''Apple, wet pomace'' and ''Grape, raisin'' to read as follows:

§ 180.608 Spirodiclofen; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of spirodiclofen, including its metabolites and degradates, in or on the commodities listed below. Compliance with the following tolerance levels is to be determined by measuring only spirodiclofen, 3-(2,4-dichlorophenyl)-2-oxo-1-oxaspiro[4.5]dec-3-en-4-yl 2,2-dimethylbutanoate.

Commodity	Parts per million
* * * * *	
Apple, wet pomace	2.4
* * * * *	
Grape, raisin	6.0
* * * * *	

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[FR Doc. 2012–29902 Filed 12–11–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0099; FRL–9373–3]

Flubendiamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation modifies tolerances for residues of flubendiamide in or on multiple food commodities which are identified, and discussed in detail later in this document. Bayer CropScience LP in c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.) requested these tolerances, and revisions to tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 12, 2012. Objections and requests for hearings must be received on or before February 11, 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–2007–0099, 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: Carmen Rodia, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; fax number: (703) 308–0029; email address: *rodia.carmen@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://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–2007–0099 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 11, 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–2007–0099, 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.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 May 23, 2012 (77 FR 30481) (FRL–9347–8), 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 2F7981) by Bayer CropScience LP in c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.), P.O. Box 12014, Research Triangle Park, NC 27709–2014. The petition requested that the established tolerances listed in 40 CFR 180.639 for residues of the insecticide flubendiamide, N^2-[1, 1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4-[l, 2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on Apple, wet pomace be increased from 2.0 parts per million (ppm) to 5.0 ppm; and Fruit, pome, group 11 be increased from 0.70 ppm to 1.5 ppm. That document

referenced a summary of the petition prepared by Bayer CropScience LP in c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.), the registrant, which is available in the docket, *http://www.regulations.gov.* There were no substantive comments received in response to the notice of filing.

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

Flubendiamide has a low acute toxicity via the oral and dermal routes of exposure. Though it is a slight irritant to the eye, flubendiamide is not a skin irritant and it is not a skin sensitizer under the conditions of the guinea pig maximization test.

In the mammalian toxicology database, the primary target organ of flubendiamide exposure is the liver, with secondary effects reported in the thyroid and kidney at equivalent or higher doses; no-observed-adverse-effect-levels (NOAELs) established to protect for liver toxicity are protective of effects seen in the thyroid and kidney. Adverse adrenal effects were also noted in the dog.

Buphthalmia (eye enlargement), opacity, and exophthalmus with hemorrhage appearing only in infancy, were observed in rat offspring in the reproductive and developmental neurotoxicity (DNT) studies. There was no clear dose-response relationship for this effect, but ocular toxicity was noted in three rat studies and accompanied by histopathological findings of synechia, hemorrhage, keratitis, iritis, and cataracts. Therefore, bupthalmos is considered an effect of treatment. No evidence of cancer was seen for flubendiamide in cancer bioassays in mice and rats. Flubendiamide was also negative in mutagenicity testing. Accordingly, flubendiamide was classified as ''Not Likely To Be Carcinogenic to Humans.''

More detailed information on the studies received and the nature of the adverse effects caused by flubendiamide as well as the NOAEL and the lowest-observed-adverse effect-level (LOAEL) from the toxicity studies can be found in the document entitled, ''Flubendiamide: Human Health Risk Assessment for Proposed Uses on Corn, Cotton, Tobacco, Tree Fruit, Tree Nuts, Vine Crops and Vegetable Crops,'' dated April 3, 2008, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES.** Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2007–0099. Double-click on the document to view the referenced information on pages 65–70 of 105.

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 flubendiamide used for human risk assessment is shown in the following Table 1.

TABLE 1—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUBENDIAMIDE 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 (Females, 13–49 years of age). Acute Dietary (General Population, including infants and children).	NOAEL = 99.5 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	aRfD = 0.995 mg/kg/day. aPAD = 0.995 mg/kg/day	2-generation reproduction, 1-generation reproduction, and DNT studies as three co-critical studies (using 1,200 ppm [99.5 mg/kg/day] from the DNT as the highest NOAEL for eye effects and a LOAEL from the 1-generation reproduction study of 127 mg/kg/day), based on buphthalmia (enlargement of eyes), ocular opacity, retinal degeneration, hemorrhage, cataract, and atrophy of the optic nerve.

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

Exposure/scenario	Point of departure and uncertainty/safety factors	RfD, PAD, LOC for risk assessment	Study and toxicological effects
Chronic Dietary (General Population, including infants and children).	NOAEL = 2.4 mg/kg/day. UF_A = 10x UF_H = 10x FQPA SF = 1x	cRfD = 0.024 mg/kg/day. cPAD = 0.024 mg/kg/day	2-year rat cancer study, 1-year chronic dog study, and 1-year chronic rat study as three co-critical studies, using the chronic rat study NOAEL of 50 ppm (2.4 mg/kg/day) with LOAEL from the 2-year cancer rat study of 33.9 mg/kg/day, based on liver toxicity, fatty change, hypertrophy, ↑ liver weight and ↑ Gamma Glutamyl Transferase (GGT).
Cancer (oral, dermal, and inhalation).	Classification: Not likely to be carcinogenic to humans based on negative genotoxicity and carcinogenicity in long-term cancer studies in rats and mice.		

FQPA SF = Food Quality Protection Act Safety Factor. milligrams/kilograms/day = mg/kg/day. UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). Reference dose. Population adjusted dose. (a = acute; c = chronic). DNT = developmental neurotoxicity test.

A summary of the toxicological endpoints for flubendiamide used for human risk assessment can be found in the document entitled, ''Flubendiamide: Human Health Risk Assessment for Proposed Uses on Corn, Cotton, Tobacco, Tree Fruit, Tree Nuts, Vine Crops and Vegetable crops,'' dated April 3, 2008, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2007–0099. Double-click on the document to view the referenced information on pages 37–38 of 105.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to flubendiamide, EPA considered exposure under the petitioned-for tolerances as well as all existing flubendiamide tolerances in 40 CFR 180.639. Acute and chronic aggregate dietary (food and drinking water) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model, Version 3.16—Food Commodity Intake Database (DEEMFCID™) which uses food consumption information from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat In America (NHANES/WWEIA). This dietary survey was conducted from 2003 to 2008. The analyses were performed to support Section 3 requests for increases in the tolerances for pome fruit and wet apple pomace as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for flubendiamide. In estimating acute dietary exposure, EPA used DEEMFCID™ along with food consumption information from the USDA's 2003–2008 NHANES/WWEIA survey. As to residue levels in food, for the acute assessment, the modeled exposure estimates are based on tolerance level residues, assuming 100% of crops were treated. In addition, experimental processing (where available) factors were assumed for both registered and requested crop uses.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA's 2003–2008 NHANES/WWEIA survey. EPA assumed a subset of the currently registered crops contains residues at the average residue levels found in the crop field trials. For the newly proposed crops, livestock commodities, and the remaining currently registered crops, EPA assumed tolerance level residues. In addition, experimental processing factors were used where available. Finally, EPA assumed 100% of crops were treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that flubendiamide should be classified as ''Not Likely To Be Carcinogenic to Humans.'' As a result, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary for flubendiamide, and was not conducted.

iv. *Anticipated residue and percent crop treated (PCT) information.* Section 408(b)(2)(E) of FFDCA authorizes EPA to use available data and information on the anticipated residue levels of pesticide residues in food and the actual levels of pesticide residues that have been measured in food. If EPA relies on such information, EPA must require, pursuant to FFDCA section 408(f)(1), that data be provided 5 years after the tolerance is established, modified, or left in effect, demonstrating that the levels in food are not above the levels anticipated. For the present action, EPA will issue such data call-ins as are required by FFDCA section 408(b)(2)(E) and authorized under FFDCA section 408(f)(1). Data will be required to be submitted no later than 5 years from the date of issuance of these tolerances.

2. *Dietary exposure from drinking water.* The Agency used Tier II screening level water exposure models in the dietary exposure analysis and risk assessment for flubendiamide in drinking water. These simulation models take into account data on the physical, chemical and fate/transport characteristics of flubendiamide. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at *http://www.epa.gov/oppefedl/models/water/index.htm.*

Flubendiamide is persistent and potentially mobile in terrestrial and aquatic environments. These fate properties suggest that it has a potential to move into surface water and ground water. Potential residues in drinking water were included in the acute and chronic dietary analyses based on surface water results from the Tier II, Pesticide Root Zone Modeling/Exposure Analysis Modeling System(PRZM/EXAMS) Index Reservoir model as these values were higher than the groundwater estimates from the Screening Concentration in Ground Water (SCI–GROW) model. Estimated acute and chronic drinking water values were 24.57 parts per billion (ppb) and 11.46 ppb, respectively.

A summary of the dietary exposure from drinking water for flubendiamide used for human risk assessment can be found in the documents entitled, ''Flubendiamide: Acute and Chronic Aggregate Dietary (Food and Drinking

Water) Exposure Assessment for the Increased Tolerance on Pome Fruit,'' dated September 11, 2012, by going to *http://www.regulations.gov.* The referenced document is available in the docket established by this action, which is described under **ADDRESSES**. Locate and click on the hyperlink for docket ID number EPA–HQ–OPP–2007–0099. Double-click on the document to view the referenced information on pages 2–4 of 29.

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). Flubendiamide is not registered for any specific use patterns that would result in residential exposure.

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 flubendiamide to share a common mechanism of toxicity with any other substances, and flubendiamide does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that flubendiamide 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 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.* While both the rat and rabbit developmental studies did not identify teratogenic effects and showed no evidence of increased prenatal susceptibility, adverse eye effects (eye enlargement) were noted in postnatal rat pups older than 14 days in multiple studies (the 2-generation reproduction and 1-generation supplemental studies). Additionally, the DNT study reported eye effects appearing in some offspring between lactation days 14 and 42, even though exposure stopped at lactation day 21, indicating a possible delay (a latent response) from the time of last exposure to onset of bupthalmos. These eye effects did not occur in adult rats. Since the iris and chamber angle are differentiating and specializing into definite structures during postnatal days 5 to 20, neonatal rats appear to have an increased susceptibility to flubendiamide exposure as compared to adults.

In addition to the reported eye effects in the DNT study, there was also a balanopreputial separation (separation of the prepuce (foreskin) from the glans penis *(balanus))* delay. While this effect is generally considered adverse per se, it is not assumed to be a developmental effect from *in utero* exposure. Here, delayed balano-preputial separation is considered secondary to reduced postnatal pup body weight as a result of postnatal exposure. Furthermore, it was resolved within the appropriate age range of puberty and no effects on reproductive function were observed in the multigeneration study in rats. Delayed balanopreputial separation was seen only at doses causing maternal toxicity and is not more severe than the maternal effects of hepatotoxicity seen at the common pup/maternal LOAEL of the DNT study. Accordingly, the delayed balanopreputial separation seen in the DNT study does not cause concern for increased sensitivity to the young for flubendiamide.

Human microsomes have been shown to be capable of approximately 4 times higher hydroxylation rates of flubendiamide as compared to female mouse microsomes and may be able to efficiently metabolize and excrete flubendiamide, preventing accumulation of the parent compound. It remains unclear whether the ability to metabolize and clear the parent compound is the only requirement to avoid ocular toxicity. Due to the potential ocular toxicity, this perinatal ocular effect is considered in the human health risk assessment for flubendiamide.

3. *Conclusion.* EPA evaluated the quality of the toxicity and exposure data and, based on these data, has determined that the safety of infants and children would be adequately protected if the FQPA SF were reduced to lX. That decision is based on the following findings:

i. The toxicology database for flubendiamide is complete with the exception of a subchronic neurotoxicity study which is now a new data requirement under 40 CFR part 158; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. Flubendiamide is not a neurotoxic chemical based on neurotoxicity assessments conducted in the acute and developmental neurotoxicity studies and as part of the chronic rat study. Additionally, in several short-term studies in rats (subacute and subchronic feeding, plaque-forming cell assay, one-generation pilot, developmental toxicity) no neurobehavioral signs were observed at doses up to and exceeding the limit dose; therefore, an additional database uncertainty factor is not needed to account for potential neurotoxicity.

ii. Although susceptibility was identified in the toxicological database (eye effects), the selected regulatory PODs (which are based on clear NOAELs) are protective of these effects; therefore, the human health risk assessment is protective.

iii. There are no residual uncertainties identified in the exposure databases and the exposure assessment is protective. The acute dietary food exposure assessment utilizes tolerance-level residues, the chronic dietary food exposure assessment utilizes, in part, average residue levels found in the crop field trials/livestock commodities and, in part, tolerance-level residues. Both assessments assume that 100% of crops with requested or existing uses of flubendiamide are treated. The drinking water assessment generated estimated drinking water concentrations (EDWCs) using models and associated modeling parameters which are designed to provide conservative, health protective, high-end estimates of water concentrations. The highest relevant EDWCs were used in the dietary (food and drinking water) exposure assessment. By using these screening-level exposure assessments in the acute and chronic dietary (food and drinking water) assessments, risk is not underestimated for flubendiamide.

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 population adjusted dose (aPAD) and chronic population adjusted dose (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.

For this action, there is potential exposure to flubendiamide from food and drinking water, but not from residential use sites (as there are no proposed or existing residential uses for flubendiamide). Since hazard was identified via the oral route over both the acute and chronic duration, the aggregate risk assessments considers exposures from food and drinking water consumed over the acute and chronic durations.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, EPA has concluded that acute dietary exposure from food and water to flubendiamide will utilize 3.1% of the aPAD for the general U.S. population and 5% of the aPAD for the most highly exposed population subgroup, children aged 1 to 2 years old.

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic dietary exposure to flubendiamide from food and water will utilize 20% of the cPAD for the general U.S. population and 58% of the cPAD for the most highly exposed population subgroup, children aged 1 to 2 years old. There are no proposed or existing residential uses for flubendiamide. Based on the explanation in Unit III.C.3., regarding residential use patterns, chronic residential exposure to residues of flubendiamide is not expected.

3. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of cancer in cancer bioassays in mice and rat, flubendiamide is not expected to pose a cancer risk.

4. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general U.S. population or to infants and children from aggregate exposure to flubendiamide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Liquid Chromatography with tandem Mass Spectrometry detection ((LC/MS/MS), Methods 00816/M002 and 00912) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Fort 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.

There are currently no established Codex, Canadian or Mexican MRLs for residues of flubendiamide in/on apple, wet pomace or fruit, pome, group 11 commodities.

C. Revisions to Petitioned-for Tolerances

The Agency's *''Guidance for Setting Pesticide Tolerances Based on Field Trial Data,''* was utilized for determining appropriate tolerance levels for many raw agricultural commodities (RACs) which showed quantifiable residues in or on samples that were treated according to the proposed use patterns. The following revisions to tolerance levels were made:

The recommended tolerance levels are the same values as in the petition. The Organization of Economic Coordination and Development (OECD) calculation procedure was utilized to derive the tolerance estimate for pome fruit based on all apple field trial data and all pear field trial data (D386262, S. Funk, 04/01/2011). The new apple pomace tolerance is derived from the highest average apple field trial result (1.21 ppm) and the processing factor for conversion of apples to apple pomace (3.6X) from a previously reviewed study. The proposed increases in tolerances for pome fruit and wet apple pomace have no effect on the dietary burdens of livestock. Therefore, the established tolerances for meat, milk, poultry, and eggs are adequate.

V. Conclusion

Therefore, the established tolerances for residues of flubendiamide, *N*^{2}-[1,1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-*N*^{1}-[2-methyl-4-[1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamidein or on apple, wet pomace is being increased to 5.0 ppm. The established tolerance for fruit, pome, group 11 is being increased to 1.5 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) (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: December 6, 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. Section 180.639 is amended as follows:

■ a. In paragraph (a)(1) revise the introductory text and the entries for ''apple, wet pomace,'' and ''fruit, pome, group 11.''

■ b. Revise the introductory text to paragraph (d).

The revised text reads as follows:

§ 180.639 Flubendiamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of flubendiamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only flubendiamide N^2-[1, 1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N^1-[2-methyl-4- [1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1,2-benzenedicarboxamide, in or on the following commodities:

Commodity	Parts per million
* * * * *	
Apple, wet pomace	5.0
* * * * *	
Fruit, pome, group 11	1.5

* * * * *

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of flubendiamide, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified in the table is to be determined by measuring only flubendiamide N2-[1, 1-dimethyl-2-(methylsulfonyl)ethyl]-3-iodo-N1-[2-methyl-4- [1,2,2,2-tetrafluoro-1-(trifluoromethyl)ethyl]phenyl]-1, 2-benzenedicarboxamide, in or on the following commodities:

* * * * *

[FR Doc. 2012–29979 Filed 12–11–12; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2011–0541; FRL–9360–3]

Fenpyroximate; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of the insecticide fenpyroximate in or on multiple commodities identified and discussed later in this document. In addition, this regulation removes established tolerances for certain commodities/groups superseded by this action. The Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 12, 2012. Objections and requests for hearings must be received on or before February 11, 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–2011–0541, is available either electronically through *http://www.regulations.gov* or in hard copy 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: Sidney Jackson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; telephone number: (703) 305–7610; email address: *jackson.sidney@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).

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/*