CTG document No.	Title	Adopted: 10/14/2020 Submitted: 12/29/2020 SIP approved: 6/29/2022	Adopted: 10/14/2020 Submitted: 12/29/2020 SIP approved: 11/4/2024
(A) EPA–450/2–78–029	Control of Volatile Organic Emissions from Manufacture of Synthesized Pharmaceutical Products.	X	
(B) EPA–453/R–08–003	Control Techniques Guidelines for Miscellaneous Metal and Plastic Parts Coatings Tables 3–6.	X	
(C) EPA–453/R–08–004	Control Techniques Guidelines for Fiberglass Boat Manufacturing Materials	X	
(D) EPA–453/B–16–001)	Control Techniques Guidelines for the Oil and Natural Gas Industry	.....	X

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[FR Doc. 2024–25560 Filed 11–1–24; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2023–0397; FRL–12201–01–OCSPP]

Mefenoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenoxam in or on Palm, oil. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective November 4, 2024. Objections and requests for hearings must be received on or before January 3, 2025, 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–2023–0397, is available at *https://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 and for the OPP Docket is (202) 566–1744. Please review the visitor instructions and additional information about the docket 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; main telephone number: (202) 566–1030; email address: *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 Office of the Federal Register's e-CFR site at *https://www.ecfr.gov/current/title-40*.

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–2023–0397 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 January 3, 2025. 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–2023–0397, by one of the following methods:

- *Federal eRulemaking Portal: 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.
- *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 *https://www.epa.gov/dockets/where-send-comments-epa-dockets*.

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of September 12, 2023 (88 FR 62499) (FRL–10579–07–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 3E9048) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide mefenoxam, in or on palm oil at 0.02 parts per million (ppm). That document referenced a summary of the petition

prepared by Syngenta Crop Protection, LLC., the registrant, which is available in the docket, *https://www.regulations.gov*. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

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 tolerances established by this action. EPA's assessment of exposures and risks associated with mefenoxam follows.

In an effort to streamline its publications in the **Federal Register**, EPA is not reprinting sections of the rule that repeat what has been previously published in tolerance rulemakings for the same pesticide chemical. Where scientific information concerning a particular chemical remains unchanged, the content of those sections would not vary between tolerance rulemakings, and EPA considers referral back to those sections as sufficient to provide an explanation of the information EPA considered in making its safety determination for the new rulemaking.

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

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Mefenoxam (metalaxyl-m) is a systemic phenylamine fungicide which inhibits protein synthesis in fungi. Mefenoxam is an R-isomer enriched formulation. Metalaxyl is the racemic R/S isomer formulation. The Agency compared the available chemistry and toxicity data for mefenoxam and metalaxyl and concluded that metalaxyl data may be used in support of mefenoxam regulatory actions because the two chemicals have similar toxicity.

Specific information on the studies received and the nature of the adverse effects caused by mefenoxam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in Unit III.A. of the final rule published in the **Federal Register** of December 21, 2018 (83 FR 65541) (FRL–9985–52).

B. Toxicological Points of Departure/Levels of Concern

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

A summary of the toxicological endpoints for mefenoxam used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of December 21, 2018 (83 FR 65541) (FRL–9985–52).

C. Exposure Assessment

Much of the exposure assessment remains the same although updates have occurred to accommodate exposures from petitioned-for tolerances. These updates are discussed in this section; for a description of the rest of the EPA approach to and assumptions for the exposure assessment, please reference Unit III.C. of the December 2018, rulemaking.

1. *Dietary exposure from food and feed uses.* EPA's dietary exposure assessments have been updated to include the additional exposure from the petitioned-for tolerances of mefenoxam on the crops requested in this action. In evaluating dietary exposure to mefenoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing mefenoxam and metalaxyl tolerances in 40 CFR 180.546 and 180.408, respectively.

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. The acute dietary assessment is based on tolerance levels adjusted to account for all of the residues of concern and assumes 100 percent crop treated (PCT). The assessment was conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 4.02, EPA with 2005–2010 food consumption information from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). Empirical processing factors were included where available. Otherwise, DEEM–FCID default processing factors were used.

ii. *Chronic exposure.* There is no increase in hazard from repeat exposures to mefenoxam. Therefore, a chronic dietary POD was not selected. The acute endpoint and acute dietary

exposure assessment are protective of potential effects from chronic duration dietary exposures.

iii. *Cancer.* EPA has concluded that mefenoxam does not pose a cancer risk to humans based on no evidence of carcinogenicity observed in the relevant studies. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

2. *Dietary exposure from drinking water.* Drinking water exposure modeling for mefenoxam is not necessary because exposure estimates for metalaxyl are expected to exceed those for mefenoxam and are therefore protective. Maximum annual application rates for metalaxyl, up to 12.3 lb ai/A, were modeled. These rates are approximately twice those of mefenoxam. The maximum estimated drinking water concentrations (EDWCs) based on metalaxyl are 350 µg/L for acute exposure (which is based on surface water sources) and 135 µg/L for chronic exposure (which is based on groundwater sources).

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 residential uses for mefenoxam being proposed as part of this action or that have been added since the most recent risk assessment that would impact the residential (non-occupational) or residential post-application exposure and risk estimates found in the most recent risk assessment of mefenoxam; therefore, EPA relied on the previously assessed residential exposure for assessing aggregate risk.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to mefenoxam and metalaxyl with any other substances and mefenoxam and metalaxyl do not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that mefenoxam and metalaxyl 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.* Section 408(b)(2)(C) of FFDCA 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.

EPA continues to conclude that there are reliable data to support the reduction of the (FQPA) (SF) to 1X. See Unit III.D. of the December 2018, rulemaking for a discussion of the Agency's rationale for that determination.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* The acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water is 27% of the acute population-adjusted dose (aPAD) for the general U.S. population, and 55% of the aPAD for the highest exposed population group, all infants. Because there are no acute residential exposures from mefenoxam, the acute aggregate exposure and risk is equal to the acute dietary exposure and risk. As these levels are below the Agency's level of concern (LOC) of 100% of the aPAD, the Agency concludes that aggregate exposure to mefenoxam will not pose an acute risk.

2. *Chronic risk.* No hazard endpoint was selected for chronic dietary exposure for mefenoxam; therefore, a chronic dietary analysis was not warranted. However, chronic dietary exposure was estimated for inclusion in the short-term aggregate analysis.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus average chronic exposure to food and water (considered to be a background exposure level). Mefenoxam 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 mefenoxam.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 270 for children 1 to 2 years old, the most highly exposed group. Because EPA's level of concern for mefenoxam is 100, which means any MOE below 100 may indicate risks of concern, this MOE is not of concern.

4. *Intermediate-term risk.* There are no intermediate-term residential exposures for mefenoxam, and therefore an intermediate-term aggregate exposure assessment was not warranted.

5. *Aggregate cancer risk for U.S. population.* Mefenoxam is classified as ''not likely to be carcinogenic to humans'', therefore, EPA concludes that exposure to mefenoxam will not pose an aggregate cancer risk.

6. *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 mefenoxam residues.

More detailed information on this action can be found in the document titled ''Metalaxyl-M (Mefenoxam)''. Human Health Risk Assessment for Establishment of a Tolerance without U.S. Registration for use on Palm Oil.'' in docket ID number EPA–HQ–OPP–2023–0397.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available enforcement analytical methods, see Unit IV.A. of the December 21, 2018, rulemaking.

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. Tolerances/maximum residue limits (MRLs) to support uses of mefenoxam in Canada are established for residues of metalaxyl, including metabolites that can be converted to the 2,6–DMA moiety, each expressed as metalaxyl equivalents. However, no MRLs are established for palm fruit in Codex and Canada; thus, harmonization is not an issue for this commodity.

C. Response to Comments

Three comments were received in response to the notice of filing. One comment was received from an anonymous commenter applauding the government's process to petition for new uses. The other two comments were criticizing chemicals that are not relevant to this action.

V. Conclusion

Therefore, tolerances are established for residues of mefenoxam [methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-D-alaninate], in or on palm, oil at 0.02 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA 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). 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 23, 2024.

Charles Smith,

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 table 1 to paragraph (a) by adding, in alphabetical order, an entry for ''Palm, oil'' to read as follows:

§ 180.546 Mefenoxam; tolerances for residues.

(a) * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Palm, oil [1]	0.02
* * * * *	

[1] There is no U.S. registration as of November 4, 2024.

* * * * *

[FR Doc. 2024–25564 Filed 11–1–24; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 271

[EPA–R04–RCRA–2024–0116; FRL–11972–04–R4]

North Carolina: Final Authorization of State Hazardous Waste Management Program Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final action.

SUMMARY: On June 26, 2023, North Carolina submitted to the