



BILLING CODE 6560-50-P

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2019-0346; FRL-10012-87]

### Mefenoxam; Pesticide Tolerances

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of mefenoxam in or on the tree nut, crop group 14-12 and almond, hulls. Syngenta Crop Protection requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2019-0346, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805.

Due to the public health concerns related to COVID-19, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: [RDFRNotices@epa.gov](mailto:RDFRNotices@epa.gov).

## **SUPPLEMENTARY INFORMATION**

### **I. General Information**

#### *A. Does this action apply to me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

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

#### *B. How can I get electronic access to other related information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at

[http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

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

Under FFDCa section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. 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-2019-0346 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*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

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. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2019-0346, by one of the following methods:

- *Federal eRulemaking Portal*: <http://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.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed

information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of June 24, 2020 (85 FR 37806) (FRL-10010-82), 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 9F8759) by Syngenta Crop Protection LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.546 be amended by establishing a tolerance for residues of mefenoxam, (methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-*DL*-alaninate) including its metabolites and degradate, in or on tree nuts crop group 14-12 at 0.3 parts per million (ppm). Syngenta's petition was intended to cover residues of mefenoxam in or on nut commodities from domestic use of the pesticide, although EPA erroneously stated in the Notice of Filing that Syngenta had requested a tolerance to cover residues of mefenoxam on imported nut commodities. EPA hereby clarifies that error and has evaluated the request as submitted by the petition. The error did not substantially impact the way EPA evaluated the petition. In addition, although not mentioned in EPA's document, Syngenta's petition also requested that currently established tolerances for residues of metalaxyl in/on almond and walnut at 0.5 ppm be removed from 40 CFR 180.408, under the premise these commodities would be adequately covered by the proposed tree nut, crop group 14-12 tolerance for mefenoxam, which is the single enantiomer of the racemic mixture metalaxyl. A summary document of the petition prepared by Syngenta Crop Protection, the registrant, is available in the docket, <http://www.regulations.gov>. One comment was received in response to the notice of filing, although it was not germane to the petition for mefenoxam tolerances.

### III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA 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.” Section 408(b)(2)(A)(ii) of 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.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA 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....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for mefenoxam including exposure resulting from the tolerance established by this action. EPA's assessment of exposures and risks associated with mefenoxam follows.

On December 21, 2018, EPA published in the *Federal Register* a final rule establishing tolerances for residues of mefenoxam in or on several commodities based on the Agency's conclusion that aggregate exposure to mefenoxam is safe for the general population, including infants and children. *See* 83 FR 65541 (FRL-9985-52). Because the Agency's position concerning several sections of that document have not changed, EPA is incorporating them by reference here—the toxicological profile and points of departure, description of the assumptions

for assessing exposure from residues in or on food, in drinking water, and residential exposures, the Agency's conclusion about cumulative risk, and Agency's determination regarding the children's safety factor. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the December 21, 2018 *Federal Register* action, as well as the new mefenoxam tolerance can be found at <http://www.regulations.gov> in the document titled "Mefenoxam (Metalaxyl\_M). Human Health Risk Assessment for the Establishment of Permanent Tolerances and New Uses in/on Wasabi, Cacao, and Crop Group Expansion from Kiwifruit to Fruit, Small, Vine Climbing, Except Grape, Crop Subgroup 13-07E." dated June 5, 2018, in docket ID EPA-HQ-OPP-2017-0562 and the document titled, "Mefenoxam (Metalaxyl-M). Human Health Risk Assessment for the Proposed New Use in/on Tree Nuts, Crop Group 14-12 and the Establishment of a Permanent Tolerance." in docket ID number EPA-HQ-OPP-2019-0346.

EPA's exposure assessments have been updated to include the additional exposure from use of mefenoxam on tree nut, crop group 14-12. EPA's aggregate exposure assessment incorporated this additional dietary exposure, as well as exposures from drinking water and residential sources, although those latter exposures are not impacted by the new uses on the tree nut, crop group 14-12 and thus have not changed since the last assessment.

Acute dietary risks are below the Agency's level of concern: 52% of the acute population adjusted dose (aPAD) for children 1 to 2 years old, the population group of concern. Due to the lack of a chronic endpoint, a chronic dietary risk is not expected. As required by the FFDCA, EPA considered aggregate exposures to mefenoxam, i.e., exposures from food, drinking water, and residential uses, in its risk assessment. There are no residential uses expected to result in acute, intermediate-term, or chronic exposures; therefore, aggregate risks for those exposure

durations are equal to the dietary risks for those exposure durations and not of concern.

Based on the absence of increased hazard from repeated exposures to mefenoxam, short-term aggregate risk assessments are protective of potential effects from longer-term exposures. Additionally, residential exposures are not expected to occur beyond the short-term time interval.

Using the exposure assumptions described for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate margins of exposures above the level of concern of 100 for all scenarios assessed and are not of concern.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to mefenoxam residues.

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

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

There are adequate residue analytical methods for enforcing tolerances for mefenoxam residues of concern in/on the registered plant and livestock commodities. These several methods include gas chromatography equipped with an alkali flame ionization detector (GC/AFID), gas chromatography equipped with a nitrogen/phosphorus detector (GC/NPD), the multiresidue method in PAM, Vol. I Section 302 (Protocol D) in the nitrogen-specific mode, and gas-liquid chromatography/mass spectrometry in the chemical ionization mode with selected ion monitoring (SIM) of the M+1 ion at  $m/z$  268 for determining residues in/on nut crops and livestock.

The methods 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 FFDCa section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCa section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established an MRL for mefenoxam or metalaxyl in or on the tree nut, crop group 14-12.

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

There are no revisions to the requested tolerance petition of mefenoxam. The petition requested that upon establishment of tolerances in or on tree nuts crop group 14-12 at 0.3 ppm, the currently established tolerances for residues of metalaxyl in or on almond and walnuts at 0.5 ppm be removed from 40 CFR 180.408, because residues in or on these commodities were anticipated to be adequately covered by the new tree nut crop group 14-12 tolerance. EPA has decided not to remove the existing tolerances for metalaxyl on almond and walnut. Existing registrations permit use of metalaxyl on almond and walnut, and those uses would result in residues of metalaxyl on those commodities that would not be covered by the new mefenoxam tolerances. Therefore, removal of such tolerances would result in adulterated commodities.



Although a tolerance on almond hulls was not requested, available processing data demonstrates that residues from treated almonds concentrate on hulls during processing; therefore, a separate tolerance is needed to cover those residues. Based on application rates for mefenoxam and extrapolating from the available data concerning concentration during processing for metalaxyl, EPA concludes a tolerance level of 5 ppm for residues of mefenoxam in or on almond hulls is appropriate. EPA is establishing that tolerance here. The FFDCFA anticipates that residues of pesticides applied to raw agricultural commodities may pass through to processed commodities and allows tolerances on raw agricultural commodities to cover processed forms of those commodities as long as residues remain within tolerance levels. 21 U.S.C. 346a(a)(2). Where residues concentrate in the processed food, a separate tolerance is necessary. Given the potential to pass-through, EPA examines whether tolerances on the raw agricultural commodities will cover residues on the processed food, and if not, establishes them. EPA believes it is reasonable to expect that a tolerance may need to be established in processed forms of commodities for which tolerances on the raw agricultural commodities are requested.

## **V. Conclusion**

Therefore, tolerances are established for residues of mefenoxam, including its metabolites and degradates in or on the tree nut, crop group 14-12 at 0.3 ppm and almond hulls at 5 ppm.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCFA section 408(d) 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, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled

“Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997), nor is it considered a regulatory action under Executive Order 13771, entitled “Reducing Regulations and Controlling Regulatory Costs” (82 FR 9339, February 3, 2017). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions 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 Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In

addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the *Federal Register*. 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: October 9, 2020.

**Marietta Echeverria,**  
*Acting Director, Registration Division, Office of Pesticide Programs.*

Therefore, for the reasons stated 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. In § 180.546 amend paragraph (a) by designating the table as Table 1 to paragraph (a) and adding in alphabetical order to newly designated Table 1 to paragraph (a) entries for “Almond, hulls” and “Tree nut, crop group 14-12” to read as follows:

**§ 180.546 Mefenoxam; tolerances for residues.**

\* \* \* \* \*

Table 1 to paragraph (a)

<b>Commodity</b>	<b>Parts per million</b>
* * * * *	* *
Almond hulls	5
* * * * *	* *
Tree nut, crop group 14-12	0.3
* * * * *	* *

\* \* \* \* \*