are not of concern.

6. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, acetamiprid is not likely to be carcinogenic to humans.

7. *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 acetamiprid residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Approved tolerance enforcement methods for acetamiprid residues in crops are available, including methods using gas chromatography with electron capture detection (GC/ECD) analysis for vegetables and non-citrus fruits, high-performance liquid chromatography with ultraviolet detection (HPLC/UV) analysis for citrus fruits only, and HPLC with tandem mass spectrometric detection (LC/MS/MS) analysis for vegetables and non-citrus fruits. An approved HPLC/UV tolerance enforcement method for livestock matrices is available.

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](mailto: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 FFDC 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 tolerance levels established in this action are harmonized with the established Codex MRLs for all commodities.

### *C. Revisions to Petitioned-For Tolerances*

Based upon review of the data supporting the petition, EPA is establishing tolerances that vary from what the petitioner requested. Specifically, EPA is correcting commodity definitions for the following commodities: “caraway, black, seed” and “caraway, seed” to “caraway, black”; “cumin, seed” to “cumin”; “fennel, seed” to “fennel, common, seed”; “grains of paradise, seed” to “grains of paradise”; “malabar tamarind” to “tamarind, seed”; “mustard, black, seed”, “mustard, brown, seed”, and “mustard, white, seed” to “mustard, seed”; and “wattle seed” to “wattleseed”.

EPA is also establishing tolerance values that are consistent with OECD rounding class practice by dropping trailing zeroes. EPA is establishing tolerances at 2 ppm, rather than the requested 2.0 ppm, for the following spices: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black; celery, seed; chervil, seed; chinese nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin; dill, seed; fennel, common, seed; fennel flower, seed; fenugreek, seed; grains of paradise; guarana; honewort, seed; lovage, seed; mahaleb; tamarind, seed; milk thistle; mustard, seed; and wattleseed.

## **V. Conclusion**

Therefore, tolerances are established for residues of acetamiprid, in or on pepper, black at 0.1 ppm and the following spices at 2 ppm: ambrette, seed; angelica, seed; angelica, dahurian, seed; anise, seed; annatto, seed; candlebush; caraway, black; celery, seed; chervil, seed; chinese

nutmeg tree; coriander, seed; cubeb, seed; culantro, seed; cumin; dill, seed; fennel, common, seed; fennel flower, seed; fenugreek, seed; grains of paradise; guarana; honewort, seed; lovage, seed; mahaleb; milk thistle; mustard, seed; nutmeg; poppy seed; sesame, seed; tamarind, seed and wattleseed.

## **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 tolerances 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.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:** July 2, 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 § 180.578, by:

a. Adding the heading “Table 1 to Paragraph (a)(1)” to the table in paragraph (a)(1);

b. Adding the following commodities in alphabetical order to the table in paragraph (a)(1): “ambrette, seed”; “angelica, seed”; “angelica, dahurian, seed”; “anise, seed”; “annatto, seed”; “candlebush”; “caraway, black”; “celery, seed”; “chervil, seed”; “chinese nutmeg tree”; “coriander, seed”; “cubeb, seed”; “culantro, seed”; “cumin”; “dill, seed”; “fennel, common, seed”; “fennel flower, seed”; “fenugreek, seed”; “grains of paradise”; “guarana”; “honestwort, seed”; “lovage, seed”; “mahaleb”; “milk thistle”; “mustard, seed”; “nutmeg”; “pepper, black”; “poppy seed”; “sesame, seed”; “tamarind, seed”; “wattleseed”; and

c. Adding an end note 2 to the table in paragraph (a)(1).

The additions read as follows:

**§ 180.578 Acetamiprid; tolerances for residues.**

(a) \* \* \*

(1) \* \* \*

**Table 1 to Paragraph (a)(1)**

| Commodity                             | Parts per million |
|---------------------------------------|-------------------|
| * * * *                               | * * *             |
| Ambrette, seed <sup>2</sup>           | 2                 |
| Angelica, seed <sup>2</sup>           | 2                 |
| Angelica, dahurian, seed <sup>2</sup> | 2                 |
| Anise, seed <sup>2</sup>              | 2                 |
| Annatto, seed <sup>2</sup>            | 2                 |
| * * * *                               | * * *             |
| Candlebush <sup>2</sup>               | 2                 |
| * * * *                               | * * *             |
| Caraway, black <sup>2</sup>           | 2                 |

|                                   |       |
|-----------------------------------|-------|
| Celery, seed <sup>2</sup>         | 2     |
| * * * *                           | * * * |
| Chervil, seed <sup>2</sup>        | 2     |
| Chinese nutmeg tree <sup>2</sup>  | 2     |
| * * * *                           | * * * |
| Coriander, seed <sup>2</sup>      | 2     |
| * * * *                           | * * * |
| Cubeb, seed <sup>2</sup>          | 2     |
| Culantro, seed <sup>2</sup>       | 2     |
| Cumin <sup>2</sup>                | 2     |
| Dill, seed <sup>2</sup>           | 2     |
| * * * *                           | * * * |
| Fennel flower, seed <sup>2</sup>  | 2     |
| Fennel, common, seed <sup>2</sup> | 2     |
| Fenugreek, seed <sup>2</sup>      | 2     |
| * * * *                           | * * * |
| Grains of paradise <sup>2</sup>   | 2     |
| * * * *                           | * * * |
| Honeywort, seed <sup>2</sup>      | 2     |
| * * * *                           | * * * |
| Lovage, seed <sup>2</sup>         | 2     |
| Mahaleb <sup>2</sup>              | 2     |
| Milk, thistle <sup>2</sup>        | 2     |
| Mustard, seed <sup>2</sup>        | 2     |
| Nutmeg <sup>2</sup>               | 2     |
| * * * *                           | * * * |
| Pepper, black <sup>2</sup>        | 0.1   |
| Poppy, seed <sup>2</sup>          | 2     |
| * * * *                           | * * * |
| Sesame, seed <sup>2</sup>         | 2     |
| * * * *                           | * * * |
| Tamarind, seed <sup>2</sup>       | 2     |
| * * * *                           | * * * |
| Wattleseed <sup>2</sup>           | 2     |

<sup>1</sup> There are no U.S. registrations as of February 10, 2010, for the use of acetamiprid on dried tea.

<sup>2</sup> There are no U.S. registrations for these commodities as of **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

\* \* \* \*