



## **ENVIRONMENTAL PROTECTION AGENCY**

### **40 CFR Part 180**

**[EPA-HQ-OPP-2017-0418; FRL-6704-02-OCSP]**

**RIN 2070-ZA16**

### **Fenoxaprop-ethyl, Flufenpyr-ethyl, Imazapyr, Maleic hydrazide, Pyrazon, Quinclorac, Triflumizole, et al.; Tolerance and Tolerance Exemption Actions**

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

**ACTION:** Supplemental notice of proposed rulemaking.

**SUMMARY:** On February 5, 2019, the Environmental Protection Agency (EPA or Agency) proposed tolerance and tolerance exemption actions for several pesticides under the Federal Food, Drug, and Cosmetic Act (FFDCA). EPA is issuing this supplemental notice of proposed rulemaking to modify the previously proposed tolerance exemptions for one of those pesticides: maleic hydrazide.

**DATES:** Comments must be received on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPP-2017-0418, through <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. 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:** Robert Little, Pesticide Re-Evaluation Division (7508M), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave, NW., Washington, DC 20460-0001; telephone number: (202) 566-2219; email address: [little.robert@epa.gov](mailto:little.robert@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 issuing this supplemental notice of proposed rulemaking to modify the exemptions from the requirement of a tolerance for residues of the pesticide maleic hydrazide previously proposed in *Fenoxaprop-ethyl, Flufenpyr-ethyl, Imazapyr, Maleic hydrazide, Pyrazon, Quinclorac, Triflumizole, et al.; Proposed Tolerance and Tolerance Exemption Actions* (FRL-9970-24; 84 FR 1691, February 5, 2019) (“2019 Proposed Rule”). Specifically, the Agency previously proposed to establish tolerance exemptions for residues of maleic hydrazide when used as a plant growth regulator or herbicide in or on onion, bulb and potato, and when present in or on potato chips as a result of application to the growing potato plant. EPA is now proposing to establish a single tolerance exemption for residues of maleic hydrazide when used as a plant growth regulator or herbicide, without limiting the exemption to specific commodities.

Further discussion of this action and the Agency's rationale can be found in Unit III of this rulemaking.

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

Section 408(e) of the Federal Food, Drug and Cosmetic Act (FFDCA), 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.

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. As part of the registration review of a pesticide, EPA also evaluates the existing tolerances for the pesticide. Any tolerance changes identified as necessary or appropriate during registration review are summarized in the registration review decision documents for each pesticide active ingredient or registration review case (e.g., in the Proposed Interim Decision (PID), Interim Decision (ID), Proposed Final Decision (PFD), and Final Decision (FD)). Registration review decision documents for maleic hydrazide can be found in the public docket at <https://www.regulations.gov/> in docket identification (ID) number EPA-HQ-OPP-2017-0418.

Prior to issuing the final regulation, FFDCA section 408(e)(2) requires EPA to issue a notice of proposed rulemaking for a 60-day public comment period, unless the Administrator for good cause finds that it would be in the public interest to have a shorter period and states the reasons in the proposed rulemaking. EPA has determined that such good cause exists here. The Agency previously issued the 2019 Proposed Rule for a 60-day public comment period that closed on April 8, 2019, and did not receive any comments. In the 2019 Proposed Rule, EPA proposed tolerance and tolerance exemption actions that were identified as necessary or appropriate during registration review for several pesticides. This supplemental notice of proposed rulemaking modifies the proposed tolerance exemption for only one of those pesticides, maleic hydrazide; the remainder of the 2019 Proposed Rule is unchanged. EPA finds

that it would be in the public interest to have a shorter 30-day public comment period for this supplemental notice to allow the Agency to move forward sooner with issuing a final rule implementing the necessary or appropriate actions that it previously proposed while also providing an adequate opportunity for public comment on the discrete modification described in this supplemental notice. EPA is seeking comment only on the issues discussed in this supplemental notice and is not reopening comment on any other aspects of the 2019 Proposed Rule. After consideration of public comments on this supplemental notice, EPA intends to finalize this action and all applicable actions of the 2019 Proposed Rule in one final rule.

*D. What should I consider as I prepare my comments for EPA?*

1. *Submitting CBI.* Do not submit CBI to EPA through email or <https://www.regulations.gov>. If you wish to include CBI in your comment, 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 so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets>.

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

This supplemental notice of proposed rulemaking provides a 30-day public comment period. After considering comments that are received in response to this supplemental notice, EPA will issue a final rule. At the time of the final rule, you may file an objection or request a hearing on the action taken in the final rule. 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. After the filing deadline specified in the final rule, issues resolved in the final rule cannot be raised again in any subsequent proceedings.

## **II. Background**

*A. What is a tolerance?*

A “tolerance” represents the maximum level for residues of a pesticide chemical legally allowed in or on food, which includes raw agricultural commodities and processed foods and feed for animals. Under the FFDCFA, residues of a pesticide chemical that are not covered by a tolerance or exemption from the requirement of a tolerance are considered unsafe. *See* 21 U.S.C. 346a(a)(1). Foods containing unsafe residues are deemed adulterated and may not be distributed in interstate commerce. *See* 21 U.S.C. 331(a) and 342(a)(2)(B). Consequently, for a food-use pesticide (*i.e.*, a pesticide use that is likely to result in residues in or on food) to be sold and distributed in the United States, the pesticide must not only have appropriate tolerances or exemptions under the FFDCFA, but also must be registered under FIFRA. Food-use pesticides not registered in the United States must have tolerances or exemptions in order for commodities treated with those pesticides to be imported into the United States. For additional information about tolerances, go to <https://www.epa.gov/pesticide-tolerances/about-pesticide-tolerances>.

*B. What is registration review?*

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. *See also* 40 CFR 155.40(a). The registration review program is intended to make sure that, as the ability to assess risk evolves and as policies and practices change, all registered pesticides can continue to be used without causing unreasonable adverse effects on human health and the environment. As part of the registration review of a pesticide, EPA also evaluates whether existing tolerances are safe, whether any changes to existing tolerances are necessary or appropriate, and whether any new tolerances are necessary to cover residues from registered pesticides. In addition, any tolerance changes identified as necessary or appropriate during registration review of a pesticide are summarized in the registration review decision documents for each pesticide active ingredient or registration review case. Additional information about pesticide registration review is available at <https://www.epa.gov/pesticide-reevaluation>.

### *C. EPA's Safety Assessment*

FFDCA section 408(b) authorizes EPA to establish a tolerance, if the Agency determines that a tolerance is safe; FFDCA section 408(c) authorizes EPA to establish an exemption from the requirement of a tolerance if the Agency determines that the exemption is safe. *See* 21 U.S.C. 346a(b) and (c). If EPA determines that a tolerance or exemption is not safe, EPA must modify or revoke that tolerance or exemption. The FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” 21 U.S.C. 346a(b)(2)(A)(ii), (c)(2)(A)(ii). 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 the 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[s.]” 21 U.S.C. 346a(b)(2)(C). In addition, FFDCA section 408(b)(2)(D) contains several factors EPA must consider when making determinations about establishing, modifying, or revoking tolerances. 21 U.S.C. 346a(b)(2)(D). FFDCA section 408(c)(2)(B) requires that EPA, when making determinations about exemptions, to take into account, among other things, the considerations set forth in FFDCA section 408(b)(2)(C) and (D). 21 U.S.C. 346a(c)(2)(B).

Furthermore, when establishing tolerances or exemptions from the requirement of a tolerance, FFDCA sections 408(b)(3) and (c)(3) require that there be a practical method for detecting and measuring pesticide chemical residue levels in or on food, unless in the case of exemptions, EPA determines that such method is not needed and states the reasons therefore in the rulemaking. 21 U.S.C. 346a(b) and (c).

Consistent with its obligations under FIFRA section 3(g), 7 U.S.C. 136a(g), and FFDCA section 408, 21 U.S.C. 346a, EPA has reviewed the available scientific data and other relevant

information on toxicity and exposure of maleic hydrazide. As part of registration review, the Agency has published a risk assessment detailing the risks from aggregate exposure, including to infants and children, for maleic hydrazide. The toxicity and exposure analyses, which support the safety determination contained in Unit III., can be found in the human health risk assessment document and related registration review decision documents for maleic hydrazide in the public docket at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2009-0387.

After considering all available information, EPA has determined it is appropriate based on the underlying safety assessments to take the tolerance exemption action being proposed in this supplemental notice of proposed rulemaking.

### **III. Proposed Modification**

During registration review, EPA determined that there are no risks of concern from exposure to residues of maleic hydrazide, based on its low toxicity and lack of toxicological endpoints for human health risk assessment. The Agency concluded that it would be appropriate to revoke the existing tolerances for residues of maleic hydrazide in or on “Onion, bulb”, “Potato”, and “potato, chips” and establish an exemption from the requirement of a tolerance for all commodities instead. In the registration review supporting document *Maleic Hydrazide, and its Potassium Salt: Qualitative Risk Assessment for Registration Review and Screen of the Hydrazine Impurity*, dated June 18, 2014 (“Maleic Hydrazide Risk Assessment,”), EPA identified as appropriate a single tolerance exemption covering all commodities, to read as follows: “An exemption from the requirement of a tolerance is established for residues of the pesticide maleic hydrazide, including its metabolites and degradates, when used as a plant growth regulator or herbicide.” The Agency further stated that if the existing tolerances were maintained and not replaced with a tolerance exemption, then additional tolerances for maleic hydrazide residues in livestock commodities would need to be established.

In the 2019 Proposed Rule, the Agency proposed to revoke the existing tolerances for “Onion, bulb”, “Potato”, and “potato, chips”. However, rather than proposing to establish a

single tolerance exemption covering all commodities, EPA instead proposed to establish tolerance exemptions covering only the commodities for which tolerances existed. Specifically, the Agency proposed to establish tolerance exemptions for residues of maleic hydrazide when used as a plant growth regulator or herbicide in or on onion, bulb and potato, and when present in or on potato chips as a result of application of maleic hydrazide to the growing potato plant. Moreover, the Agency did not propose to establish tolerances or exemptions for any livestock commodities.

This supplemental notice of proposed rulemaking modifies the previously proposed tolerance exemptions by proposing to establish a single tolerance for all commodities, rather than limiting the exemption to specific commodities. Specifically, EPA is now proposing to establish a single tolerance exemption for residues of maleic hydrazide when used as a plant growth regulator or herbicide. This proposed modification is supported by the registration review of maleic hydrazide and is consistent with the Maleic Hydrazide Risk Assessment. Moreover, a tolerance exemption covering all commodities would eliminate the need for the Agency to establish tolerances or exemptions for livestock commodities. All supporting documents for the registration review of maleic hydrazide, including the Maleic Hydrazide Risk Assessment, can be found in the public docket online at <https://www.regulations.gov> using the docket ID number EPA-HQ-OPP-2009-0387.

As discussed in Unit II.D., based on the supporting registration review documents, 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 maleic hydrazide residues. The proposed exemption from the requirement of a tolerance is considered safe. An analytical method is not needed for enforcement purposes since the Agency is not proposing to establish a numerical tolerance for residues of maleic hydrazide in or on any food commodities.

#### **IV. Proposed Effective Date**

EPA is proposing that this tolerance exemption action would be effective on the date of

publication of the final rule in the *Federal Register*.

## 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 proposes to establish or modify a pesticide tolerance or a tolerance exemption under FFDCA section 408.

### 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 or exemptions from the requirement of 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. This determination takes into account an EPA analysis for tolerance establishments and modifications that published in the *Federal Register* of May 4, 1981 (46 FR 24950 (FRL-1809-5)).

Any comments about the Agency's determination for this rulemaking should be submitted to EPA along with comments on the supplemental notice of proposed rulemaking and will be

addressed in the final 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 supplemental notice of proposed rulemaking modifies proposed tolerance exemption 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 or exemption 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) and (c)(2)(B)). The Agency’s consideration is documented in the maleic hydrazide registration review documents, located in docket ID number EPA-HQ-OPP-2017-0418 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.

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

**Dated:** August 5, 2025

**Edward Messina,**

*Director, Office of Pesticide Programs.*

For the reasons set forth in the preamble, EPA is proposing to amend 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. Remove § 180.175.

3. Add § 180.1349 to Subpart D to read as follows:

**§ 180.1349 Maleic hydrazide; exemption from the requirement of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of the pesticide maleic hydrazide, including its metabolites and degradates, when used as a plant growth regulator or herbicide.

[FR Doc. 2025-15095 Filed: 8/7/2025 8:45 am; Publication Date: 8/8/2025]