2008); 2271, "Variances" (operative August 29, 2008); 2273, "Labeling of Equipment Dispensing Gasoline Containing MTBE" (operative August 29, 2008).

(*2*) "California Procedures for Evaluating Alternative Specifications for Phase 3 Reformulated Gasoline Using the California Predictive Model," as last amended August 7, 2008.

(*3*) "Procedures for Using the California Model for California Reformulated Gasoline Blendstocks for Oxygenate Blending (CARBOB)," as last amended August 7, 2008.

(ii) Additional material.

(A) California Air Resources Board.

(*1*) Executive Order S–09–001, dated February 3, 2009, adopting the 2009 RFG Revision.

(376) The following revisions to the California Diesel Fuel Regulations were submitted on February 3, 2009 (2009 Diesel Fuels Revision), by the Governor's Designee.

(i) *Incorporation by reference.*

(A) California Air Resources Board.

(*1*) Title 13, California Code of Regulations, Division 3 (Air Resources Board), Chapter 1 (Motor Vehicle Pollution Control Devices), Article 1 (General Provisions), sections 1956.8, "Exhaust Emissions Standards and Test Procedures—1985 and Subsequent Model Heavy-Duty Engines and Vehicles" (operative December 31, 2008); 1960.1, "Exhaust Emissions Standards and Test Procedures—1981 through 2006 Model Passenger Cars, Light-Duty and Medium-Duty Vehicles" (operative March 26, 2004); 1961, "Exhaust Emissions Standards and Test Procedures—2004 and Subsequent Model Passenger Cars, Light-Duty and Medium-Duty Vehicles" (operative June 16, 2008); Chapter 5 (Standards for Motor Vehicle Fuels), Article 2 (Standards for Diesel Fuel), sections 2281, "Sulfur Content of Diesel Fuel" (operative August 4, 2005); 2282, "Aromatic Hydrocarbon Content of Diesel Fuel" (operative August 4, 2005); 2284, "Lubricity of Diesel Fuel" (operative August 4, 2005); 2285, "Exemption from Diesel Fuel Requirements for Military-Specification Fuels Used in Qualifying Military Vehicles" (operative August 14, 2004); Chapter 14 (Verification Procedure, Warranty and In-Use Compliance Requirements for In-Use Strategies to Control Emissions from Diesel Engines), section 2701, "Definitions" (operative January 1, 2005).

(*2*) Title 17, California Code of Regulations, Division 3 (Air Resources), Chapter 1 (Air Resources Board), Subchapter 7.5 (Airborne Toxic Control Measures), section 93114, "Airborne Toxic Control Measure To Reduce Particulate Emissions from Diesel-Fueled Engines—Standards for Nonvehicular Diesel Fuel" (operative August 14, 2004).

(ii) Additional material.

(A) California Air Resources Board.

(*1*) Executive Order S–09–001, dated February 3, 2009, adopting the 2009 Diesel Fuels Revision.

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[FR Doc. 2010–11005 Filed 5–11–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0032; FRL–8824–5]

Fluazinam; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazinam in or on bushberry subgroup 13-07B; onion, bulb, subgroup 3-07A; lettuce, head; and lettuce, leaf. This regulation additionally removes several established individual commodities and bushberry subgroup 13B, as they will be superseded by inclusion in bushberry subgroup 13-07B. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 12, 2010. Objections and requests for hearings must be received on or before July 12, 2010, 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–2009–0032. 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: Laura Nollen, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–7390; e-mail address: *nollen.laura@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 cite at *http://www.gpoaccess.gov/ecfr*. To access the harmonized test guidelines referenced in this document electronically, please go to *http://www.epa.gov/ocspp* and select "Test Methods and Guidelines."

C. 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–2009–0032 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 July 12, 2010. 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 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–2009–0032, 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. Petition for Tolerance

In the **Federal Register** of April 8, 2009 (74 FR 15971) (FRL–8407–4), 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 8E7506) by IR-4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR 180.574 be amended by establishing tolerances for residues of the fungicide fluazinam, (3-chloro- *N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl) phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on lettuce, head at 0.02 parts per million (ppm); lettuce, leaf at 2.0 ppm; onion, bulb, subgroup 3-07A at 0.15 ppm; and bushberry subgroup 13-07B at 4.5 ppm. The petition additionally requested to remove the established tolerances in or on aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, edible honeysuckle, jostaberry, Juneberry, lingonberry, native currant, salal, sea buckthorn, and bushberry subgroup 13B at 7.0 ppm. The published notice of the petition referenced a summary of the petition prepared on behalf of IR-4 by ISK Biosciences, the registrant, which is available in the docket, *http://www.regulations.gov*. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has revised the proposed tolerances for bushberry subgroup 13-07B and onion, bulb, subgroup 3-07A. EPA has also revised the tolerance expression for all established commodities to be consistent with current Agency policy. 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 fluazinam including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with fluazinam 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.

Following subchronic and chronic exposure to fluazinam, the liver appeared to be a primary target organ in rats, dogs, and mice. Signs of liver toxicity included changes in clinical chemistry (increased serum alkaline phosphatase and aspartate aminotransferase), increased absolute and/or relative liver weights, increased incidences of gross lesions (pale, enlarged, pitted, mottled, accentuated markings), and a variety of histopathological lesions. Treatment-related effects were also observed in other organs following subchronic and chronic exposure to fluazinam, but these effects were not consistently noted in all three species or in all studies in a given species.

In a developmental toxicity study in rats, fetal effects included decreases in body and placental weights, increased incidences of facial/palate clefts, diaphragmatic hernias, delayed ossification in several bone types, increases in late resorptions, as well as evidence of a greenish amniotic fluid and postimplantation loss. Maternal effects, including decreases in body weight gain/food consumption and increases in water consumption and urogenital staining, were observed at the same dose level. In the rat developmental neurotoxicity (DNT) study, effects in pups (including decreases in body weight/body weight gain and delayed preputial separation) were noted in the absence of maternal toxicity.

In an acute neurotoxicity study in rats, effects included decreases in motor activity and soft stools; these effects were considered to be due to systemic toxicity and not a result of frank neurotoxicity. No signs of neurotoxicity were observed in two subchronic neurotoxicity studies in rat up to the highest dose tested (HDT). A neurotoxic lesion described as vacuolation of the white matter of the central nervous system was observed in subchronic and chronic studies in mice and dogs; however, this lesion was found to be reversible and is attributed to an impurity (impurity 5). Based on the level of this impurity in technical grade fluazinam, the risk assessment for the

parent compound is considered protective of the effects noted.

In a rat carcinogenicity study, there was some evidence that fluazinam induced an increase in thyroid gland follicular cell tumors in male rats. In one mouse carcinogenicity study, clear evidence of a treatment-related increase of hepatocellular tumors was observed in male mice; in another mouse carcinogenicity study, there was equivocal evidence that fluazinam may have induced an increase in hepatocellular tumors in male mice. There was no evidence of statistically-significant tumor increases in female mice or rats in any study and no evidence of mutagenic activity in the submitted mutagenicity studies for fluazinam. EPA has classified fluazinam as having suggestive evidence of carcinogenicity.

Specific information on the studies received and the nature of the adverse effects caused by fluazinam as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at *http://www.regulations.gov* in document "Fluazinam. Human Health Risk Assessment for the Proposed Uses on Apples, Carrots, Lettuce, and the Bulb Onion Subgroup (3-07A), and a Request for a Reduced Tolerance on the Bushberry Subgroup (13-07B)," pp. 60–65 in docket ID number EPA–HQ–OPP–2009–0032.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level – generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) – and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see *http://www.epa.gov/pesticides/factsheets/riskassess.htm*.

A summary of the toxicological endpoints for fluazinam used for human risk assessment is shown in the table of this unit.

TABLE—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZINAM FOR USE IN HUMAN RISK ASSESSMENT

Exposure/Scenario	Point of Departure and Uncertainty/Safety Factors	RfD, PAD, LOC for Risk Assessment	Study and Toxicological Effects
Acute dietary (Females 13–49 years of age)	NOAEL = 7milligrams/kilogram/day (mg/kg/day) UF_A = 10x UF_H = 10x FQPA SF = 1x	Acute RfD = 0.07 mg/kg/day aPAD = 0.07 mg/kg/day	Developmental Toxicity Study-Rabbits LOAEL = 12 mg/kg/day based on increased incidence of total litter resorptions and possible increased incidence of fetal skeletal abnormalities.
Acute dietary (General population including infants and children)	NOAEL = 50 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF =1x	Acute RfD = 0.5 mg/kg/day aPAD = 0.5 mg/kg/day	Acute Neurotoxicity-Rats LOAEL = 1,000 mg/kg/day based on decreased motor activity and soft stools on day of dosing.
Chronic dietary (All populations)	NOAEL = 1.1 mg/kg/day UF_A = 10x UF_H = 10x FQPA SF = 1x	Chronic RfD = 0.011 mg/kg/day cPAD = 0.011 mg/kg/day	Carcinogenicity-Mice LOAEL = 10.7 mg/kg/day based on liver histopathology and increased liver weight.
Cancer (Oral, dermal, inhalation)	Classification: Suggestive Evidence of Carcinogenicity. The cRfD is protective of cancer effects.		

UF_A = extrapolation from animal to human (interspecies). UF_H = potential variation in sensitivity among members of the human population (intraspecies). UF_L = use of a LOAEL to extrapolate a NOAEL. UF_S = use of a short-term study for long-term risk assessment. UF_{DB} = to account for the absence of data or other data deficiency. FQPA SF = Food Quality Protection Act Safety Factor. PAD = population adjusted dose (a = acute, c = chronic). RfD = reference dose. MOE = margin of exposure. LOC = level of concern.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to fluazinam, EPA considered exposure under the petitioned-for tolerances as well as all existing fluazinam tolerances in 40 CFR 180.574. EPA assessed dietary exposures from fluazinam 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. Such effects were identified for fluazinam. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 1994–1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA utilized tolerance-level residues and assumed 100 percent crop treated (PCT) for all commodities.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data from the USDA 1994–1996 and 1998 CSFII. As to residue levels in food, EPA utilized tolerance-level residues for all commodities except apple (for which the average field trial residue value was used) and assumed 100 PCT for all commodities.

iii. *Cancer*. Fluazinam has been classified as having suggestive evidence of carcinogenicity. This determination is based on weight of evidence considerations where a concern for potential carcinogenic effects in humans is raised, but the animal data are judged not sufficient for a stronger conclusion.

Carcinogenicity studies were conducted in rats and mice. In rats, increased incidences of thyroid gland follicular cell tumors were seen in males but not in females. In mice, there were conflicting results with regard to hepatocarcinogenicity. In one study, benign and malignant liver tumors were seen in males; no liver tumors were seen in females. In the second study, carcinogenic response was equivocal and tumors did not occur in a dose-related manner. In males, the dose that induced liver tumors in the first study failed to induce liver tumors in the same strain of mice in the second study. In the second study, in females, liver tumors were seen only at an excessive toxic dose. There was no evidence of mutagenicity either in *in vivo* or *in vitro* assays. No chemicals structurally related to fluazinam were identified as carcinogens.

Since the evidence for carcinogenicity is not sufficient to indicate anything greater than a suggestion of a carcinogenic potential, EPA concludes that quantification of cancer risk would not be scientifically appropriate, as it attaches greater significance to the positive cancer findings than the entire dataset warrants. Further, due to the equivocal and inconsistent nature of the cancer response in the rat and mouse studies (in rats, effects seen only in males; in mice, one study showed effects only in males but even these effects were not reproducible), EPA finds that when judged qualitatively the data indicate no greater than a negligible risk of cancer. The Agency has determined that the POD (1.1 mg/kg/day) selected for deriving the cRfD is protective of all chronic effects, including the equivocal cancer effects; therefore, the chronic dietary exposure assessment was relied upon for assessing cancer risk.

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 section 408(f)(1) of FFDCA 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 section 408(b)(2)(E) of FFDCA and authorized under section 408(f)(1) of FFDCA. 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 residues of concern in drinking water for risk assessment are parent fluazinam and its degradates, including DCPA, CAPA, DAPA, and HYPA. The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for fluazinam and its degradates in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of fluazinam and its degradates. 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 First Index Reservoir Screening Tool (FIRST), and Screening Concentration in Ground Water (SCI-GROW) models, the estimated drinking water concentrations (EDWCs) of fluazinam and its degradates for surface water are estimated to be 117 parts per billion (ppb) for acute exposures and 19.8 ppb for chronic exposures. For ground water, the EDWCs are estimated to be 0.216 ppb for both acute and chronic exposures.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. The water concentration values of 117 ppb and 19.8 ppb were used to assess the contribution to drinking water in the acute and chronic dietary risk assessments, respectively.

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). Fluazinam 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 fluazinam to share a common mechanism of toxicity with any other substances, and fluazinam does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that fluazinam 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 tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity*. The prenatal and postnatal toxicology database for fluazinam includes rat and rabbit prenatal developmental toxicity studies, a 2–generation reproductive toxicity study in rats, and a DNT study in rats. There was no evidence of increased quantitative or qualitative susceptibility in the rabbit developmental toxicity study or the rat 2–generation reproductive toxicity study; however, evidence of increased qualitative susceptibility of fetuses was observed in the rat developmental toxicity study and evidence of increased quantitative susceptibility of fetuses was observed in the rat DNT study.

In the developmental toxicity study in rats, fetal effects (increased incidences of facial/palate clefts and other rare deformities in the fetuses) were observed in the presence of minimal maternal toxicity (decreased body weight gain and food consumption, and increased water consumption and urogenital staining). In the rat DNT study, decreases in body weight/body weight gain and a delay in completion of balano-preputial separation were observed in pups in the absence of maternal effects, suggesting increased quantitative susceptibility of the offspring.

3. *Conclusion*. EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1X. That decision is based on the following findings:

i. The toxicity database for fluazinam is complete, except for immunotoxicity testing. Recent changes to 40 CFR part 158 make immunotoxicity testing (Harmonized Guideline 870.7800) required for pesticide registration; however, the existing data are sufficient for endpoint selection for exposure/risk assessment scenarios, and for evaluation of the requirements under the FQPA. The available data for fluazinam show no evidence of treatment-related effects on the immune system, and the Agency does not believe that conducting an immunotoxicity study will result in a lower POD than that currently selected for overall risk assessment. Therefore, an additional database uncertainty factor to account for potential immunotoxicity does not need to be applied.

ii. A DNT study in rat is available and shows evidence of increased quantitative susceptibility of offspring. Although the NOAEL for this study (2 mg/kg/day) is lower than that used for the aRfD for females 13-49 (7 mg/kg/day), the effects noted in the DNT study are considered to be postnatal effects attributable to multiple doses; therefore, the study endpoint is not appropriate for acute dietary exposures. The cRfD (0.011 mg/kg/day) is based on a lower NOAEL (1.1 mg/kg/day), and is considered to be protective of potential developmental effects. Therefore, the degree of concern is low for the observed effects and there are no residual uncertainties with regard to prenatal and/or postnatal neurotoxicity.

iii. Although there is qualitative evidence of increased susceptibility following *in utero* exposure to fluazinam in the rat developmental toxicity study, the degree of concern for the observed effects is low. Fetal effects were observed only at the HDT and in the presence of maternal toxicity, and there is a clear NOAEL for the fetal effects seen. Additionally, the NOAEL (50 mg/kg/day) identified in the developmental toxicity study in rats is significantly higher than the NOAEL used (7 mg/kg/day) to establish the aRfD for females 13-49. Therefore, the aRfD is protective of any potential developmental effects and there are no residual uncertainties for prenatal and/or postnatal toxicity.

iv. There are no residual uncertainties identified in the exposure databases. The acute and chronic dietary food exposure assessments were performed based on 100 PCT for all commodities. Additionally, the acute assessment is based on tolerance level residues for all commodities, and the chronic assessment is based on tolerance level residues for all commodities except apple (for which the average field trial value was used). These assumptions result in high-end estimates of dietary exposure. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to fluazinam in drinking water. Fluazinam is not registered for any specific use patterns that would result in residential exposure. These assessments will not underestimate the exposure and risks posed by fluazinam.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk*. Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure from food and water to fluazinam will occupy 20% of the aPAD for females 13-49 years old and 20% of the aPAD for children 1-2 years old, the population group receiving the greatest exposure.

2. *Chronic risk*. Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to fluazinam from food and water will utilize 40% of the cPAD for all infants less than 1 year old, the population group receiving the greatest exposure. There are no residential uses for fluazinam.

3. *Short- and intermediate-term risk*. Short- and intermediate-term aggregate exposures takes into account short- and intermediate-term residential exposures plus chronic exposure to food and water (considered to be a background exposure level). Short- and intermediate-term adverse effects were identified; however, fluazinam is not registered for any use patterns that would result in short- or intermediate-term residential exposures. Short- and intermediate-term risk is assessed based on short- and intermediate-term residential exposures plus chronic dietary exposure. Because there are no short- or intermediate-term residential exposures and chronic dietary exposure has already been assessed under the appropriately protective cPAD (which is at least as protective as the POD used to assess short-term risk), no further assessment of short- or intermediate-term risk is necessary, and EPA relies on the chronic dietary risk assessment for evaluating short- and intermediate-term risk for fluazinam.

4. *Aggregate cancer risk for U.S. population*. Based on the discussion in Unit III.A., EPA has concluded that the cPAD is protective of possible cancer effects. Because chronic exposure is 20% of the cPAD for the most highly exposed population subgroups, cancer risk resulting from exposure to fluazinam is not of concern.

5. *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 fluazinam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

An adequate enforcement methodology, gas chromatography with electron capture detection (GC/ECD), is available to enforce the tolerance expression for crop matrices. A high performance liquid chromatography with ultraviolet detection (HPLC/UV) enforcement method is also available to enforce the tolerance expression for wine grapes, which includes residues of the metabolite AMGT. These methods may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. 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 FFDCA section 408(b)(4). 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, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

There are currently no Codex or Mexican MRLs established for residues of fluazinam in or on the commodities associated with this petition. However, Canada has an approved MRL for the use of fluazinam on bushberry subgroup 13B at 7.0 ppm, which is based on an earlier joint review effort between the Canadian Pesticide Management Regulatory Agency (PMRA) and EPA.

C. Revisions to Petitioned-For Tolerances

Based on analysis of the data supporting the petition, EPA has revised the proposed tolerance for onion, bulb, subgroup 3-07A from 0.15 ppm to 0.20 ppm. EPA revised this tolerance level based on analysis of the residue field trial data using the Agency's Tolerance Spreadsheet in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*. EPA has also revised the tolerance expression to clarify:

1. That, as provided in section 408(a)(3) of FFDCA, the tolerance covers metabolites and degradates of fluazinam not specifically mentioned; and

2. That compliance with the specified tolerance levels is to be determined by measuring only the specific compounds mentioned in the tolerance expression.

Additionally, the Agency has revised the proposed tolerance for bushberry subgroup 13-07B from 4.5 ppm to 7.0 ppm. Permanent tolerances exist for residues of fluazinam in or on bushberry subgroup 13B and several individual bushberry commodities (aronia berry, buffalo currant, Chilean guava, European barberry, highbush cranberry, edible honeysuckle, jostaberry, juneberry, lingonberry, native currant, salal, and sea buckthorn) at 7.0 ppm. IR-4 petitioned the Agency to establish a tolerance for the revised bushberry subgroup 13-07B at 4.5 ppm, which would supersede the tolerances for both bushberry subgroup 13B and the individual bushberry tolerances. After reevaluating the existing data in support of the bushberry subgroup 13-07B tolerance in accordance with the Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data*, EPA has determined that the probability plot for the residue data are lognormally distributed and that the bushberry subgroup 13-07B tolerance should be established at 7.0 ppm. The revised tolerance for bushberry subgroup 13-07B at 7.0 ppm is equivalent to the existing tolerances for the individual bushberry commodities and bushberry subgroup 13B. Further, the 7.0 ppm tolerance on bushberry harmonizes with a MRL established in Canada, as discussed in Unit IV.B.

V. Conclusion

Therefore, tolerances are established for residues of fluazinam, (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), in or on bushberry subgroup 13-07B at 7.0 ppm; lettuce, head at 0.02 ppm; lettuce, leaf at 2.0 ppm; and onion, bulb, subgroup 3-07A at 0.20 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) (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: May 4, 2010.

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 180.574 is amended as follows:

■

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

■ ii. Remove the entries for "Aronia berry"; "Buffalo currant"; "Bushberry subgroup 13B"; "Chilean guava"; "European barberry"; "Highbush cranberry"; "Honeysuckle, edible"; "Jostaberry"; "Juneberry"; "Lingonberry"; "Native currant"; "Salal"; and "Sea buckthorn" from the table in paragraph (a)(1);
■ iii. Alphabetically add commodities to the table in paragraph (a)(1); and
■ iv. Revise the introductory text of paragraph (a)(2).

The amendments read as follows:

§ 180.574 Fluazinam; tolerances for residues.

(a) * * * (1) Tolerances are established for residues of fluazinam (3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluazinam.

Commodity	Parts per million
Bushberry subgroup 13-07B	7.0
* * *	* *
Lettuce, head	0.02
Lettuce, leaf	2.0
Onion, bulb, subgroup 3-07A	0.20
* * *	* *

(2) Tolerances are established for residues of fluazinam, including its metabolites and degradates, in or on the commodities in the table below. Compliance with the tolerance levels specified below is to be determined by measuring only fluazinam and its metabolite AMGT (3-[[4-amino-3-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]amino]-2-nitro-6-(trifluoromethyl) phenyl]thio]-2-(beta-D-glucopyranosyloxy) propionic acid).

* * * * *

[FR Doc. 2010–11302 Filed 5–11–10; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2009–0184; FRL–8812–6]

Flutriafol; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of flutriafol, [(±)-α-(2-fluorophenyl)-α-(4-fluorophenyl)-1*H*-1,2,4-triazole-1-ethanol], including its metabolites and degradates in or on apple at 0.20 ppm; soybean, seed at 0.35 ppm; and grain, aspirated fractions at 2.2 ppm; and cattle, goat, hog, horse and sheep liver at 0.02 ppm. Cheminova A/S, c/o Cheminova, Inc. requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 12, 2010. Objections and requests for hearings must be received on or before July 12, 2010, 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–2009–0184. 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: Tamue L. Gibson, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (703) 305–9096; e-mail address: *gibson.tamue@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 electronically available documents 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 e-CFR cite at *http://www.gpoaccess.gov/ecfr*. To access the OPPTS Harmonized Test Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*.

C. 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–2009–0184 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 July 12, 2010.

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