under the Congressional Review Act. Through this document, we correct this omission. We do not change any other aspect of the interim final rule, and its regulatory text remains unchanged.

DATES: Effective July 11, 2012.

FOR FURTHER INFORMATION CONTACT: Jacquelyn Butler, U.S. Department of Education, 1990 K Street NW., Room 8053, Washington, DC 20006–8542. Telephone: (202) 502–7890 or by email: *jacquelyn.butler@ed.gov*.

If you use a telecommunications device for the deaf (TDD) or a text telephone (TTY), call the Federal Relay Service (FRS), toll free, at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: We make the following correction to the Federal Pell Grant Program interim final rule:

On page 25898, in the first column, replace the last paragraph under the heading *Waiver of Rulemaking and Delayed Effective Date* with the following two paragraphs:

The Administrative Procedure Act (APA) generally requires that regulations be published at least 30 days before their effective date, unless the agency has good cause to implement its regulations sooner (5 U.S.C. 553(d)(3)). In addition, this interim final rule has been determined to be a major rule for purposes of the Congressional Review Act (CRA) (5 U.S.C. 801, *et seq.*). Generally, under the CRA, a major rule takes effect 60 days after the date on which the rule is published in the **Federal Register**. Section 808(2) of the CRA, however, provides that any rule which an agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rule issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the Federal agency promulgating the rule determines.

As previously stated, because this interim final rule merely reflects statutory changes and removes obsolete regulatory provisions and, in the case of new § 690.64, protects students from receiving reduced amounts of Pell Grant funds, there is good cause to waive the delayed effective dates in the APA and the CRA and make this interim final rule effective on the day it is published.

Accessible Format: Individuals with disabilities can obtain this document in an accessible format (e.g., braille, large print, audiotape, or compact disc) on request to the program contact person listed under **FOR FURTHER INFORMATION CONTACT**.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register**, in text or Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov*. Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Dated: July 6, 2012.

David A. Bergeron,

Acting Assistant Secretary for Postsecondary Education.

[FR Doc. 2012–16929 Filed 7–10–12; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0343; FRL–9354–1]

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 and for indirect or inadvertent combined residues of the methoxyfenozide on various other commodities. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action and revises the tolerance expression. The Interregional Research Project #4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective July 11, 2012. Objections and requests for hearings must be received on or before September 10, 2012, 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–2011–0343, is available at *http://www.regulations.gov* or at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, 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: Debra Rate, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 306–0309; email address: *rate.debra@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. Potentially affected entities may include, but are not limited to those engaged in the following activities:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather to provide a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

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://ecfr.gpoaccess.gov/cgi/t/text/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–2011–0343 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 September 10, 2012. 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 that does not contain any 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 a copy of your non-CBI objection or hearing request, identified by docket ID number EPA–HQ–OPP–2011–0343, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on line information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 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.htm.*

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 July 20, 2011 (76 FR 43231) (FRL–8880–1), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E7842) 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 (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl hydrazide), in or on the raw agricultural commodities fruit, citrus, group 10–10 at 1.9 parts per million (ppm); lemon, oil at 45 ppm; citrus, oil (except lemon) at 100 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.8 ppm; and beet, sugar at 0.5 ppm. In addition, the petition proposed that 40 CFR 180.544 be amended by removing the tolerance for vegetable, root, subgroup 1A from paragraph (a) and the tolerances for fruit, citrus and citrus, oil from paragraph (c). Lastly, the petition proposed to revise the tolerance expressions in 40 CFR 180.544. That notice referenced a summary of the petition prepared 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.

In the **Federal Register** of October 27, 2010 (75 FR 66092) (FRL–8848–3), EPA issued a notice pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7776) by Dow AgroSciences LLC, 9330 Zionsville Road, Indianapolis, IN 46268. The petition proposed to reestablish tolerances which were inadvertently allowed to expire in 2010. The proposed tolerances in 40 CFR 180.544 are for indirect or inadvertent combined residues of the insecticide methoxyfenozide, (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) and its metabolites RH–117,236 free phenol of methoxyfenozide; 3,5-dimethylbenzoic acid N-tert-butyl-N′-(3-hydroxy-2-methylbenzoyl) hydrazide, RH–151,055 glucose conjugate of RH–117,236; 3,5-dimethylbenzoic acid N-tert-butyl-N-[3 (β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide) and RH–152,072 the malonylglycosyl conjugate of RH–117,236, in or on the raw agricultural commodities: Vegetable, root and tuber, group 1 at 0.1 ppm; vegetable, leaves of root and tuber, group 2 at 0.2 ppm; vegetable, bulb, group 3 at 0.2 ppm; vegetable, legume, group 6 at 0.1 ppm; vegetable, foliage of legume, group 7 at 10 ppm; grain, cereal, forage, fodder, and straw, group 16 at 10 ppm; grass, forage, fodder and hay, group 17 at 10 ppm; animal feed, non-grass, group 18 at 10 ppm; and herb and spice, group 19 at 10 ppm. That notice referenced a summary of the petition prepared 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 petitions, EPA has modified the levels at which tolerances are being established for some of the commodities. 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.

Methoxyfenozide is not acutely toxic and not a dermal sensitizer. Minimal or no toxic effects were observed in studies in which methoxyfenozide was administered by the dermal or inhalation routes of exposure.

The main target organs in the rat and dog were the liver, thyroid and red blood cells (RBC). The most consistent findings across species and studies were decreased red blood cell parameters and increased liver, thyroid, adrenal and spleen weights. In the rat metabolism study, liver contained 2–9% of the administered radioactivity at maximum concentration (C_{max}), but levels decreased and bioaccumulation was not observed. Levels in the blood were negligible. The effects of methoxyfenozide on the blood (methemoglobinemia, decreased red blood cell parameters, Heinz body formation) are consistent with those of other hydrazine compounds.

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 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. The only observed effect was increased liver weight.

Dermal effects were not observed in the rat following a 28-day exposure period (5 exposure days per week for a total of 20 exposures). This finding is consistent with the relatively low dermal absorption of 2% of the applied dose, observed in an *in vivo* dermal absorption study in rats treated with an 80% wettable powder (WP) formulation product.

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 titled ''Methoxyfenozide Human Health Risk Assessment'' starting at page 14 in docket ID number EPA–HQ–OPP–2011–0343.

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 the Table of this unit.

TABLE—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 (General population 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.
Inhalation Short-Term (1–30 days) and Intermediate-Term (1–6 months).	NOAEL = 16.8 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	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).	Classification: 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).

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 USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA used tolerance level residues, Dietary Exposure Evaluation Model (DEEM) (Ver. 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 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 Screening Concentration in Ground Water (SCI–GROW) models the estimated drinking water concentrations (EDWCs) of methoxyfenozide for chronic exposures for non-cancer assessments are estimated to be 43.4 parts per billion (ppb) for surface water and 4.13 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 43.4 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: Ornamentals. EPA assessed residential exposure using the following assumptions: Adults may be exposed to methoxyfenozide from its currently registered use on ornamentals. Residential pesticide handlers may be exposed for short-term durations of exposure (1–30 days) only. The inhalation (short-term) residential exposure was assessed for a ''homeowner'' mixer/loader/applicator using a manually pressurized handwand, backpack sprayer, or hose-end sprayer.

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.*

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 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 FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

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 prenatal/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. Although a 28-day inhalation toxicity study has not been submitted, EPA has determined that this study is not needed based on a weight of evidence approach that considered all of the available hazard and exposure information, including the use of a conservative oral POD that results in MOEs ranging from 28,000 to 4,100,000 for risk via the inhalation route due to residential and occupational exposures. Therefore, there is no need for additional UFs to account for missing studies.

ii. There is no indication that methoxyfenozide is a neurotoxic chemical and there is no need for 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 dietary food exposure assessment utilized 100 PCT and tolerance-level residues (established or recommended). EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to methoxyfenozide in drinking water. 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 58% 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 for adults, 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 aggregate MOEs of 670. Because EPA's level of concern for methoxyfenozide is a MOE of 100 or below, these MOEs are 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). Because no intermediate-term adverse effect was identified, methoxyfenozide is not expected to pose an intermediate-term risk.

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 (high performance liquid chromatography (HPLC), with either tandem mass spectrometric detection (LC/MS/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.*

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 citrus fruits at 0.7 ppm, carrots at 0.5 ppm, and radishes at 0.4 ppm. These MRLs are different than the tolerances established for methoxyfenozide in the United States. Harmonization of tolerances in the currently requested commodities is not possible, as the U.S. and Codex use patterns differ potentially resulting in residues in citrus and vegetable, root, except sugar beet, subgroup 1B, which includes carrots and radishes, under U.S. use patterns that are greater than the corresponding Codex MRLs.

C. Revisions to Petitioned-For Tolerances

EPA is establishing a slightly higher tolerance of 0.90 ppm for vegetable, root, except sugar beet, subgroup 1B, than was proposed. The 0.90 ppm tolerance was calculated using the Organization for Economic Co-operation and Development (OECD) tolerance calculation procedure. Similarly, EPA is establishing tolerances for citrus commodities that are higher than that proposed by IR–4. IR–4 proposed separate tolerances for residues in lemon oil and residues in all other citrus oils. However, because residues from the citrus field trials are similar enough to warrant a crop group tolerance, and a single processing factor was used to derive the oil tolerance, EPA is establishing a conservative tolerance in citrus oil at 100 ppm, and no separate tolerance for residues in lemon oil will be established. Tolerances proposed for inadvertent residues will not be established for vegetable, root and tuber group 1 at 1 ppm since a tolerances exist in § 180.544(a) for subgroups 1A and 1D. Therefore, only a tolerance for potato will be established at the Agency determined level of 0.02 ppm. Tolerances will not be established for vegetable, bulb, group 3 at 0.20 ppm since a tolerance exists in § 180.544(a) for subgroup 3–07B. Only a tolerance for onion, bulb, subgroup 3–07A will be established at the Agency determined level of 0.10 ppm. Tolerances also are not needed for vegetable, legume group 6, grass forage, fodder, and hay group 17, since tolerances for these groups exist under § 180.544(a). Also, since a tolerance exists in § 180.544(a) for coriander, leaves, a tolerance for Herb and spice, group 19, except coriander, leaves will be established at a lower, Agency determined level of 4.5 ppm.

V. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide (benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimehtylbenzoyl)-2-(1,1-dimethylethyl hydrazide), in or on fruit, citrus, group 10–10 at 3.0 ppm; citrus, oil at 100 ppm; vegetable, root, except sugar beet, subgroup 1B at 0.90 ppm; and beet, sugar 0.50 ppm. Also, due to the tolerances established above by this document, the following existing tolerance is removed as unnecessary; vegetable, root, subgroup 1A. All of the commodities covered by this crop subgroup are covered by the tolerances for vegetable, root, except sugar beet, subgroup 1B, and beet, sugar. In addition, concurrent with the establishment of tolerances for fruit, citrus, group 10–10 at 3.0 ppm and citrus, oil at 100 ppm in § 180.544(a), the tolerances for fruit, citrus, group 10 (10 ppm) and citrus oil (100 ppm) will be removed from § 180.544(c). Tolerances will be established under § 180.544(d)(1) for onion, bulb subgroup 3–07A at 0.10 ppm and for potato at 0.02 ppm. Tolerances will be established under § 180.544(d)(2) for grain, cereal, forage, fodder and straw, group 16 except corn at 6.0 ppm; animal feed, nongrass, group 18, straw at 8.0 ppm; and herb and spice, group 19, except coriander, leaves at 4.5 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) (Pub. L. 104–4).

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), Public Law 104–113, section 12(d) (15 U.S.C. 272 note).

VII. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. 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 this final rule in the **Federal Register**. This final rule 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: June 29, 2012.

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:

■ i. Revise the introductory text in paragraph (a)(1);

■ ii. Remove the entry for ''Vegetable, root, subgroup 1A'' from the table in paragraph (a)(1), and add alphabetically the following commodities to the table;

■ iii. Revise introductory text in paragraph (a)(2); and

■ iv. Revise paragraphs (b), (c) and (d).

The amendments read as follows:

§ 180.544 Methoxyfenozide; tolerances for residues.

(a*) General.* (1) Tolerances are established for residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on the commodities listed in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide) in or on the commodity.

Commodity	Parts per million
* * * * *	
Beet, sugar, roots	0.50
* * * * *	
Citrus, oil	100
* * * * *	
Fruit, citrus, group 10–10	3.0
* * * * *	
Vegetable, root, except sugar beet, Subgroup 1B	0.90
* * * * *	

(2) Tolerances are established for residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on the commodities in the following table. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of methoxyfenozide [3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide] and its glucuronide metabolite (β-D-Glucopyranuronic acid, 3-[[2-(1,1-dimethylethyl)-2-(3,5-dimethylbenzoyl)-hydrazino]carbonyl]-2-methylphenyl-), calculated as the stoichiometric equivalent of methoxyfenozide.

* * * * *

(b) *Section 18 emergency exemptions.* Time-limited tolerances specified in the following table are established for residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on the specified agricultural commodities, resulting from use of the pesticide pursuant to FFIFRA section 18 emergency exemptions. Compliance with the tolerance levels specified in the following table is to be determined by measuring only methoxyfenozide [benzoic acid, 3-methoxy-2-methyl-, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl)hydrazide]. The expired tolerances will be revoked on the date specified in the table.

* * * * *

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent tolerances.* (1) Tolerances are established for the indirect or inadvertent residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on the raw agricultural commodities in the following table, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section. Compliance with the tolerance levels specified in the following table is to be determined by measuring only methoxyfenozide [3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide].

Commodity	Parts per million
Onion, bulb, subgroup 3–07A	0.10
Potato	0.02

(2) Tolerances are established for the indirect or inadvertent residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on the raw agricultural commodities in the following table, when present therein as a result of the application of methoxyfenozide to growing crops as listed in paragraph (a) of this section. Compliance with the tolerance levels specified in the following table is to be determined by measuring only the sum of methoxyfenozide [3-methoxy-2-methylbenzoic acid, 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide] and the following metabolites (all calculated as the stoichiometric equivalent of methoxyfenozide): free phenol of methoxyfenozide [3,5-dimethylbenzoic acid N-tert-butyl-N′-(3-hydroxy-2-methylbenzoyl) hydrazide], the glucose conjugate of the phenol [3,5-dimethyl benzoic acid N-tert-butyl-N′-[3 (β-D-glucopyranosyloxy)-2-methylbenzoyl]-hydrazide] and the malonylglycosyl conjugate of the phenol [3,5-dimethyl benzoic acid N-tert-butyl-N′-[3 (β-D-6-malonyl-glucopyranosyl-1-oxy)-2-methylbenzoyl]-hydrazide].

Commodity	Parts per million
Animal feed, nongrass, group 18, straw	8.0
Grain, cereal, forage, fodder and straw group 16, except corn	6.0
Herb and spice, group 19, except coriander, leaves	4.5

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0507; FRL–9353–7]

RIN 2070–ZA16

Dicloran and Formetanate; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.