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: March 11, 2011.

Keith A. Matthews,

Director, Biopesticides and Pollution Prevention 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 180.1206, paragraph (c) is revised to read as follows:

§ 180.1206 *Aspergillus flavus* AF36; exemption from the requirement of a tolerance.

* * * * *

(c) An exemption from the requirement of a tolerance is established for residues of *Aspergillus flavus* AF36 in or on corn, field, forage; corn, field, grain; corn, field, stover; corn, field, aspirated grain fractions; corn, sweet, kernel plus cob with husk removed; corn, sweet, forage; corn, sweet, stover; corn, pop, grain; and corn, pop, stover, when applied/used as an antifungal agent.

[FR Doc. 2011–6545 Filed 3–22–11; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0099; FRL–8863–8]

Flubendiamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes, modifies and/or revokes 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-benzenedicarboxamide, in or on multiple food and livestock commodities which are identified, and will be 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 March 23, 2011. Objections and requests for hearings must be received on or before May 23, 2011, 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: EPA has established a docket for this action under docket identification (ID) number EPA–HQ–OPP–2007–0099. All documents in the docket are listed in the docket index available at *http://www.regulations.gov.* Although listed in the index, some information is not publicly available, *e.g.,* Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at *http://www.regulations.gov,* or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305–5805.

FOR FURTHER INFORMATION CONTACT: Carmen Rodia, Registration Division (7504P), 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; *e-mail 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. 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://www.gpoaccess.gov/ecfr.*

C. How can I file an objection or hearing request?

Under section 408(g) of FFDCA, 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 May 23, 2011. 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–2007–0099, by one of the following methods:

• *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

• *Mail:* Office of Pesticide Programs (OPP) Regulatory Public Docket (7502P), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001.

• *Delivery:* OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Rm. S–4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. Deliveries are only accepted during the Docket Facility's normal hours of operation (8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays). Special arrangements should be made for deliveries of boxed information. The Docket Facility telephone number is (703) 305–5805.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of June 8, 2010 (75 FR 32464 and 32465) (FRL–8827–5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0F7685) 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 40 CFR 180.639 be amended by establishing and/or amending 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-benzenedicarboxamide in or on artichoke, globe, flower head at 1.6 parts per million (ppm); hog, fat at 0.15 ppm; hog, kidney at 0.06 ppm; hog, liver at 0.06 ppm; hog, muscle at 0.02 ppm; low growing berry subgroup (crop sub-group 13–07G), except cranberry at 1.5 ppm; peanut, hay at 60 ppm; peanut, meal at 0.032 ppm; peanut, nutmeat at 0.02 ppm; peanut, refined oil at 0.04 ppm; pistachio at 0.06 ppm; safflower, seed at 4.5 ppm; small fruit vine climbing subgroup except fuzzy kiwifruit (crop sub-group 13–07F) at 1.4 ppm; sorghum, grain, forage at 13 ppm; sorghum, grain, grain at 5.0 ppm; sorghum, grain, stover at 18 ppm; sugarcane, cane at 0.30 ppm; sunflower, seed at 4.5 ppm; and turnip, greens at 25 ppm and by revising existing tolerances for residues of flubendiamide in or on alfalfa, forage from 0.15 ppm (rotational crop) to 25 ppm; alfalfa, hay from 0.04 ppm (rotational crop) to 65 ppm; brassica, head and stem subgroup 5A from 0.60 ppm to 4.0 ppm; brassica, leafy greens subgroup 5B from 5.0 ppm to 25 ppm; cattle, fat from 0.60 ppm to 0.8 ppm; cattle, kidney from 0.60 ppm to 0.4 ppm; cattle, liver from 0.60 ppm to 0.4 ppm; cattle, muscle from 0.07 ppm to 0.1 ppm; eggs from 0.03 ppm to 0.7 ppm; goat, fat from 0.60 ppm to 0.8 ppm; goat, kidney from 0.60 ppm to 0.4 ppm; goat, liver from 0.60 ppm to 0.4 ppm; goat, muscle from 0.07 ppm to 0.1 ppm; grain, aspirated fractions from 103 ppm to 215 ppm; horse, fat from 0.60 ppm to 0.8 ppm; horse, kidney from 0.60 ppm to 0.4 ppm; horse, liver from 0.60 ppm to 0.4 ppm; horse, muscle from 0.07 ppm to 0.1 ppm; milk, fat from 0.80 ppm to 1.0 ppm; poultry, fat from 0.15 ppm to 3.0 ppm; poultry, liver from 0.03 ppm to 0.8 ppm; poultry, muscle from 0.01 ppm to 0.1 ppm; sheep, fat from 0.60 ppm to 0.8 ppm; sheep, kidney from 0.60 ppm to 0.4 ppm; sheep, liver from 0.60 ppm to 0.4 ppm; and sheep, muscle from 0.07 ppm to 0.1 ppm. That notice 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 at *http://www.regulations.gov.* There were no substantive comments received in response to the notice of filing.

Based upon review of the data supporting the referenced petition, EPA has revised the numerical level for several of the petitioned-for tolerances for flubendiamide, and is also revoking several now superseded tolerances. 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 section 408(b)(2)(D) of FFDCA, and the factors specified in section 408(b)(2)(D) of FFDCA, 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. The first human health risk assessment for flubendiamide (April 3, 2008) was conducted for uses on corn, cotton, tobacco, tree fruit, tree nuts, vine crops, and vegetable crops. Since that time, no new toxicology data has been submitted to the Agency. The following summary represents all the salient features regarding hazard characterization and endpoint selection for flubendiamide.

Flubendiamide has a low acute toxicity via the oral, dermal and inhalation 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 (LOC) 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 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) (a = acute, c = chronic) 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 toxicological endpoints for flubendiamide used for human risk assessment is shown in Table 1 of this unit.

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

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).	NOAEL = 99.5 milligrams/kilograms/day (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.
Acute Dietary (General Population, including infants and children).	.		
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.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). FQPA SF = Food Quality Protection Act Safety Factor.

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 dietary (food and drinking water) exposure assessments were conducted using the Dietary Exposure Evaluation Model, Version 2.03—Food Commodity Intake Database (DEEM–FCID™) which uses food consumption information from the United States Department of Agriculture's (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). EPA assessed dietary exposures from flubendiamide in food for the proposed new uses 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 DEEM–FCID™ along with food consumption information from the USDA 1994–1996 and 1998 CSFII. 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 DEEM–FCID™ along with the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA assumed a subset of the currently registered crops contain 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 cancer dietary exposure assessment for the purpose of assessing cancer risk is unnecessary for flubendiamide, and was not conducted.

iv. *Anticipated residue 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/oppefed1/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. The Agency has completed a drinking water assessment for flubendiamide using screening level water exposure models that were based on the existing and proposed uses. For the 1-in-10-year peak, the highest Tier 2 Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) Estimated Drinking Water Concentrations (EDWC) for flubendiamide was 24.57 parts per billion (ppb), based on application to corn. For the 1-in-10-year annual average, the highest PRZM/EXAMS EDWC was 11.46 ppb, also based on application to corn.

A summary of the dietary exposure from drinking water for flubendiamide used for human risk assessment can be found in the documents entitled, "Flubendiamide: Human Health Risk Assessment for Proposed Uses on Alfalfa, Globe Artichokes, the Low Growing Berry Subgroup 13–07G (except Cranberry), Peanuts, Pistachios, the Small Fruit Vine Climbing (except Fuzzy Kiwifruit) Subgroup 13–07F, Safflower, Sorghum, Sugarcane, Sunflower, and Turnip Greens, and an Increased Application Rate for Brassica (Cole) Leafy Vegetables," dated November 30, 2010, 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 page 27 of 62.

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 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 pre-natal susceptibility, adverse eye effects (eye enlargement) were noted in post-natal 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 post-natal 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 balano-preputial 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 post-natal 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 1x. 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 acutely, developmentally and incorporated within the chronic rat study. 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. There are no treatment-related neurotoxic findings in the acute neurotoxicity and DNT studies in rats; although eye effects were observed in the DNT study. As noted in Unit III.B., the PODs employed in the risk assessment are protective of this effect.

iii. 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.

iv. 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 average residue levels found in the crop field trials/livestock commodities and both assume 100% of crops with requested uses of flubendiamide are treated. The drinking water assessment generated 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 aPAD and 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 data summarized and referenced in Unit III.A., flubendiamide has been classified as "Not Likely to be Carcinogenic to Humans," and 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; *e-mail 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 section 408(b)(4) of FFDCA.

The Codex Alimentarius is a joint U.N. 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, section 408(b)(4) of FFDCA requires that EPA explain the reasons for departing from the Codex level. There are currently no MRLs established by Codex, Canada, or Mexico for flubendiamide.

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:

Based upon review of the data supporting PP 0F7685, recalculated beef and dairy cattle, swine, and poultry dietary burdens, and re-evaluation of previously submitted animal feeding studies, EPA has determined that the established tolerances for residues of flubendiamide for milk fat, and the meat and fat of cattle, goat, horse and sheep should be increased to 1.0 ppm, 0.08 ppm and 0.70 ppm, respectively. For swine (hog), EPA has determined that the proposed tolerances for hog, fat at 0.15 ppm; hog, kidney at 0.06 ppm; hog, liver at 0.06 ppm; and hog, muscle at 0.02 ppm should be established as permanent tolerances for residues of flubendiamide in or on hog, fat at 0.15 ppm, and the proposed tolerances for hog, kidney; hog, liver; and hog, muscle should be increased and established as permanent tolerances for residues of flubendiamide in or on hog, meat and hog, meat byproducts; at 0.15 ppm and 0.03 ppm, respectively. For poultry, EPA has determined that the established tolerances for eggs, fat, liver and meat should be increased to 0.40 ppm, 3.0 ppm, 0.60 ppm and 0.10 ppm, respectively.

As part of this regulation, permanent tolerances for residues of flubendiamide in or on alfalfa, forage (25 ppm) and alfalfa, hay (65 ppm) resulting from direct application to the primary crop are being established. These tolerances supersede the currently listed tolerances for indirect or inadvertent residues of flubendiamide in or on alfalfa, forage (0.15 ppm) and alfalfa, hay (0.04 ppm), and; therefore, the indirect/inadvertent residue tolerances are being revoked from 40 CFR 180.639(d).

V. Conclusion

Therefore, new tolerances are being established 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-benzenedicarboxamide], in or on artichoke, globe at 1.6 parts per million (ppm); berry, low growing, subgroup 13–07G, except cranberry at 1.5 ppm; fruit, small vine climbing except fuzzy kiwifruit, subgroup 13–07F at 1.4 ppm; hog, fat at 0.15 ppm; hog, meat byproducts at 0.15 ppm; hog, meat at 0.03 ppm; peanut, hay at 60 ppm; peanut, meal at 0.03 ppm; peanut, nutmeat at 0.02 ppm; peanut, refined oil at 0.03 ppm; pistachio at 0.06 ppm; safflower, seed at 5.0 ppm; sorghum, grain, forage at 12 ppm; sorghum, grain, grain at 5.0 ppm; sorghum, grain, stover at 14 ppm; sugarcane, cane at 0.30 ppm; sunflower, seed at 5.0 ppm; and turnip, greens at 25 ppm.

The established tolerances for residues of flubendiamide for milk fat, and the meat and fat of cattle, goat, horse and sheep are being increased to 1.0 ppm, 0.08 ppm and 0.70 ppm, respectively. For poultry, the established tolerances for eggs, fat, liver and meat are being increased to 0.40 ppm, 3.0 ppm, 0.60 ppm and 0.10 ppm, respectively.

The established tolerances for residues of flubendiamide for brassica, head and stem, subgroup 5A; brassica, leafy greens, subgroup 5B; and grain, aspirated grain fractions are being increased to 3.0 ppm, 25 ppm, and 153 ppm, respectively.

The established tolerances for indirect or inadvertent residues of flubendiamide in or on alfalfa, forage (0.15 ppm) and alfalfa, hay (0.04 ppm) are being revoked from 40 CFR 180.639(d), and established as permanent tolerances, in 40 CFR 180.639(a)(2), for residues of flubendiamide in or on alfalfa, forage at 25 ppm; and alfalfa, hay at 65 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes tolerances under section 408(d) of FFDCA 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 section 408(d) of FFDCA, 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 section 408(n)(4) of FFDCA. 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: March 15, 2011.

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 revised to read as follows:

§ 180.639 Flubendiamide; tolerances for residues.

(a) *General.* (1) Tolerances are established for residues of the insecticide flubendiamide *per se* 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
Almond, hulls	9.0
Apple, wet pomace	2.0
Corn, field, forage	8.0
Corn, field, grain	0.03
Corn, field, stover	15
Corn, pop, grain	0.02
Corn, pop, stover	15
Corn, sweet, forage	9.0
Corn, sweet, kernel plus cob with husks removed	0.01
Corn, sweet, stover	25
Cotton gin byproducts	60
Cotton, undelinted seed	0.90
Fruit, pome, group 11	0.70
Fruit, stone, group 12	1.6
Grape	1.4
Nut, tree, group 14	0.06
Okra	0.30
Vegetable, cucurbit, group 9	0.20
Vegetable, fruiting, group 8	0.60
Vegetable, leafy, except *Brassica,* group 4	11

(2) 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
Alfalfa, forage	25
Alfalfa, hay	65
Artichoke, globe	1.6
Berry, low growing, subgroup 13–07G, except cranberry	1.5
Brassica, head and stem, subgroup 5A	3.0
Brassica, leafy greens, subgroup 5B	25
Cattle, fat	0.70
Cattle, meat	0.60
Cattle, meat byproducts	0.08
Egg	0.40
Fruit, small fruit vine climbing except fuzzy kiwifruit, subgroup 13–07F	1.4
Goat, fat	0.70
Goat, meat	0.60
Goat, meat byproducts	0.08
Grain, aspirated grain fractions	153
Hog, fat	0.15
Hog, meat	0.15
Hog, meat byproducts	0.03
Horse, fat	0.70
Horse, meat	0.60
Horse, meat byproducts	0.08
Milk	0.15
Milk, fat	1.0
Pea and bean, dried shelled, except soybean, subgroup 6C	0.60
Pea and bean, succulent shelled, subgroup 6B	0.05
Peanut, hay	60
Peanut, meal	0.03
Peanut, nutmeat	0.02
Peanut, refined oil	0.03
Pistachio	0.06
Poultry, fat	3.0
Poultry, liver	0.60
Poultry, meat	0.10
Rice, grain [1]	0.50
Safflower, seed	5.0
Sheep, fat	0.70
Sheep, meat	0.60
Sheep, meat byproducts	0.08
Sorghum, grain, forage	12
Sorghum, grain, grain	5.0
Sorghum, grain, stover	14
Soybean, forage	18
Soybean, hay	60
Soybean, hulls	0.80
Soybean, seed	0.25
Sugarcane, cane	0.30
Sunflower, seed	5.0
Turnip, greens	25
Vegetable, foliage of legume, except soybean, subgroup 7A	35
Vegetable, legume, edible podded, subgroup 6A	0.50

[1] There are no U.S. registrations for rice, grain.

(b) *Section 18 emergency exemptions.* [Reserved]

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

(d) *Indirect or inadvertent residues.* Tolerances are established for residues of the insecticide flubendiamide *per se* 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 raw agricultural commodities when present therein as a result of the application of flubendiamide to the growing crops listed in paragraph (a)(1) of this section:

Commodity	Parts per million
Barley, hay	0.04
Barley, straw	0.07
Buckwheat	0.07
Clover, forage	0.15
Clover, hay	0.04
Grass, forage	0.15
Grass, hay	0.04
Millet, pearl, forage	0.15
Millet, pearl, hay	0.04
Millet, proso, forage	0.15
Millet, proso, hay	0.04
Millet, proso, straw	0.07
Oats, forage	0.15
Oats, hay	0.04
Oats, straw	0.07
Rye, forage	0.15
Rye, straw	0.07
Teosinte, forage	0.15
Teosinte, hay	0.04
Teosinte, straw	0.07
Triticale, forage	0.15
Triticale, hay	0.04
Triticale, straw	0.07
Wheat, forage	0.15
Wheat, hay	0.03
Wheat, straw	0.03

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