Department that it is funding an OTRB or Other Than Urbanized grant by transmitting to the Department an information copy of each grant application upon approval of the grant.

(i) Each grant of assistance for an Other Than Urbanized program will contain a labor section identifying labor organizations representing transit employees of each subrecipient, the labor organizations representing employees of other transit providers in the service area, and a list of those transit providers. A sample format is posted on the OLMS *Web site* to facilitate the inclusion of this information in the grant application.

(ii) OTRB grants of assistance will contain a labor section identifying labor organizations representing employees of the recipient.

(2) The Department will notify labor organizations representing potentially affected transit employees of the approval of Other Than Urbanized and OTRB grants and inform them of their rights under the Special Warranty Arrangement.

§ 215.8 [Amended]

■ 8. Section 215.8 is amended as follows:

■ a. Remove ''Director,'' and add in its place ''Chief, Division of'';

■ b. Remove ''Suite N5603,''; and

■ c. Add the phrase ''or e-mailed to *OLMS-TransitGrant@dol.gov''* at the end of the paragraph.

Signed at Washington, DC, this 4th day of August, 2008.

Victoria A. Lipnic,

Assistant Secretary for Employment Standards.

Donald Todd,

Deputy Assistant Secretary, Office of Labor-Management Standards.

[FR Doc. E8–18497 Filed 8–12–08; 8:45 am]

BILLING CODE 4510–CP–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0099; FRL–8360–2]

Flubendiamide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances 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 certain food and raw agricultural commodities. Bayer CropScience, LP in c/o Nichino America, Inc. (U.S. subsidiary of Nihon Nohyaku Co., Ltd.) requested these tolerances under the Federal Food, Drug and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2008. Objections and requests for hearings must be received on or before October 14, 2008, 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. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 Room S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202–4501. 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 (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460–0001; telephone number: (703) 306–0327; 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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gpo/opptsfrs/home/guidelin.htm*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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 requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 14, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, 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 Avenue, NW., Washington, DC 20460–0001.

• *Delivery*: OPP Regulatory Public Docket (7502P), Environmental Protection Agency, Room S–4400, One Potomac Yard (South Building), 2777 S. Crystal Drive, Arlington, VA 22202–4501. Deliveries are only accepted during the Docket'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. Petition for Tolerance

In the **Federal Register** of February 28, 2007 (72 FR 9000) (FRL–8115–2), 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 6F7065) 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 part 180 be amended by establishing permanent tolerances in primary crops for residues of the insecticide 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 raw agricultural and processed commodities: Almond, hulls at 9.0 parts per million (ppm); *brassica*, head and stem subgroup at 0.60 ppm; *brassica*, leafy greens subgroup at 6.0 ppm; corn, field, forage at 8.0 ppm; corn, corn, field, grain at 0.02 ppm; field, stover at 15.0 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 15.0 ppm; corn, sweet, forage at 9.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.02 ppm; corn, sweet, stover at 25.0 ppm; cottonseed at 2.0 ppm; cotton, gin byproduct at 60.0 ppm; fruit, pome group at 0.7 ppm; fruit, stone group at 1.6 ppm; grape at 1.4 ppm; nut, tree group at 0.06 ppm; okra at 0.30 ppm; vegetable, cucurbit group at 0.20 ppm; vegetable, fruiting group at 0.30 ppm and vegetable, leafy, except *brassica* at 11.0 ppm; in or on the following rotational crop commodities: Alfalfa, forage at 0.15 ppm; alfalfa, hay at 0.04 ppm; barley, hay at 0.04 ppm; barley, straw at 0.07 ppm; buckwheat at 0.07 ppm; clover, forage at 0.15 ppm; clover, hay at 0.04 ppm; grass, forage at 0.15 ppm; grass, hay at 0.04 ppm; grass, silage at 0.27 ppm; millet, pearl, forage at 0.15 ppm; millet, pearl hay at 0.04 ppm; millet, proso, forage at 0.15 ppm; millet, proso, hay at 0.04 ppm; millet, proso, straw at 0.07 ppm; oats, forage at 0.15 ppm; oats, hay at 0.04 ppm; oats, straw at 0.07 ppm; rye, forage at 0.15 ppm; rye, straw at 0.07 ppm; sorghum, grain, forage at 0.03 ppm; sorghum, grain, stover at 0.06 ppm; soybean, forage at 0.02 ppm; soybean, hay at 0.04 ppm; teosinte, forage at 0.15 ppm; teosinte, hay at 0.04 ppm; teosinte, straw at 0.07 ppm; triticale, forage at 0.15 ppm; triticale, hay at 0.04 ppm; triticale, straw at 0.07 ppm; wheat, forage at 0.15 ppm; wheat, hay at 0.03 ppm and wheat, straw at 0.03 ppm; and in the following livestock commodities: Cattle, fat at 0.80 ppm; cattle, kidney at 0.60 ppm; cattle, liver at 0.60 ppm; cattle, muscle at 0.10 ppm; eggs at 0.03 ppm; goat, fat at 0.80 ppm; goat, kidney at 0.60 ppm; goat, liver at 0.60 ppm; goat, muscle at 0.10 ppm; hog, fat at 0.80 ppm; hog, kidney at 0.60 ppm; hog, liver at 0.60 ppm; hog, muscle at 0.10 ppm; horse, fat at 0.80 ppm; horse, kidney at 0.60 ppm; horse, liver at 0.60 ppm; horse, muscle at 0.10 ppm; milk at 0.20 ppm; poultry, fat at 0.08 ppm; poultry, liver at 0.03 ppm; poultry, muscle at 0.01 ppm; sheep, fat at 0.80 ppm; sheep, kidney at 0.60 ppm; sheep, liver at 0.60 ppm; and sheep, muscle at 0.10 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 to the public 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 this petition and EPA policy, the Agency has revised commodity definitions and/or some of the proposed tolerances and concludes that the establishment of the following tolerance is appropriate for the insecticide flubendiamide *per se* in or on the following food commodities: Almond, hulls at 9.0 ppm; apple, wet pomace at 2.0 ppm; *brassica*, head and stem, subgroup 5A at 0.60 ppm; *brassica*, leafy greens, subgroup 5B at 5.0 ppm; cattle, fat at 0.30 ppm; cattle, kidney at 0.30 ppm; cattle, liver at 0.30 ppm; cattle, muscle at 0.05 ppm; corn, field, forage at 8.0 ppm; corn, field, grain at 0.02 ppm; corn, field, stover at 15 ppm; corn, pop, grain at 0.02 ppm; corn, pop, stover at 15 ppm; corn, sweet, forage at 9.0 ppm; corn, sweet, kernel plus cob with husks removed at 0.01 ppm; corn, sweet, stover at 25 ppm; cotton gin byproducts at 60 ppm; cotton, undelinted seed at 0.90 ppm; egg at 0.01 ppm; fruit, pome, group 11 at 0.70 ppm; fruit, stone, group 12 at 1.6 ppm; goat, fat at 0.30 ppm; goat, kidney at 0.30 ppm; goat, liver at 0.30 ppm; goat, muscle at 0.05 ppm; grain, aspirated fractions at 5.0 ppm; grape at 1.4 ppm; horse, fat at 0.30 ppm; horse, kidney at 0.30 ppm; horse, liver at 0.30 ppm; horse, muscle at 0.05 ppm; milk at 0.04 ppm; milk, fat at 0.30 ppm; nut, tree, group 14 at 0.06 ppm; okra at 0.30 ppm; poultry, fat at 0.02 ppm; poultry, liver at 0.01 ppm; poultry, muscle at 0.01 ppm; sheep, fat at 0.30 ppm; sheep, kidney at 0.30 ppm; sheep, liver at 0.30 ppm; sheep, muscle at 0.05 ppm; vegetable, cucurbit, group 9 at 0.20 ppm; vegetable, fruiting, group 8 at 0.60 ppm and vegetable, leafy, except *brassica*, group 4 at 11 ppm; and in or on the following raw agricultural commodities: Alfalfa, forage at 0.15 ppm; alfalfa, hay at 0.04 ppm; barley, hay at 0.04 ppm; barley, straw at 0.07 ppm; buckwheat at 0.07 ppm; clover, forage at 0.15 ppm; clover, hay at 0.04 ppm; grass, forage at 0.15 ppm; grass, hay at 0.04 ppm; millet, pearl, forage at 0.15 ppm; millet, pearl, hay at 0.04 ppm; millet, proso, forage at 0.15 ppm; millet, proso, hay at 0.04 ppm; millet, proso, straw at 0.07 ppm; oats, forage at 0.15 ppm; oats, hay at 0.04 ppm; oats, straw at 0.07 ppm; rye, forage at 0.15 ppm; rye, straw at 0.07 ppm; sorghum, grain, forage at 0.03 ppm; sorghum, grain, stover at 0.06 ppm; soybean, forage at 0.02 ppm; soybean, hay at 0.04 ppm; teosinte, forage at 0.15 ppm; teosinte, hay at 0.04 ppm; teosinte, straw at 0.07 ppm; triticale, forage at 0.15 ppm; triticale, hay at 0.04 ppm; triticale, straw at 0.07 ppm; wheat, forage at 0.15 ppm; wheat, hay at 0.03 ppm and wheat, straw at 0.03 ppm.

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 submitted in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for the petitioned-for tolerances for residues of the insecticide flubendiamide. EPA's assessment of exposures and risks associated with establishing tolerances 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 low acute toxicity via the oral and dermal routes, is only a slight eye irritant, is non-irritating to the dermis and tests negative for skin sensitization. In the longer-term studies in the flubendiamide mammalian toxicology database, the primary target organs identified were the liver, thyroid, kidney and eyes. Liver effects reported in rats, mice and/or dogs include organ weight increase, periportal fatty change, hypertrophy and minimal foci of cellular alteration. Thyroid effects include organ weight increase, follicular cell hypertrophy and slight perturbations of triiodothyronine (TC) and thyroid stimulating hormone (TSH) in the rat and mouse. Kidney effects include increases in absolute and/or relative to body kidney weights and chronic nephropathy in the rat. Eye effects include eye enlargement, opacity and exophthalmus with hemorrhage and appear only in rat pups. Other changes include mild microcytic anemia, decreased serum triglycerides and cholesterol in female rat, increased gamma glutamyl peptidase, alkaline phosphatase and shortened activated prothrombin time in dogs, and adrenal weight increase and an increase in adrenal cortical cell hypertrophy in dogs.

The hazard assessment indicated potential toxicity resulting from exposure to flubendiamide via different routes over different durations. The observed eye effects were selected as a critical effect for the acute dietary exposure scenario; whereas liver and thyroid effects were determined critical for the chronic dietary exposure scenario. Short-term and intermediate-term dermal risks were also based on liver and thyroid effects as well as blood effects. Short-term and intermediate-term inhalation risks are based on liver toxicity as well as adrenal weight increase and an increase in adrenal cortical cell hypertrophy.

There was no evidence of carcinogenicity in rats and mice up to the limit dose at 24– and 18–months, respectively. Flubendiamide was determined to be non-mutagenic in bacteria, negative in an *in vivo* mammalian cytogenetics assay and did not cause unscheduled DNA synthesis (repair of DNA damage) in mammalian cells *in vitro*. Overall, there was no clear evidence that flubendiamide was either mutagenic or clastogenic in either *in vivo* or *in vitro* assays. The cancer classification is ''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 no-observed-adverse-effect-level (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**, and is identified as EPA–HQ–OPP–2007–0099–0005 in that docket. 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 Endpoints

For hazards that have a threshold below which there is no appreciable risk, a toxicological point of departure (POD) is identified as the basis for derivation of reference values for risk assessment. The POD may be defined as the highest dose at which no adverse effects are observed (the NOAEL) in the toxicology study identified as appropriate for use in risk assessment. However, if a NOAEL cannot be determined, the lowest dose at which adverse effects of concern are identified (the LOAEL) or a Benchmark Dose (BMD) approach is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the POD to take into account uncertainties inherent in the extrapolation from laboratory animal data to humans and in the variations in sensitivity among members of the human population as well as other unknowns. Safety is assessed for acute and chronic dietary risks by comparing aggregate food and water exposure to the pesticide to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). The aPAD and cPAD are calculated by dividing the POD by all applicable UFs. Aggregate short-term, intermediate-term and chronic-term risks are evaluated by comparing food, water and residential exposure to the POD to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded. This latter value is referred to as the Level of Concern (LOC).

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 greater than that 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, refer to *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

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**, and is identified as EPA–HQ–OPP–2007–0099–0005 in that docket. 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 and assessed dietary exposures from flubendiamide 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. In estimating acute dietary exposure, EPA used food consumption information from the Dietary Exposure Evaluation Model-Food Commodity Intake Database (DEEM-FCID™, Version 2.03), which incorporates food consumption data from the U.S. Department of Agriculture's (USDA's) Nationwide Continuing Surveys of Food Intakes by Individuals (CSFII) from 1994–1996 and 1998. The acute assessments assumed that 100% of crops with requested uses of flubendiamide are treated and that all treated crops contain residues at tolerance-level. In addition, tolerance-level residues for livestock commodities were included in these analyses to account for the potential transfer of plant residues to livestock tissues.

ii. *Chronic exposure*. In conducting the chronic dietary exposure assessment, EPA used DEEM-FCID™, Version 2.03, which incorporates food consumption data from the USDA's CSFII from 1994–1996 and 1998. The chronic assessments assumed that 100% of crops with requested uses of flubendiamide are treated and that all treated crops contain residues at the average residue levels found in the crop field trials and experimentally-determined processing factors where available. In addition, average-level residues for livestock commodities were also included in these analyses to account for the potential transfer of plant residues to livestock tissues.

iii. *Cancer*. As explained in Unit III.A., flubendiamide is considered to be ''Not Likely to be Carcinogenic to Humans.'' As a result, cancer exposure assessment is not needed for flubendiamide.

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 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.

Flubendiamide is persistent and potentially mobile in terrestrial and aquatic environments. These fate properties suggest that it has a potential to move into surface and ground water. The Agency lacks sufficient monitoring exposure data for use in risk assessments, as flubendiamide is a new active ingredient. Because the Agency does not have comprehensive monitoring data, drinking water concentration estimates are made by reliance on simulation or modeling, taking into account data on the physical and fate 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*.

Based on the Pesticide Root Zone Model/Exposure Analysis Modeling System (PRZM/EXAMS) and the Screening Concentration in Ground Water (SCI-GROW) model, the estimated drinking water concerns (EDWCs) of flubendiamide for acute exposures are estimated to be 12.93 parts per billion (ppb) for surface water and 0.06 ppb for ground water. For chronic exposures for non-cancer assessments, the EDWCs are estimated to be 11.95 ppb for surface water and 0.06 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 12.93 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 11.95 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). Flubendiamide is not registered for any specific use patterns that would result in residential exposure. That is, no residential uses are being requested for flubendiamide at this time; therefore, no residential risk assessment has been conducted.

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 website 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 ten-fold (10x) margin of safety for infants and children in the case of threshold effects to account for pre-natal and/or post-natal toxicity, and the completeness of the database on toxicity and exposure, unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10x or uses a different additional SF when reliable data available to EPA support the choice of a different factor.

2. *Pre-natal and post-natal 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) and the developmental neurotoxicity (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 5–20, neonatal rats appear to have an increased susceptibility to flubendiamide exposure as compared to adults. The DNT study also reported that pre-mating exposures are not required to elicit the eye effect in pups. 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 these effects are considered adverse, they are not assumed to be developmental effects from *in utero* exposure. Even though the delay in balanopreputial separation may be a result of post-natal exposure (sensitivity of the young), and the effect is adverse, it is considered reversible and not an indication of perinatal sensitivity/susceptibility.

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 concern for increased susceptibility of the human neonate as compared to adults, 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 for purposes of this risk assessment and the characterization of potential pre-natal and/or post-natal risks to infants and children. 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.

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 the previous paragraph, the PODs employed in the risk assessment are protective of this effect.

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 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 pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. The aPAD and cPAD represent the highest safe exposures, taking into account all appropriate SFs. EPA calculates the aPAD and cPAD by dividing the POD by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given the estimated aggregate exposure. Short-term, intermediate-term and chronic-term risks are evaluated by comparing the estimated aggregate food, water and residential exposure to the POD to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

For flubendiamide, there is potential exposure from food and drinking water, but not from residential use sites (as there are no proposed residential uses for flubendiamide). Since hazard was identified via the oral route over both the acute and chronic duration, the aggregate risk assessment 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, the acute dietary exposure from food and water to flubendiamide will occupy less than 8% of the aPAD for the mostly highly exposed population subgroup, children aged 1–2 years old.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to flubendiamide from food and water will utilize less than 15% of the cPAD for the mostly highly exposed population subgroup, children aged 1–2 years old. There are no residential uses for flubendiamide.

3. *Aggregate cancer risk for U.S. population*. 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 population or to infants and children from aggregate exposure to flubendiamide residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (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

There are currently no established CODEX, Canadian or Mexican maximum residue limits (MRLs) for residues of flubendiamide in or on various crop or livestock commodities.

C. Revisions to Petitioned-For Tolerances

Based upon review of the data submitted in support of this tolerance petition for flubendiamide and EPA policy, the Agency has revised commodity definitions and/or some of the proposed tolerances. No residue data were submitted to support the proposed uses on okra and popcorn. The available field trial data for fruiting vegetables may be translated to okra, and the submitted data for field corn may also be translated to popcorn. The proposed uses on all types of corn (field, pop and sweet) are identical.

Parent residue levels vary based on crop (for edible commodities, residues ranging from 0.018 ppm, corn, field, grain to 6.7 ppm, spinach). Most crops indicated parent residues declined with successive sampling dates and were determined to be available on the surface of plants/RACs. The Agency will allow translation of residue data from trials conducted on rotated barley, sorghum and wheat to support the proposed rotational crop tolerances for the forages, hay and straw of other types of cereal grains and grasses. The Agency

will also allow translation of residue data from trials conducted on rotated soybean to support the proposed rotational crop tolerances for the forages, fodder, hay and straw on alfalfa and clover to support the rotational plant-back intervals. Based on the transfer coefficients for livestock tissues and the relatively low dietary burden for swine of 0.02 ppm for flubendiamide, tolerances for hogs are not needed.

V. Conclusion

Therefore, tolerances are established forresidues 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.

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 rule has been exempted from review under Executive Order 12866, this rule is not subject to Executive Order 13211, *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 tolerances 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 rule. In addition, this 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) (Public Law 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: August 1, 2008.

Debra Edwards,

Director, 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 added to read as follows:

§ 180.639 Flubendiamide; tolerances for residues.

(a) *General.* 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 food commodities:

Commodity	Parts per million
Almond, hulls	9.0 ppm
Apple, wet pomace	2.0 ppm
Brassica, head and stem, subgroup 5A	0.60 ppm
Brassica, leafy greens, subgroup 5B	5.0 ppm
Cattle, fat	0.30 ppm
Cattle, kidney	0.30 ppm
Cattle, liver	0.30 ppm
Cattle, muscle	0.05 ppm
Corn, field, forage	8.0 ppm
Corn, field, grain	0.02 ppm
Corn, field, stover	15 ppm
Corn, pop, grain	0.02 ppm
Corn, pop, stover	15 ppm
Corn, sweet, forage	9.0 ppm
Corn, sweet, kernel plus cob with husks removed	0.01 ppm
Corn, sweet, stover	25 ppm
Cotton, gin byproducts	60 ppm
Cotton, undelinted seed	0.90 ppm
Egg	0.01 ppm
Fruit, pome, group 11	0.70 ppm
Fruit, stone, group 12	1.6 ppm
Goat, fat	0.30 ppm
Goat, kidney	0.30 ppm
Goat, liver	0.30 ppm
Goat, muscle	0.05 ppm
Grain, aspirated fractions	5.0 ppm
Grape	1.4 ppm
Horse, fat	0.30 ppm
Horse, kidney	0.30 ppm
Horse, liver	0.30 ppm
Horse, muscle	0.05 ppm
Milk	0.04 ppm
Milk, fat	0.30 ppm
Nut, tree, group 14	0.06 ppm
Okra	0.30 ppm
Poultry, fat	0.02 ppm
Poultry, liver	0.01 ppm
Poultry, muscle	0.01 ppm
Sheep, fat	0.30 ppm
Sheep, kidney	0.30 ppm
Sheep, liver	0.30 ppm
Sheep, muscle	0.05 ppm
Vegetable, cucurbit, group 9	0.20 ppm
Vegetable, fruiting, group 8	0.60 ppm
Vegetable, leafy, except Brassica, group 4	11 ppm

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

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

(d) *Indirect or inadvertent residues.* Tolerances are established for the indirect or inadvertent 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 *per se* to the growing crops listed in paragraph (a) of this section:

Commodity	Parts per million
Alfalfa, forage	0.15 ppm
Alfalfa, hay	0.04 ppm
Barley, hay	0.04 ppm
Barley, straw	0.07 ppm
Buckwheat	0.07 ppm
Clover, forage	0.15 ppm
Clover, hay	0.04 ppm
Grass, forage	0.15 ppm
Grass, hay	0.04 ppm
Millet, pearl, forage	0.15 ppm
Millet, pearl, hay	0.04 ppm
Millet, proso, forage	0.15 ppm
Millet, proso, hay	0.04 ppm
Millet, proso, straw	0.07 ppm
Oats, forage	0.15 ppm
Oats, hay	0.04 ppm
Oats, straw	0.07 ppm
Rye, forage	0.15 ppm
Rye, straw	0.07 ppm
Sorghum, grain, forage	0.03 ppm
Sorghum, grain, stover	0.06 ppm
Soybean, forage	0.02 ppm
Soybean, hay	0.04 ppm
Teosinte, forage	0.15 ppm
Teosinte, hay	0.04 ppm
Teosinte, straw	0.07 ppm
Triticale, forage	0.15 ppm
Triticale, hay	0.04 ppm
Triticale, straw	0.07 ppm
Wheat, forage	0.15 ppm
Wheat, hay	0.03 ppm
Wheat, straw	0.03 ppm

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0565; FRL–8374–5]

Tribenuron Methyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of tribenuron methyl in or on barley, hay; oat, forage; oat, hay; wheat, forage; and wheat, hay. E. I. DuPont de Nemours and Company requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 13, 2008. Objections and requests for hearings must be received on or before October 14, 2008, 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–2007–0565. To access the electronic docket, go to *http://www.regulations.gov*, select ''Advanced Search,'' then ''Docket Search.'' Insert the docket ID number where indicated and select the ''Submit'' button. Follow the instructions on the regulations.gov website to view the docket index or access available documents. All documents in the docket are listed in the docket index available in 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 either 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: Vickie Walters, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–5704; e-mail address: *walters.vickie@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 Access Electronic Copies of this Document?

In addition to accessing an electronic copy of this **Federal Register** document through the electronic docket at *http://www.regulations.gov*, you may access this **Federal Register** document electronically through the EPA Internet under the ''**Federal Register**'' listings at *http://www.epa.gov/fedrgstr*. You may also access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's pilot e-CFR site at *http://www.gpoaccess.gov/ecfr*.

C. Can I File an Objection or Hearing Request?

Under section 408(g) of FFDCA, 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–2007–0565 in the subject line on the first page of your submission. All requests must be in writing, and must be mailed or delivered to the Hearing Clerk as required by 40 CFR part 178 on or before October 14, 2008.

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 that is described in **ADDRESSES**. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit this copy, identified by docket ID number EPA–HQ–OPP–2007–0565, by one of the following methods:

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