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[FR Doc. 2018–27610 Filed 12–20–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0562; FRL–9985–52]

Mefenoxam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of mefenoxam in or on cacao bean; the fruit, small, vine climbing, except grape, subgroup 13–07E; and wasabi. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 21, 2018. Objections and requests for hearings must be received on or before February 19, 2019, 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–2017–0562, 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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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 Printing 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–2017–0562 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 February 19, 2019. 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–2017–0562, 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 January 26, 2018 (83 FR 3658) (FRL–9971–46), 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 7E8610) by IR–4, IR–4 Project Headquarters, Rutgers, The State University of NJ, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of the fungicide mefenoxam, including its metabolites and degradates in or on the raw agricultural commodities cacao bean, bean at 0.2 parts per million (ppm); wasabi, tops at 6.0 ppm; wasabi, stem at 3.0 ppm; and fruit, small, vine climbing, except grape, crop subgroup 13–07E at 0.10 ppm. Additionally, the petition requested to amend 40 CFR 180.546 by removing the tolerance in or on kiwifruit at 0.10 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* One comment was received in the docket for the notice of filing, but as it raised concerns about the Obama Administration's application of the National Environmental Protection Agency and Endangered Species Act, it is not relevant to this tolerance action.

Based upon review of the data supporting the petition, EPA has modified the commodity definition for cacao and the tolerance level to be consistent with the Agency's policy on significant figures.

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.

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 phenylamide 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. Therefore, for the purposes of this assessment, mefenoxam will refer to both mefenoxam and metalaxyl-m.

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 were only observed from acute exposure to rats. 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 (FOB) findings at doses lower than males, but higher than 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 developmental toxicity in studies of mefenoxam or metalaxyl. There was no indication of immunotoxicity in a mouse immunotoxicity study of mefenoxam. Metalaxyl and mefenoxam have been classified as ''not likely to be carcinogenic in humans'' based on the results of the carcinogenicity study in mice and the combined chronic toxicity and carcinogenicity study in rats.

All toxicity endpoints and points of departure (PODs) are based on convulsions that occurred minutes after dosing in the rat developmental toxicity study of metalaxyl. This POD is appropriate for acute, short-term, and intermediate-term exposure scenarios via the oral and inhalation routes. No hazard was identified for chronic or long-term exposure scenarios, or for exposure via the dermal route.

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 can be found at *http://www.regulations.gov* in the document ''*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*'' on pages 23–21 in docket ID number EPA–HQ–OPP–2017–0562.

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://www2.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 shown in Table 1 of this unit.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Acute dietary (All Populations)	NOAEL = 50 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.5 mg/kg/day. aPAD = 0.5 mg/kg/day	*Metalaxyl Prenatal Developmental Toxicity—Rat* LOAEL = 250 mg/kg/day Based on dose-related increases in clinical signs of toxicity (*e.g.,* post-dosing convulsions).

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR MEFENOXAM FOR USE IN HUMAN HEALTH RISK ASSESSMENT—Continued

Exposure/scenario	Point of departure and uncertainty/ safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic dietary (All populations)	No endpoint was identified. No systemic toxicity was observed in the reproduction and fertility effects study or in any of the chronic and subchronic toxicity studies. Toxicity was only evident in gavage-dosed animals.		
Incidental oral short-term (1 to 30 days) and intermediate-term (1 to 6 months).	NOAEL = 50 mg/kg/ day. UF_A = 10x UF_H = 10x FQPA SF = 1x	LOC for MOE = 100	*Metalaxyl Prenatal Developmental Toxicity—Rat* LOAEL = 250 mg/kg/day Based on dose-related increases in clinical signs of toxicity (*e.g.,* post-dosing convulsions).
Cancer (Oral, dermal, inhalation).	Classification: ''not likely to be carcinogenic to humans'' based on adequately conducted carcinogenicity studies in rats and mice treated with metalaxyl.		

FQPA SF = Food Quality Protection Act Safety Factor. LOAEL = lowest-observed-adverse-effect-level. LOC = level of concern. mg/kg/day = milligram/kilogram/day. MOE = margin of exposure. NOAEL = no-observed-adverse-effect-level. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. UF = uncertainty factor. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to mefenoxam, EPA considered exposure under the petitioned-for tolerances as well as all existing mefenoxam tolerances in 40 CFR 180.546. EPA assessed dietary exposures from mefenoxam 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.

Such effects were identified for mefenoxam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture's National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). As to residue levels in food, EPA assumed 100 percent crop treated (PCT), DEEM default and empirical processing factors and tolerance level residues.

ii. *Chronic exposure.* No chronic endpoint was identified and therefore no chronic dietary assessment was conducted.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that mefenoxam does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and PCT information.* EPA did not use anticipated residue or PCT information in the dietary assessment for mefenoxam. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency only considered the parent compound metalaxyl as a residue of concern (ROC). Exposure modeling for mefenoxam is not necessary because exposure estimates for metalaxyl are expected to exceed those for mefenoxam, and the two compounds are anticipated to behave identically in the environment. Therefore, EDWCs provided for metalaxyl are protective of exposures to mefenoxam through drinking water. Maximum annual application rates for metalaxyl, up to 12.3 pounds active ingredient/per Acre (lb ai/A), were modeled. These rates are approximately twice those of mefenoxam.

The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for mefenoxam/metalaxyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of mefenoxam/metalaxyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/about-water-exposure-models-used-pesticide.*

Based on the Pesticide Water Calculator (PWC version 1.52) the estimated drinking water concentrations (EDWCs) of mefenoxam/metalaxyl for acute exposures are estimated to be 350 parts per billion (ppb) for surface water and 155 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For the acute dietary risk assessment, the water concentration value of 350 ppb was used to assess the contribution to drinking water.

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).

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 resistance 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 mefenoxam (metalaxyl-m). 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.

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.* 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 metalaxyl and mefenoxam and any other substances and metalaxyl and mefenoxam do not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that metalaxyl and mefenoxam 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 *http://www2.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 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 for qualitative or quantitative offspring susceptibility in developmental toxicity studies in rabbits and rats, or in the reproduction and fertility effects study in rats. In adult rats treated with metalaxyl or mefenoxam, clinical signs and abnormal Functional Observation Battery (FOB) findings were noted only 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 mefenoxam and metalaxyl are complete.

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 functional observation battery (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.

iii. There is no evidence that mefenoxam or metalaxyl results in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to mefenoxam and 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 will not underestimate the exposure and risks posed by mefenoxam or 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.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to mefenoxam will occupy 21% of the aPAD for children 1–2 years old, the population group receiving the greatest exposure.

2. *Chronic risk.* A chronic aggregate risk assessment takes into account chronic exposure estimates from dietary consumption of food and drinking water. No adverse effect resulting from repeated exposure was identified and no chronic dietary endpoint was selected. Therefore, mefenoxam is not expected to pose a chronic risk.

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 538 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, mefenoxam is not registered for any use patterns that would result in intermediate-term residential exposure.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, mefenoxam is not expected to pose a cancer risk to humans.

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.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methods are available for determination of the residues of concern in crop commodities. The enforcement methods are common moiety methods which determine residues of metalaxyl/mefenoxam and metabolites that are convertible to 2,6-dimethylaniline (2,6–DMA). These methods include: (1) Method I in PAM, Vol. II (Method AG–348), which determines residues in plant commodities using a gas-liquid chromatography procedure employing an alkali flame ionization detector (GLC/AFID); (2) Method AG–395 (submitted for inclusion in PAM, Vol. II as Method III), an improved version of Method AG–348, which determines residues in plant commodities using GLC/nitrogen phosphorus detection (NPD); and (3) the multiresidue method in PAM, Vol. I, Section 302 (Protocol D). Method 456–98, a chiral liquid chromatography/mass spectrometric detection (LC/MS) method, is available to distinguish between R- and S-enantiomers, to determine whether metalaxyl or mefenoxam was applied.

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.

No Codex MRLs have been established for wasabi. The tolerances for the fruit, small, vine climbing, except grape, subgroup 13–07E and cacao bean are harmonized with Codex.

C. Revisions to Petitioned-For Tolerances

The Agency revised the petitioned-for tolerance on cacao to correct for the significant figures based on current practice, and to correct the commodity definition to reflect the common commodity vocabulary currently used by the Agency.

V. Conclusion

Therefore, tolerances are established for residues of mefenoxam, including its metabolites and degradates, in or on cacao, dried bean at 0.20 ppm; the fruit, small, vine climbing, except grape, subgroup 13–07E at 0.10 ppm; wasabi, stem at 3.0 ppm; and wasabi, tops at 6.0 ppm. Additionally, the existing tolerance for kiwifruit at 0.10 ppm is removed as unnecessary due to the establishment of the new tolerances.

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), 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: December 6, 2018,

Michael Goodis,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 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:

■ i. Remove the entry ''Kiwifruit'' from the table in paragraph (a).

■ ii. Add alphabetically the entries ''Cacao, dried bean''; ''Fruit, small, vine climbing, except grape, subgroup 13–07E''; ''Wasabi, stem''; and ''Wasabi, tops'' to the table in paragraph (a).

The additions read as follows:

§ 180.546 Mefenoxam; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Cacao, dried bean	0.20
* * * * *	
Fruit, small, vine climbing, except grape, subgroup 13–07E	0.10
* * * * *	
Wasabi, stem	3.0
Wasabi, tops	6.0

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[FR Doc. 2018–27764 Filed 12–20–18; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2017–0587; FRL–9987–34]

Tolfenpyrad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tolfenpyrad in or on multiple commodities which are identified and discussed later in this document. Interregional Research Project No. 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 21, 2018. Objections and requests for hearings must be received on or before February 19, 2019 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–2017–0587, 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. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, 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 Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.* To access the OCSPP test guidelines referenced in this document electronically, please go to *https://www.epa.gov/aboutepa/about-office-chemical-safety-and-pollution-prevention-ocspp.*

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–2017–0587 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 February 19, 2019. 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–2017–0587, 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 *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 *http://www.epa.gov/dockets.*