



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2023-0454; FRL-12177-02-OCSP]

RIN 2070-ZA16

### **Pesticide Tolerances; Implementing Registration Review Decisions for Certain Pesticides (Capric (Decanoic) Acid, Caprylic (Octanoic) Acid, and Pelargonic (Nonanoic) Acid)**

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

**ACTION:** Final rule.

**SUMMARY:** The Environmental Protection Agency (EPA or Agency) is finalizing several tolerance actions under the Federal Food, Drug, and Cosmetic Act (FFDCA) that the Agency previously determined were necessary or appropriate during the registration review conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). During registration review, EPA reviews all aspects of a pesticide case, including existing tolerances, to ensure that the pesticide continues to meet the standard for registration under FIFRA.

**DATES:** This rule is effective on **[INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. For actions in this final rule that lower or revoke existing tolerances, the expiration date for the existing tolerance is December 10, 2025. 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.D. of this document).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2023-0454, is available through <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:** Anita Pease, Antimicrobials Division

(7510M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (202) 566-0736; email address: [pease.anita@epa.gov](mailto:pease.anita@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 proposed action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

#### *B. What action is the Agency taking?*

EPA is finalizing several tolerance actions that the Agency proposed in the *Federal Register* of September 6, 2024 (89 FR 72775 (FRL-12177-01-OCSP)), because EPA previously determined these tolerance actions were necessary or appropriate during registration review of the pesticide active ingredients identified in Unit III. of this final rule. The tolerance actions for each pesticide active ingredient are described in Unit III. of the proposed rule and may include but are not limited to the following types of actions:

- Revising tolerance expressions;
- Modifying commodity definitions;

- Updating crop groupings;
- Removing expired tolerances;
- Revoking tolerances that are no longer needed; and
- Harmonizing tolerances with the Codex Alimentarius Commission (Codex) Maximum Residue Levels (MRLs).

As indicated in the proposed rule, this final rule may reflect the Agency's 2019 adoption of the Organization of Economic Cooperation and Development (OECD) Rounding Class Practice. More information on the OECD Rounding Class Practice can be found at [https://one.oecd.org/document/ENV/JM/MONO\(2011\)2/en/pdf](https://one.oecd.org/document/ENV/JM/MONO(2011)2/en/pdf). Where applicable, these adjustments for specific pesticides are reflected in the final regulatory text.

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

FFDCA section 408(e), 21 U.S.C. 346a(e), authorizes EPA to establish, modify, or revoke tolerances or exemptions from the requirement of a tolerance on its own initiative. After providing a 60-day public comment period, EPA may finalize the rule. EPA provided a 60-day comment period and is now finalizing the rule.

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...."

Under FIFRA section 3(g), 7 U.S.C. 136a(g), EPA is required to periodically review all

registered pesticides and determine if those pesticides continue to meet the standard for registration under FIFRA. To learn more about the registration review, please see Unit II.C. of the proposed rule “Pesticide Tolerances; Implementing Registration Review Decisions for Certain Pesticides (Capric (Decanoic) Acid, Caprylic (Octanoic) Acid, and Pelargonic (Nonanoic) Acid)” (89 FR 72775, September 6, 2024 (FRL-12177-01-OCSP)).

*D. How can I file an objection or hearing request?*

Under FFDCFA 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 chemical specific docket ID number as provided in Unit III. 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).

## II. Background

In the *Federal Register* of September 6, 2024 (89 FR 72775 (FRL-12177-01-OCSP)), EPA proposed several tolerance actions to amend established tolerance exemptions for capric (decanoic) acid, caprylic (octanoic) acid, and pelargonic (nonanoic) acid. The Agency previously determined in a March 2022 Combined Preliminary Work Plan/Proposed Interim Decision that these amendments were necessary or appropriate during registration review of these pesticide active ingredients. For additional background information, see Unit II. of the proposed rule.

EPA received six comments in response to the proposed rule. Two comments were in support of the Agency action (see <https://www.regulations.gov> for public comments identified as Document ID Nos. EPA-HQ-OPP-2023-0454-0003 and EPA-HQ-OPP-2023-0454-0007). Four comments suggested EPA eliminate redundancies but maintain tolerances on capric acid, caprylic acid, and pelargonic acid, either at the existing level or consistent with global tolerance levels (see public comments identified as Document ID Nos. EPA-HQ-OPP-2023-0454-0002, EPA-HQ-OPP-2023-0454-0004, EPA-HQ-OPP-2023-0454-0005, and EPA-HQ-OPP-2023-0454-0006). These commenters noted general concerns that consumers may assume foods are free of pesticides, that there is a potential for consumption in large quantities, and that there may be unknown long-term effects. The existing legal framework provided by section 408 of the FFDCA authorizes EPA to establish tolerances when it determines that the tolerance is safe. Upon consideration of the validity, completeness, and reliability of the available data as well as other factors that the FFDCA requires EPA to consider, EPA has determined that these exemptions from the requirement of a tolerance are safe. The commenters provided no information supporting a conclusion that the exemptions for pelargonic acid, capric acid, and caprylic acid are not safe. As stated in the “Pelargonic Acid, Salts and Esters; Fatty Acid Monoesters; Capric Acid; and Caprylic Acid Combined Preliminary Work Plan and Proposed Interim Decision” (March 2022), due to low systemic toxicity and low probability of dietary

(human) exposure when used according to label directions, no dietary endpoints were selected and therefore, no quantitative risk assessment was deemed necessary at the time. While there is the potential for dietary exposure, it is likely low due to the approved use patterns, and EPA has not identified any risks of concern due to the low toxicity. Therefore, the Agency's conclusions from the most recent qualitative risk assessment still apply; there are no dietary risks of concern for registered uses. The comments received on the proposal did not change the Agency's tolerance assessment and final decision.

### **III. Final Tolerance Actions**

#### *A. EPA's safety determination.*

As noted in the proposed rule, EPA has assessed the individual risks from exposure to capric (decanoic) acid, caprylic (octanoic) acid, and pelargonic (nonanoic) acid, as discussed in Unit III. of the proposed rule, taking into consideration all reliable data on toxicity and exposure, including for infants and children, and has included a safety finding under FFDCA section 408(b) for the tolerance actions in the proposed rule. After fully considering comments on the proposed rule, EPA is confirming the safety findings contained in Unit III. of the proposed rule.

Based on the supporting risk assessments and registration review documents, which demonstrate that the aggregate exposure for each individual chemical is below the Agency's level of concern, EPA concludes there is a reasonable certainty that no harm will result to the general population, or specifically to infants and children, from aggregate exposure to residues of capric (decanoic) acid, caprylic (octanoic) acid, and pelargonic (nonanoic) acid (Docket ID No. EPA-HQ-OPP-2021-0336). For further detail about pesticide-specific registration review findings, see the public docket that has been opened for each pesticide, which is available online at <https://www.regulations.gov> using the docket ID number listed in Unit III. of the proposed rule.

#### *B. Analytical enforcement methodology.*

Adequate enforcement methodology as described in the supporting documents is

available to enforce the tolerance expressions.

### *C. Conclusion*

Therefore, EPA is finalizing the tolerance action proposed in the September 6, 2024 proposed rule. Specifically, EPA is removing the redundant exemptions and limits for capric (decanoic) acid under 40 CFR 180.940(b) and (c) entirely, removing the 100 ppm limit for capric (decanoic) acid from 40 CFR 180.940(a), and removing the limit of 170 ppm under 40 CFR 180.1225 for capric (decanoic) acid. EPA is removing the redundant exemptions and limits for caprylic (octanoic) acid from 40 CFR 180.940(a) (limit of 52 ppm), (b), and (c) entirely, and removing the 100 ppm limits for caprylic (octanoic) acid from 40 CFR 180.940(a). EPA is also removing the redundant exemptions and limits for pelargonic (nonanoic) acid from 40 CFR 180.940(b) and (c) entirely, removing the 100 ppm limit for pelargonic (nonanoic) acid from 40 CFR 180.940(a), and removing the limit of 170 ppm under 40 CFR 180.1159(c) for pelargonic (nonanoic) acid.

### **IV. Effective and Expiration Date(s)**

These tolerance actions are 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 has set an expiration date for the existing tolerance of December 10, 2025, six months after the date of publication of the final rule in the *Federal Register*, to allow a reasonable interval for producers in exporting members of the World Trade Organization's (WTO's) Sanitary and Phytosanitary (SPS) Measures Agreement to adapt to the requirements.

### **V. 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. This exemption also applies to tolerance revocations for which extraordinary circumstances do not exist. As such, this exemption applies to the tolerance revocations in this final rule because the Agency knows of no extraordinary circumstances that warrant reconsideration of this exemption for those tolerance revocations.

*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)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities and that the Agency is certifying that this action will not have a significant economic impact on a substantial number of small entities because the action has no net burden on small entities subject to this rulemaking. As discussed in the proposed rule, this determination takes into account the EPA analysis for the establishment and modification of tolerances. EPA did not receive any comments on these conclusions as presented in the proposed rule.

*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 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 it is not a significant regulatory action under section 3(f)(1) of Executive Order 12866 (see Unit V.A.), and because EPA does not believe the environmental health or safety risks addressed by this action present a disproportionate risk to children. However, EPA's 2021 "Policy on Children's Health" applies to this action.

This rule finalizes tolerance actions under the FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue ..." (FFDCA 408(b)(2)(C)). The Agency's consideration is documented in the pesticide-specific registration review documents, located in each chemical docket at <https://www.regulations.gov>.

*I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution or Use*

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001))

because it is not a significant regulatory action under Executive Order 12866.

*J. National Technology Transfer Advancement Act (NTTAA)*

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

*K. Congressional Review Act (CRA)*

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action does not meet the criteria set forth in 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: May 23, 2025.

**Edward Messina,**

*Director, 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 § 180.940 by:

a. In table 1 to paragraph (a):

i. Adding in alphabetical order the entries for “Capric (decanoic) acid” and “Caprylic (octanoic) acid”;

ii. Removing the entries for “Decanoic acid” and “Nonanoic acid” and the two entries for “Octanoic acid”; and

iii. Adding in alphabetical order the entry for “Pelargonic (nonanoic) acid”;

b. In the table in paragraph (b):

i. Adding a table heading; and

ii. Removing the entries for “Decanoic acid”, “Nonanoic acid”, and “Octanoic acid”; and

c. In the table in paragraph (c):

i. Adding a table heading; and

ii. Removing the entries for “Decanoic acid”, “Nonanoic acid”, and “Octanoic acid”.

The additions read as follows:

**§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).**

\* \* \* \* \*

(a) \* \* \*

**Table 1 to Paragraph (a)**

<b>Pesticide Chemical</b>	<b>CAS Reg. No.</b>	<b>Limits</b>
* * *	* * *	* * *
Capric (decanoic) acid	334-48-5	None

Caprylic (octanoic) acid	124-07-2	None
* * * * *		
Pelargonic (nonanoic) acid	112-05-0	None
* * * * *		

\* \* \* \* \*

(b) \* \* \*

Table 2 to Paragraph (b)

\* \* \* \* \*

(c) \* \* \*

Table 3 to Paragraph (c)

\* \* \* \* \*

3. Amend § 180.1159 by revising the section heading and revising and republishing paragraph (c) to read as follows:

**§ 180.1159 Pelargonic (nonanoic) acid; exemption from the requirement of tolerances.**

\* \* \* \* \*

(c) An exemption from the requirement of a tolerance is established for residues of pelargonic (nonanoic) acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of pelargonic (nonanoic) acid as an antimicrobial treatment for application on food contact surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

4. Revise and republish § 180.1225 to read as follows:

**§ 180.1225 Capric (decanoic) acid; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of capric (decanoic) acid in or on all raw agricultural commodities and in processed commodities, when such residues result from the use of capric (decanoic) acid as an antimicrobial treatment in solutions containing a diluted end-use concentration of capric (decanoic) acid on food contact

surfaces such as equipment, pipelines, tanks, vats, fillers, evaporators, pasteurizers and aseptic equipment in restaurants, food service operations, dairies, breweries, wineries, beverage and food processing plants.

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