



ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2020-0009; FRL-8785-01-OCSP]

Metalaxyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of metalaxyl in or on black pepper. American Spice Trade Association 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-2020-0009, 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.

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.

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-2020-0009 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), although at this time, EPA strongly encourages those interested in submitting objections or a hearing request, to submit objections and hearing requests electronically. *See* Order Urging Electronic Service and Filing (April 10, 2020), https://www.epa.gov/sites/production/files/2020-05/documents/2020-04-10_-_order_urging_electronic_service_and_filing.pdf. At this time, because of the COVID-19 pandemic, the judges and staff of the Office of Administrative Law Judges are working remotely and not able to accept filings or correspondence by courier, personal deliver, or commercial delivery, and the ability to receive filings or correspondence by U.S. Mail is similarly limited. When submitting documents to the U.S. EPA Office of Administrative Law Judges (OALJ), a person should utilize the OALJ e-filing system, at https://yosemite.epa.gov/OA/EAB/EAB-ALJ_upload.nsf.

Although EPA's regulations require submission via U.S. Mail or hand deliver, EPA intends to treat submissions filed via electronic means as properly filed submissions during this time that the Agency continues to maximize telework due to the pandemic; therefore, EPA believes the preference for submission via electronic means will not be prejudicial. If it is impossible for a person to submit documents electronically or receive service electronically, e.g., the person does not have any access to a computer, the person shall so advise OALJ by contacting the Hearing Clerk at (202) 564-6281. If a person is without access to a computer and must file documents by U.S. Mail, the person shall notify the Hearing Clerk every time it files a document in such a manner. The address for mailing documents is U.S. Environmental Protection Agency, Office of Administrative Law Judges, Mail Code 1900R, 1200 Pennsylvania Ave., NW, Washington, DC 20460.

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-2020-0009, 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 May 29, 2020 (85 FR 32338) (FRL-10009-84), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 9E8811) by American Spice Trade Association, 1101 17th Street, NW, Suite 700, Washington, DC 20036. The petition requested that 40 CFR 180.408 be amended by establishing tolerances for residues of the fungicide metalaxyl, methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-DL-alaninate, in or on pepper, black at 1 part per million (ppm). That document referenced a summary of the petition prepared by American Spice Trade Association, the registrant, which is available in the docket, <http://www.regulations.gov>. Comments were received on the notice of filing. EPA's response to these comments is discussed in Unit IV.C. Based upon review of the data supporting the petition, EPA has modified the tolerance levels on

black pepper. The reason for these changes is explained in Unit IV.D.

III. Aggregate Risk Assessment and Determination of Safety

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.” 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 metalaxyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with metalaxyl follows.

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. EPA conducted a human health risk assessment to evaluate the safety of the requested tolerances and the assessment “Metalaxyl Human Health Risk Assessment for the Proposed Tolerances in/on White and Black Pepper without a U.S. Registration” is found in docket ID number EPA-HQ-OPP-2020-0009 at

www.regulations.gov. In that document, EPA evaluated the available hazard and exposure data to conduct dietary, residential, and aggregate assessment to determine risk to human health and refers back to the full discussions of the hazard profile, residue chemistry database, and residential exposures contained in the previous human health risk assessment conducted for the registration review of metalaxyl/mefenoxam. The human health risk assessment “Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment for Registration Review” is located in docket EPA-HQ-OPP-2009-0863-0023.

The Draft Risk Assessment reflects both mefenoxam and metalaxyl. The Agency compared the available chemistry and toxicity data for mefenoxam and metalaxyl and concluded that the toxicity studies for both chemicals can be combined for hazard characterization and dose-response assessment because the two chemicals have similar toxicity and identical chemical structures.

In rat and dog repeat dose (i.e., subchronic and chronic) oral toxicity studies, there were no indications of adverse effects up to the highest dose tested (HDT). Adverse effects (i.e., convulsions that occurred minutes after dosing) were only observed from acute exposure to rats.

There was no evidence of increased susceptibility following pre- or post-natal exposure in the prenatal developmental toxicity studies or the reproduction and fertility effects study in the animals treated with metalaxyl. In the rat developmental toxicity study of metalaxyl, maternal toxicity consisted of dose-related increased incidence of convulsions that occurred shortly after dosing, as well as other clinical signs. In a range-finding acute neurotoxicity study of mefenoxam, females showed abnormal functional observation battery findings at doses lower than males, but higher than in the rat developmental study. However, there was no indication of toxicity up to the HDT in the mefenoxam subchronic neurotoxicity study, which confirms the lack of adverse effects observed in all other repeat-dose studies.

There was no indication of immunotoxicity in a mouse immunotoxicity study of mefenoxam.

Metalaxyl is classified as “Not Likely to be Carcinogenic to Humans” based on the lack of evidence of carcinogenicity in the metalaxyl carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats.

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 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 <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for metalaxyl used for the human health risk assessment is shown in the Metalaxyl Human Health Risk Assessment for the Proposed Tolerances in/on White and Black Pepper without a U.S. Registration, and further explanation can be found in “Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment for Registration Review”.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to metalaxyl, EPA considered exposure under the existing tolerances for mefenoxam and the existing and

petitioned-for tolerances for metalaxyl. EPA assessed dietary exposures 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.

In conducting acute dietary exposure assessment, EPA used the 2003-2008 food consumption data from the U.S. Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). A partially refined acute dietary exposure assessment was conducted for metalaxyl. The refinement was based on a tolerance level adjustment to account for all residues of concern and anticipated residues were used for livestock commodities. The analysis used tolerance-level residues, adjusted to include additional residues of concern, and 100 percent crop treated (PCT).

ii. *Chronic exposure.* Because no chronic dietary endpoint was selected, a chronic dietary exposure assessment was not conducted. Nevertheless, for purposes of assessing short-term aggregate risk, EPA calculated average dietary exposures. In conducting the chronic dietary exposure assessment, EPA used tolerance level values adjusted for additional residues of concern and 100 PCT.

iii. *Cancer.* Metalaxyl is classified as "Not Likely to Be Carcinogenic to Humans" therefore, a cancer assessment is not needed.

2. *Dietary exposure from drinking water.* Drinking water exposures are not impacted by the import tolerances on black pepper; therefore, the assessment for this tolerance action relied on the second refinement for the drinking water exposure assessment (DWA) for metalaxyl and mefenoxam, in support of the Agency human health assessment for Registration Review for the estimated drinking water concentrations (EDWCs). See "Metalaxyl/Mefenoxam: Second Refinement Addendum to Drinking Water Exposure Assessment in Support of Registration Review", which is located at <https://www.regulations.gov> in docket ID number EPA-HQ-OPP-2009-0863.

That assessment modeled drinking water exposures using the Pesticide Root Zone Model (PRZM, v5, November 15, 2006) and the Variable Volume Water Body Model (VVWM, March 6, 2014) for surface water and the PRZM-GW for groundwater. Using those models, EPA calculated the following EDWCs for use in exposure assessment: 350 ppb for acute exposure assessment and 135 ppb for chronic exposure assessment.

3. *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).

Mefenoxam and metalaxyl are currently registered for the following uses that could result in residential exposures: lawns, ornamentals, gardens, and trees. EPA assessed residential exposure using the following assumptions: For residential handlers, all registered metalaxyl and mefenoxam product labels with residential use sites (lawns, ornamentals and garden and trees) require that handlers wear specific clothing (e.g., long-sleeve shirt/long pants) and chemical-resistant gloves. Therefore, EPA has made the assumption that these products are not for homeowner use and has not conducted a quantitative residential handler assessment.

There is potential for residential post-application exposures to metalaxyl. Since no dermal endpoints were identified, only incidental oral post-application exposures to small children ages 1 to <2 have been assessed. Metalaxyl and mefenoxam are registered for use on home lawns; therefore, there is the potential for incidental oral exposure (hand-to-mouth, object-to-mouth, soil ingestion and granular ingestion).

The recommended residential exposure for use in the children 1 to <2 years old aggregate assessment reflects hand-to-mouth incidental oral exposures from treated turf using a liquid formulation. Ingestion of granules is considered an episodic event and not a routine behavior. Because the Agency does not believe that this would occur on a regular basis, the concern for human health is related to acute poisoning rather than short-term residue exposure. Therefore, an acute dietary dose is used to estimate exposure and risk resulting from episodic ingestion of

granules. For these same reasons, the episodic ingestion scenario was not included in the aggregate assessment.

A summary of the residential exposures for metalaxyl used for the human health risk assessment can be found in “Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment for Registration Review” docket ID number EPA-HQ-OPP-2009-0863-0023.

Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/standard-operating-procedures-residential-pesticide>.

4. Cumulative effects from substances with a common mechanism of toxicity.

FFDCA section 408(b)(2)(D)(v) 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 any other substances and mefenoxam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that mefenoxam has a common mechanism of toxicity with other substances.

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 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.* There was no evidence of increased susceptibility in offspring in the prenatal developmental or the 2-generation reproductive toxicity studies. In adult rats treated with metalaxyl or mefenoxam, clinical signs and abnormal functional observation battery (FOB) findings were noted after a bolus gavage dose but not in repeated dose studies.

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. That decision is based on the following findings:

i. The toxicity databases for metalaxyl and mefenoxam are adequate to assess the potential for prenatal and postnatal toxicity for infants and children.

ii. In the rat prenatal developmental toxicity with metalaxyl, maternal animals exhibited clinical signs indicative of neurobehavioral effects as previously discussed. In the range-finding acute neurotoxicity study with mefenoxam, females exhibited abnormal FOB findings at doses lower than in males. In the subchronic neurotoxicity study with mefenoxam, there were no indications of neurotoxicity up to the HDT. In metalaxyl and mefenoxam treated adult animals, clinical signs and abnormal FOB findings were noted. However, a developmental neurotoxicity (DNT) study is not required for metalaxyl or mefenoxam because (1) there are no indications of increased susceptibility for infants or children; (2) the convulsions observed in the rat prenatal developmental toxicity study occurred in the maternal animals with no effects being observed in the young; (3) the convulsions occurred only after a bolus dose; (4) the available developmental and range-finding acute neurotoxicity studies provided clear NOAELs and LOAELs for evaluating effects; (5) the current POD is below the level at which any effects were seen in either study, and (6) there were no other indications of neurotoxicity in the mefenoxam or metalaxyl databases, which include a subchronic (adult rat) neurotoxicity study for mefenoxam. Therefore, there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity. See “Metalaxyl, Mefenoxam (metalaxyl-m) Human Health Draft Risk Assessment

for Registration Review” docket ID number EPA-HQ-OPP-2009-0863-0023.

iii. As discussed above in Unit III.D.2., there is no evidence that metalaxyl results in increased susceptibility in the developmental or reproductive toxicity studies; and

iv. There are no residual uncertainties in the exposure database. Dietary exposure analysis was performed incorporating all existing and proposed uses using tolerance level values to estimate residues in food commodities and anticipated residues in livestock commodities. Drinking water estimates were generated based upon conservative inputs and modeling. Similarly, potential residential post application exposures are based upon conservative, default assumptions. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to metalaxyl 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 are not expected to underestimate the exposure to metalaxyl.

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 PAD (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 MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Using the exposure assumptions described in this unit for acute exposure, EPA has concluded that acute exposure to metalaxyl from food and water will utilize 52% of the aPAD for children 1 to 2 years old, the population subgroup with the highest exposure estimate.

2. *Chronic risk.* There is no increase in hazard from repeat exposures to

metalaxyl/mefenoxam; therefore, a chronic dietary POD was not selected. Due to the lack of a chronic endpoint, a chronic dietary risk is not expected. The acute endpoint and dietary exposure assessment are protective of potential effects from chronic duration dietary exposures.

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). Mefenoxam and metalaxyl are 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 and metalaxyl. 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 an aggregate MOE of 270 for children. Because EPA's level of concern for mefenoxam is a MOE of 100 or below, this MOE is not of concern.

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; however, metalaxyl and mefenoxam are not registered for any use patterns that would result in intermediate-term residential exposure.

5. *Aggregate cancer risk for U.S. population.* Metalaxyl is classified as "Not Likely to Be Carcinogenic to Humans"; therefore, EPA does not expect metalaxyl exposures to 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 metalaxyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

There are adequate residue analytical methods for enforcing tolerances for metalaxyl

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 black pepper and livestock.

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*.

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 a MRL for metalaxyl in or on black pepper.

C. Response to Comments

Two comments were received in response to the notice of filing. One of the comments was not germane to the petition for metalaxyl tolerances.

The second comment argued against the use metalaxyl on black pepper and expressed concern about the overall toxicity of pesticides. Although the Agency recognizes that some

individuals believe that pesticides should be banned on agricultural crops, the existing legal framework provided by FFDCa section 408 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 the FFDCa requires EPA to consider, EPA has determined that these metalaxyl tolerances are safe. The commenter has provided no information supporting a contrary conclusion.

D. Revisions to Petitioned-For Tolerances

EPA is establishing the tolerance at 0.3 ppm rather than at the petitioned-for tolerance level of 1.0 ppm. EPA's analysis of the monitoring data that was submitted to support the tolerance level concludes that 0.3 ppm is sufficient to cover residues in imported black pepper.

V. Conclusion

Therefore, tolerances are established for residues of metalaxyl, methyl *N*-(2,6-dimethylphenyl)-*N*-(methoxyacetyl)-DL-alaninate, in or on pepper, black at 0.3 ppm.

VI. Statutory and Executive Order Reviews

This action establishes a tolerance 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 (CRA)

Pursuant to the CRA (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: September 3, 2021.

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 § 180.408, amend the table in paragraph (a) by:

- i. Designating the table as Table 1 to Paragraph (a).
- ii. Adding in alphabetical order an entry for “Pepper, black”.
- iii. Add footnote 1.

The additions read as follows:

§ 180.408 Metalaxyl; tolerances for residues.

* * * * *

Table 1 to Paragraph (a)

Commodity	Parts per million
* * * * *	
Pepper, black ¹	0.3
* * * * *	

¹ There are no U.S. registrations for use of this pesticide on this commodity as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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