

§ 161.100 [Amended]

■ 11. In newly redesignated § 161.100, reference to “§§ 158.150 through 158.740”, is revised to read “§§ 161.150 through 161.640” and the reference to “§ 158.108” is revised to read “§ 161.108”.

§ 161.101 [Amended]

■ 12. In newly redesignated § 161.101, reference to “§ 158.45” is revised to read “§ 161.45,” wherever it occurs.

■ 13. Newly redesignated § 161.108 is revised to read as follows:

§ 161.108 Relationship of Pesticide Assessment Guidelines to data requirements.

The Pesticide Assessment Guidelines contain the standards for conducting acceptable tests, guidance on evaluation and reporting of data, definition of terms, further guidance on when data are required, and examples of

acceptable protocols. They are available through the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703–605–6000). The following Subdivisions of the Pesticide Assessment Guidelines, referenced to the appropriate sections of this part, are currently available:

Subdivision	Title	NTIS order no.	Corresponding section(s) in this part
D	Product Chemistry	PB83–153890	161.150 – 161.190
E	Hazard Evaluation: Wildlife and Aquatic Organisms	PB83–153908	161.490
F	Hazard Evaluation: Humans and Domestic Animals	PB83–153916	161.340
G	Product Performance	PB83–153924	161.640
I	Experimental Use Permits	PB83–153932	161.20 – 161.640
J	Hazard Evaluation: Nontarget Plants	PB83–153940	161.540
K	Reentry Protection	PB85–120962	161.390
L	Hazard Evaluation: Nontarget Insect	PB83–153957	161.590
N	Environmental Fate	PB83–153973	161.290
O	Residue Chemistry	PB83–153961	161.240
R	Spray Drift Evaluation	PB84–189216	161.440

§ 161.150 [Amended]

■ 14. In newly redesignated § 161.150, references to “§§ 158.175,” and “§ 158.155,” are revised to read “§ 161.175” and “§ 161.155,” respectively, wherever they occur.

§ 161.155 [Amended]

■ 15. In newly redesignated § 161.155, reference to “§ 158.175” is revised to read “§ 161.175,” wherever it occurs.

§ 161.162 [Amended]

■ 16. In newly redesignated § 161.162, reference to “§ 158.165” is revised to read “§ 161.165.”

§ 161.165 [Amended]

■ 17. In newly redesignated § 161.165, reference to “§ 158.162” is revised to read “§ 161.162”, wherever it occurs.

§§ 161.190, 161.240, 161.290, 161.340, 161.390, 161.440, 161.490, 161.540, 161.590, and 161.640 [Amended]

■ 18. In newly redesignated §§ 161.190, 161.240, 161.290, 161.340, 161.390, 161.440, 161.490, 161.540, 161.590, and 161.640, reference to the phrase “Sections 158.50 and 158.100 through 158.102” is revised to read “Sections 161.100 through 161.102”.

§ 161.340 [Amended]

■ 19. Newly redesignated § 161.340 is further amended in paragraph (b)(22)(i) by revising the reference to “§ 158.202” to read “§ 161.202.”

Appendix A [Amended]

■ 20. Appendix A to newly redesignated part 161 is amended under the topic “How to use this Index,” in paragraph 4, by revising the phrase “in §§ 158.120 through 153.170” to read “in §§ 161.155 through 161.640”.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2007–0234; FRL–8152–4]

Fluazinam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of fluazinam in or on aronia berry; buffalo currant;

bushberry subgroup 13B; Chilean guava; European barberry; ginseng; highbush cranberry; honeysuckle, edible; jostaberry; junberry; lingonberry; native currant; pea and bean, dried shelled, except soybean, subgroup 6C, except pea; pea and bean, succulent shelled, subgroup 6B, except pea; salal; sea buckthorn; turnip, greens; vegetable, Brassica leafy, group 5; and vegetable, legume, edible-podded, subgroup 6A, except pea. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 24, 2007. Objections and requests for hearings must be received on or before December 24, 2007, 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–2007–0234. 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 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:

Susan Stanton, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 305-5218; e-mail address: stanton.susan@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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-2007-0234 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 December 24, 2007.

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-2007-0234, 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’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 30, 2007 (72 FR 21261-21263) (FRL-8124-5), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of pesticide petitions (PP 6E7137 and 6E7139) by Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, New Jersey, 08540. PP 6E7137 requested that 40 CFR 180.574 be amended by establishing tolerances for residues of the fungicide fluazinam in or on Vegetable, legume, edible podded, subgroup 6A, except pea at 0.15 parts per million (ppm); Brassica, leafy greens, subgroup 5B at 0.02 ppm; Brassica, head and stem, subgroup 5A at 0.01 ppm; and turnip, tops at 0.02 ppm; and residues of fluazinam and its metabolite AMGT in or on Bushberry subgroup 13B; berry, aronia; blueberry, lowbush; currant, buffalo; guava, chilean; barberry, European; cranberry, highbush; honeysuckle; jostaberry; Juneberry; lingonberry; currant, native; salal; and buckthorn, sea at 4.5 ppm. PP 6E7139 requested that 40 CFR 180.574 be amended by establishing tolerances for residues of fluazinam in or on ginseng at 3.0 ppm; bean, dry at 0.01 ppm; and pea and bean, succulent shelled, subgroup 6B, except pea at 0.02 ppm. That notice referenced a summary of the petition prepared by ISK Biosciences Corporation, 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 the petition, EPA has modified commodity terms and/or tolerance levels for most commodities. EPA has also determined that the tolerances for berries should include parent fluazinam only. The reasons for these changes are explained in Unit V.

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. . . .” These provisions were added to FFDCA by the Food Quality Protection Act (FQPA) of 1996.

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 the petitioned-for tolerances for residues of fluazinam on Aronia berry at 7.0 ppm; buffalo currant at 7.0 ppm; bushberry subgroup 13B at 7.0 ppm; Chilean guava at 7.0 ppm; European barberry at 7.0 ppm; ginseng at 4.5 ppm; highbush cranberry at 7.0 ppm; honeysuckle, edible at 7.0 ppm; jostaberry at 7.0 ppm; juneberry at 7.0 ppm; lingonberry at 7.0 ppm; native currant at 7.0 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except pea at 0.02 ppm; pea and bean, succulent shelled, subgroup 6B, except pea at 0.04 ppm; salal at 7.0 ppm; sea buckthorn at 7.0 ppm; turnip, greens at 0.01 ppm; vegetable, *Brassica* leafy, group 5 at 0.01 ppm; and vegetable, legume, edible-podded, subgroup 6A, except pea at 0.10 ppm. EPA’s assessment of exposures and risks associated with establishing these 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. 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 the document “Fluazinam: Human Health Risk Assessment for Proposed Use on Edible-Podded Beans, Shelled Succulent and Dried Beans, Brassica Leafy Vegetables, Bushberries, and Ginseng”. The referenced document is available in the docket established by this action, which is described under **ADDRESSES**, and is identified as EPA-HQ-OPP-2007-0234-0003 in that docket.

B. Toxicological Endpoints

For hazards that have a threshold below which there is no appreciable risk, the toxicological level of concern (LOC) is derived from 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) is sometimes used for risk assessment. Uncertainty/safety factors (UFs) are used in conjunction with the LOC 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 risks by comparing aggregate 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 LOC by all applicable UFs. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the margin of exposure (MOE) called for by the product of all applicable UFs is not exceeded.

For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk and estimates risk in terms of the probability of occurrence of additional adverse cases. Generally, cancer risks are considered non-threshold. 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 can be found at <http://www.regulations.gov> in document “Fluazinam: Human Health Risk Assessment for Proposed Use on Edible-Podded Beans, Shelled Succulent and Dried Beans, Brassica Leafy Vegetables,

Bushberries, and Ginseng” at pages 25-26 in docket ID number EPA-HQ-OPP-2007-0234.

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 also considered exposure to residues of the metabolite AMGT, which has been identified as a metabolite of toxicological concern in all crops except peanuts, root and tuber vegetables and bulb vegetables. EPA assessed dietary exposures from fluazinam and AMGT 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 U.S. Department of Agriculture (USDA) 1994-1996 and 1998 Nationwide Continuing Surveys of Food Intake by Individuals (CSFII). As to residue levels in food, EPA assumed all foods for which there are tolerances were treated and contain tolerance-level residues of fluazinam. AMGT residues were calculated based on the mean ratio of metabolite to parent seen in field trials. For crops where this information was not available (*Brassica* and legume vegetables), a conservative, upper-bound ratio derived from metabolism studies was used to estimate AMGT residues.

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 assumed all foods for which there are tolerances were treated and contain tolerance-level residues of fluazinam. AMGT residues were calculated as described for the acute dietary exposure assessment.

iii. *Cancer.* In accordance with the 2005 Guidelines for Carcinogen Risk Assessment, for fluazinam there is “Suggestive evidence of carcinogenic potential.” 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. Additionally, it is noted that the point of departure (1.1 milligrams/kilograms/day) (mg/kg/day)) selected for deriving the chronic reference dose will adequately account for all chronic effects determined to result from exposure to fluazinam in chronic animal studies, including the equivocal cancer effects.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue or PCT information in the dietary assessment for fluazinam. Tolerance level residues and 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring data to complete a comprehensive dietary exposure analysis and risk assessment for fluazinam in drinking water. 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 environmental fate characteristics of fluazinam. 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 Groundwater (SCI-GROW) models, the estimated environmental concentrations (EECs) of fluazinam for acute exposures are estimated to be 71.0 parts per billion (ppb) for surface water and 0.187 ppb for ground water. The EECs for chronic exposures are estimated to be 17.7 ppb for surface water and 0.187 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 71.0 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 17.7 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). Fluazinam is not registered for use on any sites 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."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to fluazinam and 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 not assumed that fluazinam has 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 of FFDCA provides that EPA shall apply an additional ("10X") tenfold margin of safety for infants and children in the case of threshold effects to account for

prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the FQPA safety factor. In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA safety factor value based on the use of traditional UFs and/or special FQPA safety factors, as appropriate.

2. *Prenatal and postnatal sensitivity.* The prenatal and postnatal toxicology database for fluazinam includes rat and rabbit developmental toxicity studies, a developmental neurotoxicity study in rats and a 2-generation reproduction toxicity study in rats.

There was no evidence of increased qualitative or quantitative susceptibility of fetuses following *in utero* exposure to fluazinam in the rabbit developmental study and no evidence of increased susceptibility of offspring in the 2-generation reproduction study in rats. However, there was evidence of increased qualitative susceptibility of fetuses to fluazinam in the developmental toxicity study in rats. In this study, increased incidences of facial/palate clefts and other rare deformities in the fetuses were observed in the presence of minimal maternal toxicity. In a developmental neurotoxicity study, decreases in body weight and body weight gain and a delay in completion of balano-preputial separation were observed in pups. These effects were seen in the absence of maternal effects, suggesting increased quantitative susceptibility of the offspring.

Although there is qualitative evidence of increased susceptibility in young in the developmental toxicity study in rats, there are no residual uncertainties with regard to prenatal and/or postnatal toxicity following *in utero* exposure of rats or rabbits. Considering the overall toxicity profile and the doses and endpoints selected for risk assessment for fluazinam, the degree of concern for the effects observed in the study is low. There is a clear NOAEL for the fetal effects seen, the effects occurred in the presence of maternal toxicity, and they were only seen at the highest dose tested. Additionally, the NOAEL of 50 mg/kg/day identified in this developmental toxicity study in rats is significantly higher than the NOAEL used (7 mg/kg/day) to establish the acute Reference Dose (aRfD) of 0.07 mg/kg/day (females 13-49); thus, the aRfD is

protective of any potential developmental effects.

Quantitative evidence of increased susceptibility was also observed in a developmental neurotoxicity study in rats. In pups, there were decreases in body weight and body weight gain during lactation, and delayed preputial separation observed at 10 mg/kg/day (NOAEL=2 mg/kg/day). Although the NOAEL of 2 mg/kg/day is lower than that used for the acute RfD for females 13-49 (7 mg/kg/day), the effects noted in the developmental neurotoxicity study are attributable to multiple doses and are considered postnatal effects. Therefore, the study endpoint is not appropriate either for acute dietary exposures or for use with the population subgroup females 13-49 (with this subgroup the concern is for prenatal exposures). The chronic RfD of 0.011 mg/kg/day is based on a lower NOAEL of 1.1 mg/kg/day and is considered protective of potential developmental effects.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA safety factor to 1X. That decision is based on the following findings:

i. The toxicity database for fluazinam is complete in regard to pre- and postnatal toxicity and neurotoxicity.

ii. A developmental neurotoxicity study (DNT) in rats was submitted to address the presence of neurotoxic lesions observed after fluazinam exposure in sub-chronic and chronic toxicity studies and to address the qualitative susceptibility seen in the rat developmental toxicity study. In the DNT study, there were no neurotoxic effects observed in either dams or pups. However, there was evidence of quantitative susceptibility for other effects in the DNT study, based on decreases in body weight and body weight gain, and delayed preputial separation in pups in the absence of maternal toxicity. There are no residual uncertainties for these effects, and toxicity endpoints and traditional UFs to be used in the risk assessment will be protective of these potential developmental effects.

iii. Although there is qualitative evidence of increased susceptibility in the prenatal developmental study in rats, the risk assessment team did not identify any residual uncertainties after establishing toxicity endpoints and traditional UFs to be used in the risk assessment of fluazinam. The degree of concern for prenatal and/or postnatal toxicity is low.

iv. There are no residual uncertainties identified in the exposure databases.

The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. Conservative ground and surface water modeling estimates were used. These assessments will not underestimate the exposure and risks posed by fluazinam.

E. Aggregate Risks and Determination of Safety

Safety is assessed for acute and chronic risks by comparing aggregate exposure to the pesticide to the aPAD and cPAD. The aPAD and cPAD are calculated by dividing the LOC by all applicable UFs. For linear cancer risks, EPA calculates the probability of additional cancer cases given aggregate exposure. Short-, intermediate-, and long-term risks are evaluated by comparing aggregate exposure to the LOC to ensure that the MOE called for by the product of all applicable UFs is not exceeded.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, EPA performed two different acute risk assessments – one focusing on females 13 to 49 years old and designed to protect against prenatal effects and the other focusing on acute effects relevant to all other population groups. The more sensitive acute endpoint was seen as to prenatal effects rather than other acute effects. For females 13 to 49 years old, the acute dietary exposure from food and water will occupy 8% of the aPAD addressing prenatal effects. As to acute effects other than prenatal effects, the acute dietary exposure from food and water to fluazinam will occupy 3% of the aPAD for infants less than 1-year 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 exposure to fluazinam from food and water will utilize 16% of the cPAD for infants less than 1-year old, the population group with the greatest estimated exposure. There are no residential uses for fluazinam that result in chronic residential exposure to fluazinam.

3. *Short-term risk.* Short-term aggregate exposure takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluazinam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure

takes into account residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Fluazinam is not registered for use on any sites that would result in residential exposure. Therefore, the aggregate risk is the sum of the risk from food and water, which do not exceed the Agency's level of concern.

5. *Aggregate cancer risk for U.S. population.* The Agency has determined that quantification of human cancer risk is not necessary for fluazinam and that the chronic risk assessment based on the established cPAD is protective of potential cancer effects. Based on the results of the chronic risk assessment discussed above in Unit III.E.2, EPA concludes that fluazinam is not expected to pose a cancer risk.

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

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with electron-capture detection) is available to enforce the tolerance expression. The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; e-mail address: residuemethods@epa.gov.

B. International Residue Limits

There are no established or proposed Codex MRLs for residues of fluazinam in plant or animal commodities.

V. Conclusion

Based upon review of the data supporting the petition, EPA has modified the proposed tolerances as follows:

- The tolerances for Bushberry subgroup 13B and related berries were increased from 4.5 ppm to 7.0 ppm based on analyses 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. Although IR-4 proposed tolerances for combined residues of fluazinam and AMGT on these commodities, EPA determined, based on the low levels of AMGT seen in the field trials, that only parent fluazinam should be included in the tolerance expression.

- The commodity terms for dry beans and succulent shelled legumes were

revised to read “Pea and bean, dried shelled, except soybean, subgroup 6C, except pea” and “Pea and bean, succulent shelled, subgroup 6B, except pea” to agree with recommended commodity terms in the Office of Pesticide Program’s Food and Feed Commodity Vocabulary. Tolerances for these commodities were increased from 0.01 ppm to 0.02 ppm (dried) and from 0.02 ppm to 0.04 ppm (succulent) to account for the 50% dissipation of residues observed in the storage stability study.

- The commodity term for edible-podded legume vegetables was revised to read “Vegetable, legume, edible-podded, subgroup 6A, except pea” to agree with the Food and Feed Commodity Vocabulary. The tolerance level was decreased from 0.15 ppm to 0.10 ppm based on maximum residues seen in the field trials, since 80% of the residues were non-detectable and, therefore, not appropriate for analysis using the Tolerance Spreadsheet.

- IR-4 proposed separate tolerances of 0.02 ppm and 0.01 ppm for “Leafy Brassica greens subgroup” and “Head and stem Brassica subgroup”, respectively. EPA determined that a single tolerance of 0.01 ppm covering the entire crop group “Vegetable, Brassica leafy, group 5” would be appropriate, based on the results of field trials showing no residues above the method limit of quantitation (LOQ) in any of the representative commodities (broccoli, cabbage and mustard greens). The tolerance for turnip greens was revised from 0.02 to 0.01 ppm on the same basis.

- The tolerance for ginseng was increased from 3.00 ppm to 4.5 ppm to account for dissipation of residues observed in the storage stability study.

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 Aronia berry at 7.0 ppm; buffalo currant at 7.0 ppm; bushberry subgroup 13B at 7.0 ppm; Chilean guava at 7.0 ppm; European barberry at 7.0 ppm; ginseng at 4.5 ppm; highbush cranberry at 7.0 ppm; honeysuckle, edible at 7.0 ppm; jostaberry at 7.0 ppm; juneberry at 7.0 ppm; lingonberry at 7.0 ppm; native currant at 7.0 ppm; pea and bean, dried shelled, except soybean, subgroup 6C, except pea at 0.02 ppm; pea and bean, succulent shelled, subgroup 6B, except pea at 0.04 ppm; salal at 7.0 ppm; sea buckthorn at 7.0 ppm; turnip, greens at 0.01 ppm; vegetable, *Brassica* leafy, group 5 at 0.01 ppm; and vegetable, legume, edible-podded, subgroup 6A, except pea at 0.10 ppm.

VI. Statutory and Executive Order Reviews

This final rule establishes a tolerance 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 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 6, 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: October 11, 2007.

Donald R. Stubbs,

Acting 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 by removing the heading *General* from paragraph (a)(1) and adding *General* to paragraph (a) and by alphabetically adding the following commodities to the table in paragraph (a)(1) to read as follows:

§ 180.574 Fluazinam; tolerances for residues.

(a) *General.* (1) * * *

Commodity	Parts per million
Aronia berry	7.0
Buffalo currant	7.0
Bushberry subgroup 13B	7.0
Chilean guava	7.0
European barberry	7.0
Ginseng	4.5
Highbush cranberry	7.0

Commodity	Parts per million
Honeysuckle, edible	7.0
Jostaberry	7.0
Juneberry	7.0
Lingonberry	7.0
Native currant	7.0
Pea and bean, dried shelled, except soybean, subgroup 6C, except pea	0.02
Pea and bean, succulent shelled, subgroup 6B, except pea	0.04
* * * *	*
Salal	7.0
Sea buckthorn	7.0
Turnip, greens	0.01
Vegetable, Brassica leafy, group 5	0.01
Vegetable, legume, edible-podded, subgroup 6A, except pea	0.10

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[FR Doc. E7-20581 Filed 10-23-07; 8:45 am]
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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2007-0471; FRL-8151-5]

Bifenthrin; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of bifenthrin in or on mayhaw; vegetable, root, subgroup 1B except sugar beet and garden beet; beet, garden, roots; beet, garden, tops; radish, tops; soybean, seed; soybean, hulls; soybean, refined oil; groundcherry; pepino; peanut; pistachio; and grain, aspirated fractions. Interregional Research Project Number 4 (IR-4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective October 24, 2007. Objections and requests for hearings must be received on or before December 24, 2007, 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-2007-0471. 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](http://www.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](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: Shaja R. Brothers, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-3194; e-mail address: brothers.shaja@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), e.g., agricultural workers; greenhouse, nursery, and floriculture workers; farmers.
- Animal production (NAICS code 112), e.g., cattle ranchers and farmers, dairy cattle farmers, livestock farmers.
- Food manufacturing (NAICS code 311), e.g., agricultural workers; farmers; greenhouse, nursery, and floriculture workers; ranchers; pesticide applicators.
- Pesticide manufacturing (NAICS code 32532), e.g., agricultural workers; commercial applicators; farmers; greenhouse, nursery, and floriculture workers; residential users.

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 the 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-2007-0471 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 December 24, 2007.

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-2007-0471, 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