

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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: September 26, 2013.

**Lois Rossi,**  
*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(g), 346a and 371.

■ 2. In § 180.364, remove the entry for "Canola, seed" from the table in paragraph (a)(1) and add alphabetically "Canola, seed" to the table in paragraph (a)(2) to read as follows:

**§ 180.364 Glyphosate; tolerances for residues.**

- (a) \* \* \*
- (2) \* \* \*

Commodity	Parts per million
Canola, seed .....	20
* * * * *	

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2012-0912; FRL-9399-6]

**Methoxyfenozide; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of methoxyfenozide in or on multiple commodities which are identified and discussed later in this document. Additionally, this regulation removes several established time-limited and permanent tolerances, as they will be

superseded by tolerances established by this document. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 2, 2013. Objections and requests for hearings must be received on or before December 2, 2013, 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-2012-0912, 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), EPA West 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:** Lois Rossi, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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](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 <http://www.epa.gov/ocspp> and select "Test Methods and Guidelines."

*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-2012-0912 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 December 2, 2013. 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-2012-0912, 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 16, 2013 (78 FR 3377) (FRL-9375-4), 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 2E8118) by IR-4, 500 College Road East, Suite 201W, Princeton, NJ 08540. The petition requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide) in or on atemoya at 0.6 parts per million (ppm); berry, low growing, except cranberry, subgroup 13-07G at 1.5 ppm; biriba at 0.6 ppm; caneberry subgroup 13-07A at 6 ppm; cherimoya at 0.6 ppm; custard apple at 0.6 ppm; date at 7 ppm; fruit, pome, group 11-10 at 1.5 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1 ppm; grain, aspirated grain fractions at 80 ppm; herb subgroup 19A, except chive at 400 ppm; ilama at 0.6 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed at 0.5 ppm; sorghum, grain, forage at 9 ppm; sorghum, grain, grain at 4 ppm; sorghum, grain, stover at 15 ppm; sorghum, sweet, forage at 9 ppm; sorghum, sweet, grain at 4 ppm; sorghum, sweet, stalk at 9 ppm; sorghum, sweet, stover at 15 ppm; soursop at 0.6 ppm; sugar apple at 0.6 ppm; and vegetable, fruiting, group 8-10 at 2 ppm.

Additionally, the petition requested that EPA establish tolerances under paragraph (d)(2) for indirect or inadvertent residues of methoxyfenozide in or on rapeseed subgroup 20A at 1.0 ppm and sunflower subgroup 20B at 1.0 ppm, and to amend the tolerance for herb and spice, group 19, except coriander, leaves at 4.5 ppm to spice subgroup 19B at 4.5 ppm. Upon approval of the proposed tolerances listed under "New Tolerances," the petition finally requested that EPA remove the following commodities from paragraph (a)(1): Bean, dry seed at 0.24 ppm; coriander, leaves at 30 ppm; grape at 1.0 ppm; fruit, pome, group 11 at 1.5 ppm; okra at 2.0 ppm; pea, dry seed at 2.5 ppm; strawberry at 1.5 ppm; and vegetable, fruiting, group 8 at 2.0 ppm. That document referenced a summary of the petition prepared on behalf of IR-4 by Dow AgroSciences, LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerance levels for several commodities. The Agency has also removed the time-limited tolerances for several commodities and the established tolerance in or on grain, aspirated grain fractions. The reasons for these changes are explained in Unit IV.C.

## III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . . ."

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for 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.

The main target organs identified from the toxicity studies on methoxyfenozide were the liver, thyroid, and red blood cells, though many of the available short-term or subchronic toxicity studies showed

little or no toxicity. Effects of methoxyfenozide on the blood in mammals (methemoglobinemia, decreased red blood cell parameters, Heinz body formation) are consistent with those of other hydrazine compounds. Hematologic parameters in the rat and dog were affected by exposure to methoxyfenozide. Mild anemia (decreases in red blood cell count, hematocrit and hemoglobin) was observed in both species following chronic dietary exposure, along with methemoglobinemia and red blood cell structural abnormalities. Increased platelets were also observed. An increase in the cellularity of rib and sternum bone marrow, along with macrophage pigmentation in the liver and spleen, were reported in the dog. No significant hematological changes were seen in the dog or rat subchronic studies, or the rat 2 week range-finding studies; however, hematological effects were observed in the dog 2 week range-finding study, along with increased spleen weight. No hematological effects were reported in the mouse.

Increased liver weight and periportal hypertrophy were observed in the rat and dog. These findings were observed in the rat following 2-week, subchronic or chronic dietary exposure and in the dietary reproductive toxicity study, and in the dog following chronic exposure. In the rat 2-week toxicity study, increased adrenal gland weight and minimal hypertrophy of the zone fasciculata, and increased thyroid follicular cell hypertrophy/hyperplasia were also observed. Thyroid hypertrophy and altered colloid and increased adrenal weights were observed in the rat chronic oral study, and the incidence and severity of chronic progressive glomerulonephropathy was increased. Thyroid weights were increased in the dog following chronic exposure.

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 toxicity or neurohistopathology were observed in other guideline studies.

No maternal or developmental effects were observed in either the rat or rabbit developmental toxicity studies. In the rat 2-generation reproductive toxicity study, no offspring or reproductive toxicity was observed, and parental effects were limited to increased liver

weight and microscopic periportal hypertrophy. In an immunotoxicity study in the rat, no immunotoxicity was observed.

There was no evidence of carcinogenicity in the rat combined chronic toxicity and carcinogenicity study or the mouse carcinogenicity study. No mutagenic or clastogenic potential was observed in the battery of genotoxicity studies on methoxyfenozide. Based on these findings, methoxyfenozide has been 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 Risk Assessment to Support Proposed New Uses on Herbs, Caneberries, Dates and Sorghum; to Establish Rotational Crop Tolerances in the Rapeseed and Sunflower Oilseed Subgroups; as well as to Extend and Update Crop Group Tolerances on Multiple Commodities” at pp. 35–41 in docket ID number EPA–HQ–OPP–2012–0192.

#### *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://](http://www.epa.gov/pesticides/factsheets/riskassess.htm)

[www.epa.gov/pesticides/factsheets/riskassess.htm](http://www.epa.gov/pesticides/factsheets/riskassess.htm).

A summary of the toxicological endpoints for methoxyfenozide used for human risk assessment is discussed in Unit III.B. of the final rule published in the **Federal Register** of July 11, 2012 (77 FR 40806) (FRL–9354–1).

#### *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 Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM–FCID) Version 3.16, which uses food consumption data from the U.S. Department of Agriculture’s (USDA’s) National Health and Nutrition Examination Survey, “What We Eat in America” (NHANES/WWEIA) from 2003 through 2008. As to residue levels in food, EPA utilized tolerance-level residues, DEEM (Version 7.81) default processing factors as necessary, an empirical processing factor for orange juice, and 100 percent crop treated (PCT) for all commodities.

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 PCT information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for methoxyfenozide. Tolerance level residues and/or 100 PCT 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://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of methoxyfenozide for chronic exposures for non-cancer assessments are estimated to be 51.6 parts per billion (ppb) for surface water and 251 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 251 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 the following uses that could result in residential exposures: Ornamental uses, including on residential property. EPA assessed residential exposure using the following assumptions: Adult handlers were assessed for short-term inhalation exposures from mixing, loading, and applying methoxyfenozide using a manually pressurized hand wand, backpack sprayer, or hose-end sprayer. Since the short- and intermediate-term toxicological endpoints are the same, only short-term exposures have been assessed and are assumed to be protective of intermediate-term exposures. A postapplication exposure assessment was not conducted for adults because the handler assessment is expected to be protective of postapplication exposure via the inhalation route. Although there is also potential for dermal exposure, there is no expectation of dermal risk to any population, including infants and children, based on the lack of dermal toxicity for methoxyfenozide. Furthermore, the potential for postapplication oral exposures to children is not expected since the extent to which young children engage in activities associated with areas where residential ornamentals are grown or use these areas for prolonged periods of play is low. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

[www.epa.gov/pesticides/trac/science/trac6a05.pdf](http://www.epa.gov/pesticides/trac/science/trac6a05.pdf).

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCFA 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 Web site at <http://www.epa.gov/pesticides/cumulative>.

#### D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA 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.* Based on the results in the developmental toxicity studies in rats and rabbits and in the 2-generation reproduction study in rats, no increased sensitivity of fetuses or pups, as compared to adults, was demonstrated for methoxyfenozide. There are no concerns or residual uncertainties for pre- or postnatal toxicity following exposure to methoxyfenozide.

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 uncertainty factors (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., residential exposures to children or toddlers are not expected. 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 is not expected.

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 for adult handlers. 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). Methoxyfenozide is currently registered for uses that could result in intermediate-term residential exposure. However, based on the information in Unit III.C.3., an intermediate-term aggregate exposure assessment was not performed and is not necessary.

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 methodology, using high performance liquid chromatography (HPLC), with either mass spectrometric detection (LC/MS) or ultraviolet detection (HPLC/UV), is available to enforce the tolerance expression.

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](mailto:residuemethods@epa.gov).

##### B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has established MRLs for methoxyfenozide in or on commodities associated with this action. Codex has established MRLs in or on grapes at 1 milligram/kilogram (mg/kg); pepper and tomato at 2 mg/kg; pome fruits at 2 mg/kg; and strawberries at 2 mg/kg. The U.S. tolerances for small vine climbing fruit, except fuzzy kiwifruit subgroup 13-07F at 1.0 ppm (represented by grape); and vegetable, fruiting, group 8-10 (represented by commodities including pepper and tomato) at 2.0 ppm are harmonized with the Codex MRLs for grape and for pepper and tomato, respectively.

Additionally, the EPA is establishing a tolerance in or on fruit, pome, group 11-10 at 2.0 ppm, which is increased from the current tolerance of 1.5 ppm for fruit, pome, group 11, in order to harmonize with the Codex MRL in or on fruit, pome at 2 mg/kg. The Agency is also establishing a tolerance in or on berry, low growing, subgroup 13-07G, except cranberry (represented by strawberry) at 2.0 ppm, in order to harmonize with the Codex MRL in or on strawberry at 2 mg/kg. The 13-07G tolerance is being increased from the current tolerance of 1.5 ppm in or on strawberry.

The recommended tolerance of 0.50 ppm in or on pea and bean, dried shelled, except soybeans subgroup 6C, was proposed at the Agency's request to better harmonize with the existing Codex MRL of 0.5 mg/kg in or on dried beans. This tolerance will supersede the current tolerances in or on dried beans at 0.24 ppm, and in or on dried peas at 2.5 ppm. The Codex has not established MRLs for other commodities associated with this action.

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

Based on the data supporting the petition, EPA has revised the proposed tolerances for several commodities, as follows: Date from 7.0 ppm to 8.0 ppm; grain, aspirated grain fractions from 80 ppm to 120 ppm; sorghum, grain, forage from 9.0 ppm to 15 ppm; sorghum, grain, grain from 4.0 ppm to 6.0 ppm; sorghum, grain, stover from 15 ppm to 20 ppm; sorghum, sweet, forage from 9.0 ppm to 15 ppm; sorghum, sweet, grain from 4.0 ppm to 6.0 ppm; sorghum sweet, stalk from 9.0 ppm to 15 ppm; and sorghum, sweet, stover from 15 ppm to 20 ppm. The Agency revised these tolerance levels based on analysis of the residue field trial data using the Organization for Economic Cooperation and Development (OECD) tolerance calculation procedures. As previously discussed, EPA has also revised the following proposed tolerances in order to harmonize with established Codex MRLs: Berry, low growing, subgroup 13-07G, except cranberry from 1.5 ppm to 2.0 ppm, and fruit, pome, group 11-10 from 1.5 ppm to 2.0 ppm.

EPA is establishing a tolerance in or on herb subgroup 19A, except chive at 400 ppm. The petition to the Agency requested concurrently to amend the established tolerance for indirect or inadvertent residues in or on herb and spice, group 19, except coriander, leaves at 4.5 ppm to spice subgroup 19B at 4.5 ppm, because a permanent tolerance in or on subgroup 19A was proposed to be established and an inadvertent tolerance is no longer needed when a commodity has a tolerance allowing for direct treatment. However, because the permanent tolerance being established in or on herb subgroup 19A does not include a tolerance for chive and chive is not included in subgroup 19B, the Agency determined that it is also necessary to maintain a tolerance for the indirect or inadvertent residues of methoxyfenozide in or on chive, as the commodity was previously covered by the group 19 indirect or inadvertent residue tolerance. Therefore, EPA is also establishing an individual tolerance for the indirect or inadvertent residues of methoxyfenozide in or on chive at 4.5 ppm.

Additionally, EPA determined that the time-limited tolerances in or on sorghum, forage at 30.0 ppm; sorghum, grain at 0.05 ppm; and sorghum, stover at 60.0 ppm should be removed because the tolerances expired on December 31, 2012, and because they will be superseded by permanent tolerances for these commodities. Finally, the Agency has determined that the established

tolerance in or on grain, aspirated fractions at 2.0 ppm should be removed, as it will be superseded by the grain, aspirated grain fractions tolerance at 120 ppm.

**V. Conclusion**

Therefore, tolerances are established for residues of methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide) in or on atemoya at 0.60 ppm; berry, low growing, subgroup 13-07G, except cranberry at 2.0 ppm; biriba at 0.60 ppm; caneberry subgroup 13-07A at 6.0 ppm; cherimoya at 0.60 ppm; custard apple at 0.60 ppm; date at 8.0 ppm; fruit, pome, group 11-10 at 2.0 ppm; fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F at 1.0 ppm; grain, aspirated grain fractions at 120 ppm; herb subgroup 19A, except chive at 400 ppm; ilama at 0.60 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed at 0.50 ppm; sorghum, grain, forage at 15 ppm; sorghum, grain, grain at 6.0 ppm; sorghum, grain, stover at 20 ppm; sorghum, sweet, forage at 15 ppm; sorghum, sweet, grain at 6.0 ppm; sorghum, sweet, stalk at 15 ppm; sorghum, sweet, stover at 20 ppm; soursop at 0.60 ppm; sugar apple at 0.60 ppm; and vegetable, fruiting, group 8-10 at 2.0 ppm. This regulation additionally establishes tolerances for indirect or inadvertent residues in or on rapeseed subgroup 20A at 1.0 ppm and sunflower subgroup 20B at 1.0 ppm. The regulation also amends the tolerance for indirect or inadvertent residues in or on herb and spice, group 19, except coriander, leaves at 4.5 ppm to spice subgroup 19B at 4.5 ppm and chive at 4.5 ppm.

This regulation additionally removes the established tolerances in or on bean, dry, seed at 0.24 ppm; coriander, leaves at 30 ppm; fruit, pome, group 11 at 1.5 ppm; grain, aspirated fractions at 2.0 ppm; grape at 1.0 ppm; okra at 2.0 ppm; pea, dry, seed at 2.5 ppm; strawberry at 1.5 ppm; and vegetable, fruiting, group 8 at 2.0 ppm. Finally, this regulation removes the time-limited tolerances in or on sorghum, forage at 30.0 ppm; sorghum, grain at 0.05 ppm; and sorghum, stover at 60.0 ppm.

**VI. Statutory and Executive Order Reviews**

This final rule 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 final rule has been exempted from review under Executive Order 12866, this final rule 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 final rule 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 final rule 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 final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (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 of 1995 (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: September 26, 2013.

**Lois Rossi,**

*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:

- a. Remove bean, dry, seed; coriander, leaves; fruit, pome, group 11; grain, aspirated fractions; grape; okra; pea, dry seed; strawberry; and vegetable, fruiting, group 8 from the table in paragraph (a)(1).
- b. Remove and reserve paragraph (b).
- c. Remove herb and spice, group 19, except coriander, leaves from the table in paragraph (d)(2).
- d. Add the following commodities in alphabetical order to the tables in paragraphs (a)(1) and (d)(2) as shown.

**§ 180.544 Methoxyfenozide; tolerances for residues.**

- (a) \* \* \*
- (1) \* \* \*

Commodity	Parts per million
* * * *	
Atemoya .....	0.60
* * * *	
Berry, low growing, subgroup 13-07G, except cranberry .....	2.0
Biriba .....	0.60
* * * *	
Caneberry subgroup 13-07A .....	6.0
* * * *	
Cherimoya .....	0.60

Commodity	Parts per million
* * * *	*
Custard apple .....	0.60
Date .....	8.0
* * * *	*
Fruit, pome, group 11-10 .....	2.0
Fruit, small, vine climbing, except fuzzy kiwifruit, subgroup 13-07F .....	1.0
* * * *	*
Grain, aspirated grain fractions ....	120
* * * *	*
Herb subgroup 19A, except chive	400
* * * *	*
Llama .....	0.60
* * * *	*
Pea and bean, dried shelled, except soybean, subgroup 6C, except pea, blackeyed, seed and pea, southern, seed .....	0.50
* * * *	*
Sorghum, grain, forage .....	15
Sorghum, grain, grain .....	6.0
Sorghum, grain, stover .....	20
Sorghum, sweet, forage .....	15
Sorghum, sweet, grain .....	6.0
Sorghum, sweet, stalk .....	15
Sorghum, sweet, stover .....	20
Soursop .....	0.60
* * * *	*
Sugar apple .....	0.60
* * * *	*
Vegetable, fruiting, group 8-10 ....	2.0
* * * *	*

(b) Section 18 emergency exemptions.

[Reserved]

\* \* \* \*

(d) \* \* \*

(2) \* \* \*

Commodity	Parts per million
* * * *	*
Chive .....	4.5
* * * *	*
Rapeseed subgroup 20A .....	1.0
Spice subgroup 19B .....	4.5
Sunflower subgroup 20B .....	1.0

[FR Doc. 2013-24127 Filed 10-1-13; 8:45 am]

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**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 180**

[EPA-HQ-OPP-2012-0885; FRL-9397-8]

**Sedaxane; Pesticide Tolerances**

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

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of sedaxane in or on potato and potato, wet peel. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective October 2, 2013. Objections and requests for hearings must be received on or before December 2, 2013, 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-2012-0885, 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), EPA West 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:** Lois Rossi, Registration Division, Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (703) 305-7090; email address: [RDfRNNotices@epa.gov](mailto:RDfRNNotices@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](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-2012-0885 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 December 2, 2013. 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-2012-0885, 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, 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.regulations.gov>.