



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2017-0494; FRL-9985-06]

Methoxyfenozide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide in or on imported tea. Dow Agrosiences, LLC 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-2017-0494, 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-2017-0494 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2017-0494, 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 November 27, 2017 (82 FR 56017) (FRL-9968-55), 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 7E8601) by Dow Agrosciences, LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide methoxyfenozide, in or on tea, dried at 20 parts per million (ppm) and tea, instant at 20 ppm. That document referenced a summary of the petition prepared by Dow Agrosciences, LLC, 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.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCFA 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 FFDCFA 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 FFDCFA 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 FFDCFA section 408(b)(2)(D), and the factors specified in FFDCFA 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 methoxyfenozide including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with methoxyfenozide 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.

Many of the available short-term or subchronic toxicity studies on methoxyfenozide showed little or no toxicity. The main target organs identified from the toxicity studies in the rat and dog were the liver, thyroid, and red blood cells (RBCs). The most consistent findings across species and studies were transiently decreased RBC parameters and increased liver, thyroid, adrenal, and spleen weights. Increases in thyroid and adrenal weights were observed in the rat chronic oral study. Thyroid weights were also increased in the dog following chronic exposure. However, no accompanying histopathology was observed.

Acute and subchronic oral neurotoxicity studies in the rat did not show evidence of potential neurotoxicity. In the acute study, decreased hindlimb grip strength on Day 0 was reported in males. This finding was only observed at the limit dose in males and was not observed in the subchronic neurotoxicity study and was therefore not considered evidence of neurotoxicity. No clinical signs of neurotoxicity or neurohistopathology were observed in other guideline studies.

No maternal or developmental effects were observed in either the rat or rabbit oral developmental toxicity studies. In the rat 2-generation reproductive toxicity study, parental effects were limited to increased liver weight and microscopic periportal hypertrophy. No offspring or reproductive toxicity was observed. In a 28-day dietary immunotoxicity study in the rat, no immunotoxicity was observed, and the only observed effect was increased liver weight.

There was no evidence of carcinogenicity in the rat dietary 24-month chronic toxicity/carcinogenicity study or the mouse dietary 18-month carcinogenicity study. No mutagenic or clastogenic potential was observed in the battery of genotoxicity studies on methoxyfenozide. Based on these findings, methoxyfenozide is classified as “not likely to be carcinogenic to humans.”

Specific information on the studies received and the nature of the adverse effects caused by methoxyfenozide 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 document, “Methoxyfenozide. Human Health Draft Risk Assessment for Registration Review and New Use Risk Assessment to Support the Registration of Proposed Use on Chives, and Crop Group Expansions for Stone Fruit and Tree Nuts” at pp. 42-47 in docket ID number EPA-HQ-OPP-2014-0591.

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 methoxyfenozide used for human risk assessment is shown in Table 1 of this unit.

Table 1. -- Summary of Toxicological Doses and Endpoints for Methoxyfenozide 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 including infants and children and females 13-49 years of age)	No hazard was identified for a single oral exposure.		
Chronic dietary (All populations)	NOAEL= 10.2 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Chronic RfD = 0.10 mg/kg/day cPAD = 0.10 mg/kg/day	Co-critical studies: Combined oral chronic toxicity/carcinogenicity-rat LOAEL = 411/491 mg/kg/day [M/F], based on hematological changes (decreased RBC parameters), periportal liver hypertrophy, thyroid hypertrophy and altered colloid; possibly increased adrenal weight.

			Chronic oral toxicity-dog NOAEL = 9.8/12.6 mg/kg/day [M/F] LOAEL = 106.1/110.6 mg/kg/day, based on hematological changes (decreased RBC parameters, slight methemoglobinemia) and increased serum bilirubin.
Incidental oral short-term (1 to 30 days)	NOAEL= 16.8 mg/kg/day UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE ≤100	Two-week oral range-finding study-dog LOAEL = 90.8 mg/kg/day based on hematological changes (decreased RBC parameters, increased Heinz body count, reticulocyte counts, erythrocyte morphology and methemoglobinemia) and increased spleen weights.
Dermal short-term (1 to 30 days) or Intermediate-term (1 to 6 months)	No toxicity, i.e., no hazard, was identified for dermal exposure.		
Inhalation short-term (1 to 30 days) and Intermediate-term (1 to 6 months)	NOAEL= 16.8 mg/kg/day (Inhalation toxicity considered equivalent to oral toxicity.) UF _A = 10x UF _H = 10x FQPA SF = 1x	Residential LOC for MOE ≤100	Two-week oral range-finding study-dog LOAEL = 90.8 mg/kg/day based on hematological changes (decreased RBC parameters, increased Heinz body count, reticulocyte counts, erythrocyte morphology and methemoglobinemia) and increased spleen weights.
Cancer (Oral, dermal, inhalation)	Not likely to be carcinogenic to humans.		

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 methoxyfenozide, EPA considered exposure under the petitioned-for tolerances as well as all existing methoxyfenozide tolerances in 40 CFR 180.544. EPA assessed dietary exposures from methoxyfenozide 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. No such effects were identified in the toxicological studies for methoxyfenozide; therefore, a quantitative acute dietary exposure assessment is unnecessary.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the United States Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA used tolerance-level residues, 100 percent crop treated (100%CT), and default processing factors for most processed commodities that do not have individual tolerances; the only exception being a processing factor for orange juice based on a processing study.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that methoxyfenozide 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 percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for methoxyfenozide. Tolerance level residues and/or 100% CT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for methoxyfenozide in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of methoxyfenozide. 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 FQPA Index Reservoir Screening Tool (FIRST) for surface water, along with the Screening Concentration In Ground Water (SCI-GROW) model and Pesticide Root Zone Model Ground Water (PRZM GW) models for groundwater, the estimated drinking water concentrations (EDWCs) of methoxyfenozide for chronic exposures for non-cancer assessments are estimated to be 7.57 ppb for surface water and 214 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For chronic dietary risk assessment, the water concentration of value 214 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). Methoxyfenozide is currently registered for use on ornamentals in and around home gardens, which could result in residential exposures. EPA assessed residential exposure using the following assumptions: Residential handlers were assessed for potential short-term inhalation exposures from mixing, loading, and applying methoxyfenozide. A quantitative dermal assessment for residential handlers was not conducted since there is no systemic toxicity associated with dermal exposures to

methoxyfenozide. Adult post-application exposures were not quantitatively assessed since no dermal hazard was identified for methoxyfenozide and inhalation exposures are typically negligible in outdoor settings. Furthermore, the inhalation exposure assessment performed for residential handlers is representative of worse case inhalation exposures and is considered protective for post-application inhalation exposure scenarios.

Post-application oral exposure to children is not expected since the extent to which young children engage in activities associated with areas where treated ornamentals are grown (or utilize these areas for prolonged periods of play) is low. Therefore, an incidental oral post-application exposure assessment was not conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <https://www2.epa.gov/pesticide-science-and-assessing-pesticide-risks/framework-assessing-non-occupational-non-dietary>.

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.”

EPA has not found methoxyfenozide to share a common mechanism of toxicity with any other substances, and methoxyfenozide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that methoxyfenozide does not 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 is no evidence of qualitative or quantitative susceptibility of the developing fetus or offspring, based on the developmental and reproductive toxicity study results for methoxyfenozide. No developmental toxicity was observed in either the rat or rabbit developmental toxicity studies, and there was no evidence of offspring or reproductive toxicity in the rat 2-generation reproductive toxicity study.

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 database for methoxyfenozide is complete.
- ii. There is no indication that methoxyfenozide is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional UFs to account for neurotoxicity.

iii. There is no evidence that methoxyfenozide 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 chronic dietary food exposure assessment was 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 methoxyfenozide in drinking water. Based on the discussion in Unit III.C.3, regarding residential use patterns, EPA does not expect residential uses of methoxyfenozide to result in post-application exposure of children or incidental oral exposures of toddlers. These assessments will not underestimate the exposure and risks posed by methoxyfenozide.

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. No adverse effect resulting from a single oral exposure was identified and no acute dietary endpoint was selected. Therefore, methoxyfenozide is not expected to pose an acute risk.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to methoxyfenozide from food and water

will utilize 84 % of the cPAD for children 1-2 years old, the population group receiving the greatest exposure. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of methoxyfenozide result in risk estimates (MOEs > 100) which are not of concern.

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). Methoxyfenozide 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 methoxyfenozide.

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 530. Because EPA's level of concern for methoxyfenozide 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, methoxyfenozide is not registered for any use patterns that would result in intermediate-term residential exposure. Intermediate-term risk is assessed based on intermediate-term residential exposure plus chronic dietary exposure. Because there is no intermediate-term residential exposure and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess intermediate-term risk), no further assessment of intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating intermediate-term risk for methoxyfenozide.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, methoxyfenozide 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 methoxyfenozide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodologies, using high performance liquid chromatography (HPLC), with either tandem mass spectrometric detection (LC-MS/MS), or ultraviolet detection (HPLC-UV) or the multiresidue QuEChERS method, combined with an HPLC-MS/MS, are available to enforce the tolerance expression.

The methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

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 FFDCFA 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 methoxyfenozide in or on tea.

C. Response to Comments

EPA received three comments, only one of which was specific to the petition for methoxyfenozide tolerances. The specific comment opposed “allowing such high residues” but did not provide any information relevant to the safety of the pesticide. The Agency recognizes that some individuals believe that pesticides should be banned on agricultural crops; however, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The comment appears to be directed at the underlying statute and not EPA’s implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

V. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide, in or on imported tea, dried at 20 ppm and tea, instant at 20 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); Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997); or 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: March 4, 2019.

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 § 180.544, add alphabetically the commodities “Tea, dried” and “Tea, instant” to the table in paragraph (a) to read as follows:

§ 180.544 Methoxyfenozide; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * *	* * *
Tea, dried ¹	20
Tea, instant ¹	20
* * *	* * *

¹There are no U.S. registrations as of [insert date of publication in the **Federal Register**] for use on tea.

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