

that otherwise satisfies the provisions of the Clean Air Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. As required by section 3 of Executive Order 12988 (61 FR 4729, February 7, 1996), in issuing this rule, EPA has taken the necessary steps to eliminate drafting errors and ambiguity, minimize potential litigation, and provide a clear legal standard for affected conduct. EPA has complied with Executive Order 12630 (53 FR 8859, March 15, 1988) by examining the takings implications of the rule in accordance with the "Attorney General's Supplemental Guidelines for the Evaluation of Risk and Avoidance of Unanticipated Takings" issued under the executive order. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, 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 the rule in the **Federal Register**. This rule is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by November 6, 2001. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action regarding changes to Maryland's control of iron and steel production installations may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides.

Dated: August 10, 2001.

Donald S. Welsh,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart V—Maryland

2. Section 52.1070 is amended by adding paragraph (c)(153) to read as follows:

§ 52.1070 Identification of plan.

* * * * *

(c) * * *

(153) Revisions to the Maryland State Implementation Plan submitted on April 2, 1992 and October 10, 2000 by the Maryland Department of the Environment:

(i) Incorporation by reference.

(A) Letter dated April 2, 1992 from the Maryland Department of the Environment transmitting revisions to the testing and observation procedures for iron and steel production operations

(B) The following revised Maryland provisions, effective February 17, 1992.

(1) Revised COMAR 26.11.10.07.

(2) Technical Memorandum 91-01, Supplement 1—Appendix A, Test Method 5 and Method 8.

(C) Letter dated October 10, 2000 from the Maryland Department of the Environment transmitting revisions to regulations and technical memoranda governing control of iron and steel production operations.

(D) The following revised Maryland provisions, effective November 2, 1998.

(1) Revisions to COMAR 26.11.01.04C(2).

(2) Revisions to the following provisions of COMAR 26.11.10: Paragraphs .02A., .02B(2), .02B(3), .03A(2)(a) through (c), .03A(2)(e), .03B [introductory paragraph], .03B(5) [formerly cited as .03B(6)], .04B(2) introductory paragraph [combined with provision formerly cited as .04B(2)(a)], .04B(2)(c)(i) and .04B(2)(c)(ii) [formerly cited as .04B(2)(e)(i) and .04B(2)(e)(ii) respectively], .04B(2)(f), .04B(3) through(5), and .05.

(3) Removal of the following provisions: COMAR 26.11.10.01B(1)

[existing provision .01B(2) is renumbered as .01B(1)], .03B(1) [existing provisions .03B(2) through(5) are renumbered as .03B(1) through (4)], .03B(7), .03B(8), .03C, .03D, .04A(2) and .04A(3) [existing provision .04A(1) is renumbered as .04A], .04B(2)(b), and .04B(2)(h) [existing provisions .04B(2)(c) through (g) and (i) are renumbered as .04B(2)(a) through (f)].

(4) Addition of COMAR 26.11.10.01B(2) and new .03C.

(5) Technical Memorandum 91-01, Supplement 3—Test Methods 1004, 1004F, 1004G, 1004H, and 1004I.

(E) Revisions to COMAR 26.11.10.03C(1) [formerly cited as .03C], and the addition of Paragraphs .03C(2) and .03C(3); effective October 2, 2000.

(ii) Additional Materials—Remainder of the state submittals pertaining to the revisions listed in paragraph (c)(153) (i) of this section.

[FR Doc. 01-22366 Filed 9-6-01; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[OPP-301160; FRL-6797-3]

RIN 2070-AB78

Fluazinam; Pesticide Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes a tolerance for residues of fluazinam in or on peanuts and potatoes. ISK Biosciences Corporation requested this tolerance under the Federal Food, Drug, and Cosmetic Act, as amended by the Food Quality Protection Act of 1996.

DATES: This regulation is effective September 7, 2001. Objections and requests for hearings, identified by docket control number OPP-301160, must be received by EPA on or before November 6, 2001.

ADDRESSES: Written objections and hearing requests may be submitted by mail, in person, or by courier. Please follow the detailed instructions for each method as provided in Unit VI. of the **SUPPLEMENTARY INFORMATION**. To ensure proper receipt by EPA, your objections and hearing requests must identify docket control number OPP-301160 in the subject line on the first page of your response.

FOR FURTHER INFORMATION CONTACT: By mail: Cynthia Giles-Parker, Registration Division (7505C), Office of Pesticide

Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460; telephone number: (703) 305-7740; and e-mail address: *giles-parker.cynthia@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected categories and entities may include, but are not limited to:

Cat-egories	NAICS	Examples of Potentially Affected Entities
Industry	111	Crop production
	112	Animal production
	311	Food manufacturing
	32532	Pesticide manufacturing

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in the table could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining whether or not this action might apply to certain entities. If you have 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 Additional Information, Including Copies of this Document and Other Related Documents?

1. *Electronically.* You may obtain electronic copies of this document, and certain other related documents that might be available electronically, from the EPA Internet Home Page at *http://www.epa.gov/*. To access this document, on the Home Page select "Laws and Regulations", "Regulations and Proposed Rules," and then look up the entry for this document under the "Federal Register—Environmental Documents." You can also go directly to the **Federal Register** listings at *http://www.epa.gov/fedrgstr/*. To access the OPPTS Harmonized Guidelines referenced in this document, go directly to the guidelines at *http://www.epa.gov/opptsfrs/home/guidelin.htm*. A frequently updated electronic version of

40 CFR part 180 is available at *http://www.access.gpo.gov/nara/cfr/cfrhtml_180/Title_40/40cfr180_00.html*, a beta site currently under development.

2. *In person.* The Agency has established an official record for this action under docket control number OPP-301160. The official record consists of the documents specifically referenced in this action, and other information related to this action, including any information claimed as Confidential Business Information (CBI). This official record includes the documents that are physically located in the docket, as well as the documents that are referenced in those documents. The public version of the official record does not include any information claimed as CBI. The public version of the official record, which includes printed, paper versions of any electronic comments submitted during an applicable comment period is available for inspection in the Public Information and Records Integrity Branch (PIRIB), Rm. 119, Crystal Mall #2, 1921 Jefferson Davis Hwy., Arlington, VA, from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The PIRIB telephone number is (703) 305-5805.

II. Background and Statutory Findings

In the **Federal Register** of December 6, 2000 (65 FR 76253) (FRL-6573-7), EPA issued a notice pursuant to section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a as amended by the Food Quality Protection Act of 1996 (FQPA) (Public Law 104-170) announcing the filing of a pesticide petition (PP) for tolerance by ISK Biosciences Corporation, 5970 Heisley Road, Suite 200, Mentor, Ohio, 44060. This notice included a summary of the petition prepared by ISK Biosciences Corporation, the registrant. There were no comments received in response to the notice of filing.

The petition requested that 40 CFR part 180 be amended by establishing a tolerance for residues of the fungicide fluazinam, 3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine, in or on peanuts and potatoes at 0.02 part per million (ppm).

Section 408(b)(2)(A)(i) of the 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) 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) 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...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of section 408 and a complete description of the risk assessment process, see the final rule on Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997) (FRL-5754-7).

III. Aggregate Risk Assessment and Determination of Safety

Consistent with section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure, consistent with section 408(b)(2), for a tolerance for residues of fluazinam on peanuts and potatoes at 0.02 ppm. EPA's assessment of exposures and risks associated with establishing the tolerance follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by fluazinam are discussed in the following Table 1 as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies reviewed.

TABLE 1.—TOXICOLOGICAL PROFILE OF FLUAZINAM TECHNICAL

Guideline No.	Study Type	Results
870.3100	90-Day oral toxicity rats	NOAEL: Males = 3.8 mg/kg/day; Females = 4.3 mg/kg/day

TABLE 1.—TOXICOLOGICAL PROFILE OF FLUAZINAM TECHNICAL—Continued

Guideline No.	Study Type	Results
		LOAEL Males = 38 mg/kg/day; Females = 44 mg/kg/day based on increased liver weights and liver histopathology in males, and increased lung and uterus weights in females.
870.3150	90-Day oral toxicity dogs	NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on retinal effects, increased relative liver weight, liver histopathology and possible increased serum alkaline phosphatase in females and possible marginal vacuolation of the cerebral white matter (equivocal)
870.3200	21-Day dermal toxicity rats	Systemic NOAEL = 10 mg/kg/day LOAEL = 100 mg/kg/day based on increased AST and cholesterol levels in clinical chemistry determinations (males) Dermal NOAEL = not identified LOAEL = 10 mg/kg/day based on erythema, acanthosis, and dermatitis
870.3250	90-Day dermal toxicity	Not Available
870.3465	90-Day inhalation toxicity	Not Available
870.3700	Prenatal developmental toxicity rats	Maternal NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on decreased body weight gain and food consumption and increased water consumption and urogenital staining Developmental NOAEL = 50 mg/kg/day LOAEL = 250 mg/kg/day based on decreased fetal body weights and placental weights, increased facial/cleft palates, diaphragmatic hernia, and delayed ossification in several bone types, greenish amniotic fluid and possible increased late resorptions and postimplantation loss
870.3700	Prenatal developmental toxicity rabbits	Maternal NOAEL = 4 mg/kg/day LOAEL = 7 mg/kg/day based on decreased food consumption and increased liver histopathology. Developmental NOAEL = 7 mg/kg/day LOAEL = 12 mg/kg/day based on an increase in total litter resorptions and possible fetal skeletal abnormalities
870.3700	Prenatal developmental toxicity rabbits	Maternal NOAEL = 3 mg/kg/day LOAEL = not identified (>3 mg/kg/day) Developmental NOAEL = 3 mg/kg/day LOAEL = not identified (>3 mg/kg/day)
870.3800	Reproduction and fertility effects rats	Parental/Systemic NOAEL = 1.9 mg/kg/day LOAEL = 9.7 mg/kg/day based on liver pathology in F ₁ males Reproductive NOAEL = 10.6 mg/kg/day LOAEL = 53.6 mg/kg/day based on decreased number of implantation sites and decreased litter sizes to day 4 postpartum for F ₁ females (F ₂ litters). Offspring NOAEL = 8.4 mg/kg/day LOAEL = 42.1 mg/kg/day based on reduced F ₁ and F ₂ pup body weight gains during lactation.
870.4100	Chronic toxicity rats	NOAEL = Males: 1.9 mg/kg/day; Females: 4.9 mg/kg/day LOAEL = Males: 3.9 mg/kg/day; Females: not identified (>4.9 mg/kg/day) based on increased testicular atrophy in males and no effects in females
870.4100	Chronic toxicity dogs	NOAEL = 1 mg/kg/day LOAEL = 10 mg/kg/day based on gastric lymphoid hyperplasia in both sexes and nasal dryness in females
870.4300	Combined chronic toxicity/carcinogenicity rats	NOAEL = Males: 0.38 mg/kg/day; Females: 0.47 mg/kg/day LOAEL = Males: 3.8 mg/kg/day; Females: 4.9 mg/kg/day based on liver toxicity in both sexes, pancreatic exocrine atrophy in females and testicular atrophy in males. Some evidence of carcinogenicity (thyroid gland follicular cell tumors) in male rats, but not in females.
870.4200	Carcinogenicity mice	NOAEL = Males: 1.1 mg/kg/day; Females: 1.2 mg/kg/day

TABLE 1.—TOXICOLOGICAL PROFILE OF FLUAZINAM TECHNICAL—Continued

Guideline No.	Study Type	Results
		LOAEL = Males: 10.7 mg/kg/day; Females: 11.7 mg/kg/day based on increased incidences of brown macrophages in the liver of both sexes, eosinophilic vacuolated hepatocytes in males, and increased liver weight in females Clear evidence of carcinogenicity (hepatocellular tumors) in male mice, but not in females
870.4200	Carcinogenicity mice	NOAEL = Males: <126 mg/kg/day, Females: <162 mg/kg/day LOAEL = Males: 126 mg/kg/day; Females: 162 mg/kg/day based on increased liver weights and liver and brain histopathology in both sexes Equivocal/some evidence of carcinogenicity (hepatocellular tumors) in male mice, but not in females
870.5100	Bacterial reverse mutation assay (Ames test)	Negative with and without S9 up to cytotoxic concentrations.
870.5100	Bacterial reverse mutation assay (Ames test)	Negative with and without S9 up to cytotoxic concentrations.
870.5300	<i>In vitro</i> mammalian gene mutation assay	Negative with S9 activation up to 9 µg/ml. Negative without S9 activation up to 0.3 µg/ml. Compound tested to cytotoxic concentrations.
870.5300	<i>In vitro</i> mammalian gene mutation assay	Negative with and without S9 activation up to 5 µg/ml. Compound tested to cytotoxic concentrations.
870.5375	<i>In vitro</i> mammalian chromosome aberration (CHL cells)	Negative with and without S9 up to cytotoxic concentrations. Cells harvested at 24 and 48 hours in nonactivated studies and at 24 hours in activated studies.
870.5395	Mammalian erythrocyte micronucleus test	Negative at 24 hour sacrifice (500, 1,000, 2,000 mg/kg). Negative at 24, 48, and 72 hour sacrifices (2,000 mg/kg).
870.5550	UDS in primary rat hepatocytes	Negative; however there were several serious study deficiencies: treatment time shorter than recommended, no data supporting the claim of cytotoxicity, data variability for major endpoints.
870.5550	Differential killing/growth inhibition in <i>B. subtilis</i>	Negative, however only one replicate plate/dose was used.
870.6200	Acute neurotoxicity screening battery rats	Systemic NOAEL = 50 mg/kg LOAEL = 1,000 mg/kg based on soft stools and decreased motor activity on day of dosing. Neurotoxicity NOAEL = 2,000 mg/kg LOAEL = not identified (>2,000 mg/kg)
870.6200	Subchronic neurotoxicity screening battery rats	Neurotoxicity NOAEL = Males: 233 mg/kg/day; Females: 280 mg/kg/day LOAEL = not identified (Males: >233 mg/kg/day; Females: > 280 mg/kg/day)
870.6300	Developmental neurotoxicity	Not Available
870.7485	Metabolism and pharmacokinetics rats	Only 33–40% of the administered dose was absorbed. Most of the administered dose was recovered in the feces (>89%). Excretion via the urine was minor (<4%). Total biliary radioactivity, however, represented 25–34% of the administered dose, indicating considerable enterohepatic circulation.
870.7600	Dermal penetration	Not Available
Special studies:	4-Week dietary (Range-finding) rats	NOAEL = Males: 5.1 mg/kg/day; Females: 5.3 mg/kg/day LOAEL = Males: 26.4 mg/kg/day; Females: 25.9 mg/kg/day based on decreased body weight gain and food consumption, increased serum phospholipids, increased total cholesterol, increased relative liver weights, and liver histopathology.
	4-Week dietary (Range-finding) mice	NOAEL = Males: 7.6 mg/kg/day; Females: 8.2 mg/kg/day LOAEL = Males: 36 mg/kg/day; Females: 43 mg/kg/day based on decreased body weight gain, increased serum glucose, increased kidney weights.

TABLE 1.—TOXICOLOGICAL PROFILE OF FLUAZINAM TECHNICAL—Continued

Guideline No.	Study Type	Results
	4-Week dietary (Range-finding) mice	NOAEL = not identified (Males; <555 mg/kg/day; Females: <658 mg/kg/day) LOAEL = Males: 555 mg/kg/day; Females: 658 mg/kg/day based on vacuolation of white matter in brain, increased liver weights, histopathology in liver.
	90-Day dietary (Special liver study) rats	NOAEL = not determined (Males: <37.6 mg/kg/day, Females: <44.7 mg/kg/day) LOAEL = Males: 37.6 mg/kg/day, Females: 44.7 mg/kg/day based on increased relative liver weights and liver histopathology.
	11-Week oral toxicity (Special retinal study) dogs	NOAEL/LOAEL not determined.
	7-Day inhalation toxicity rats (Test Material: Frowncide WP (51.9% a.i.))	NOAEL = Males: 1.38 mg/kg/day; Females: 1.49 mg/kg/day LOAEL = Males: 3.97 mg/kg/day; Females: 4.25 mg/kg/day based on increased testes weight (males) and increased liver weight (females).
	Developmental toxicity (range-finding) rats	Maternal and developmental NOAELS and LOAELS were not assigned.
	Eight special mechanistic studies to assess the CNS white matter vacuolation	White matter vacuolation in the CNS of mice, rats, and dogs was found to be due to Impurity-5.

B. Toxicological Endpoints

The dose at which no adverse effects are observed (the NOAEL) from the toxicology study identified as appropriate for use in risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect 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. An UF of 100 is routinely used, 10X to account for interspecies differences and 10X for intraspecies differences.

For dietary risk assessment (other than cancer) the Agency uses the UF to calculate an acute or chronic reference dose (acute RfD or chronic RfD) where

the RfD is equal to the NOAEL divided by the appropriate UF (RfD = NOAEL/UF). Where an additional safety factor is retained due to concerns unique to the FQPA, this additional factor is applied to the RfD by dividing the RfD by such additional factor. The acute or chronic Population Adjusted Dose (aPAD or cPAD) is a modification of the RfD to accommodate this type of FQPA Safety Factor.

For non-dietary risk assessments (other than cancer) the UF is used to determine the LOC. For example, when 100 is the appropriate UF (10X to account for interspecies differences and 10X for intraspecies differences) the LOC is 100. To estimate risk, a ratio of the NOAEL to exposures (margin of exposure (MOE) = NOAEL/exposure) is calculated and compared to the LOC.

The linear default risk methodology (Q*) is the primary method currently used by the Agency to quantify carcinogenic risk. The Q* approach

assumes that any amount of exposure will lead to some degree of cancer risk. A Q* is calculated and used to estimate risk which represents a probability of occurrence of additional cancer cases (e.g., risk is expressed as 1×10^{-6} or one in a million). Under certain specific circumstances, MOE calculations will be used for the carcinogenic risk assessment. In this non-linear approach, a "point of departure" is identified below which carcinogenic effects are not expected. The point of departure is typically a NOAEL based on an endpoint related to cancer effects though it may be a different value derived from the dose response curve. To estimate risk, a ratio of the point of departure to exposure ($MOE_{cancer} = \text{point of departure/exposures}$) is calculated. A summary of the toxicological endpoints for fluazinam used for human risk assessment is shown in the following Table 2:

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZINAM FOR USE IN HUMAN RISK ASSESSMENTS¹

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary females 13-50 years of age	Developmental NOAEL = 7 mg/kg/day; UF = 100; Acute RfD = 0.07 mg/kg/day	FQPA SF = 10; aPAD = acute RfD/FQPA SF = 0.007 mg/kg/day	Developmental toxicity, rabbits. Developmental LOAEL = 12 mg/kg/day based on increased incidence of total litter resorptions and possibly increased incidence of fetal skeletal abnormalities.

TABLE 2.—SUMMARY OF TOXICOLOGICAL DOSES AND ENDPOINTS FOR FLUAZINAM FOR USE IN HUMAN RISK ASSESSMENTS¹—Continued

Exposure Scenario	Dose Used in Risk Assessment, UF	FQPA SF* and Endpoint for Risk Assessment	Study and Toxicological Effects
Acute Dietary general population including infants and children	NOAEL = 50 mg/kg/day UF = 100; Acute RfD = 0.50 mg/kg/day	FQPA SF = 3; aPAD = acute RfD/FQPA SF = 0.167 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 = 100; Chronic RfD = 0.011 mg/kg/day	FQPA SF = 3; cPAD = chronic RfD/FQPA SF = 0.00367 mg/kg/day	Carcinogenicity, mice. LOAEL = 10.7 mg/kg/day based on liver histopathology and increased liver weight.
Cancer (oral, dermal, inhalation)	Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential ²	Quantification of human cancer risk not required. ²	Increases in thyroid gland follicular cell tumors in male rats; increases in hepatocellular (liver) tumors in male mice. ²

* The reference to the FQPA Safety Factor refers to any safety factor retained or reduced due to concerns unique to the FQPA.

¹ UF = uncertainty factor, FQPA SF = FQPA safety factor, NOAEL = no observed adverse effect level, LOAEL = lowest observed adverse effect level, PAD = population adjusted dose (a = acute, c = chronic), RfD = reference dose, LOC = level of concern, MOE = margin of exposure

²Cancer Assessment Document - Evaluation of the Carcinogenic Potential of Fluazinam, March 29, 2001, HED Doc. No. 014512.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* No tolerances have been established for the residues of fluazinam. Risk assessments were conducted by EPA to assess dietary exposures from fluazinam in food as follows:

i. *Acute exposure.* Acute dietary 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. The Dietary Exposure Evaluation Model (DEEM®) analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide Continuing Surveys of Food Intake by Individuals (CSFII) and accumulated exposure to the chemical for each commodity. The following assumptions were made for the acute exposure assessments: A DEEM acute dietary exposure analysis was performed using tolerance residue levels and 100% CT data for all commodities (Tier 1). The DEEM defaults were used for all processing factors.

ii. *Chronic exposure.* In conducting this chronic dietary risk assessment the DEEM® analysis evaluated the individual food consumption as reported by respondents in the USDA 1989–1992 nationwide CSFII and accumulated exposure to the chemical for each commodity. The following assumptions were made for the chronic exposure assessments: A DEEM chronic dietary exposure analysis was

performed using tolerance residue levels and 100% CT data for all commodities (Tier 1). The DEEM defaults were used for all processing factors.

iii. *Cancer.* Since fluazinam has been classified as Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential, an exposure assessment was not performed.

2. *Dietary exposure from drinking water.* The Agency lacks sufficient monitoring exposure 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 physical characteristics of fluazinam.

The Agency uses the Generic Estimated Environmental Concentration (GENEEC) or the Pesticide Root Zone/Exposure Analysis Modeling System (PRZM/EXAMS) to estimate pesticide concentrations in surface water and SCIGROW, which predicts pesticide concentrations in groundwater. In general, EPA will use GENEEC (a tier 1 model) before using PRZM/EXAMS (a tier 2 model) for a screening-level assessment for surface water. The GENEEC model is a subset of the PRZM/EXAMS model that uses a specific high-end runoff scenario for pesticides. GENEEC incorporates a farm pond scenario, while PRZM/EXAMS incorporate an index reservoir

environment in place of the previous pond scenario. The PRZM/EXAMS model includes a percent crop area factor as an adjustment to account for the maximum percent crop coverage within a watershed or drainage basin.

None of these models include consideration of the impact processing (mixing, dilution, or treatment) of raw water for distribution as drinking water would likely have on the removal of pesticides from the source water. The primary use of these models by the Agency at this stage is to provide a coarse screen for sorting out pesticides for which it is highly unlikely that drinking water concentrations would ever exceed human health levels of concern.

Since the models used are considered to be screening tools in the risk assessment process, the Agency does not use estimated environmental concentrations (EECs) from these models to quantify drinking water exposure and risk as a percent of reference dose (%RfD) or percent of adjusted dose (%PAD). Instead, drinking water levels of comparison (DWLOCs) are calculated and used as a point of comparison against the model estimates of a pesticide's concentration in water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food, and from residential uses. Since DWLOCs address total aggregate exposure to fluazinam they are further discussed in the aggregate risk sections below.

Based on the GENEEC and SCI-GROW models the estimated environmental concentrations (EECs) of fluazinam for acute exposures are estimated to be 18.0 parts per billion (ppb) for surface water and 0.10 ppb for ground water. The EECs for chronic exposures are estimated to be 3.15 ppb for surface water and 0.10 ppb for ground 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 exposure to substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) 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 does not have, at this time, available data to determine whether fluazinam has a common mechanism of toxicity with other substances or how to include this pesticide in a cumulative risk assessment. Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, 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 the final rule for Bifenthrin Pesticide Tolerances (62 FR 62961, November 26, 1997).

D. Safety Factor for Infants and Children

1. *Safety factor for infants and children—i. In general.* FFDCA section 408 provides that EPA shall apply an additional 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 that a different margin of safety will be safe for infants and children. Margins of safety are incorporated into EPA risk assessments either directly through use of a margin of exposure (MOE) analysis

or through using uncertainty (safety) factors in calculating a dose level that poses no appreciable risk to humans.

ii. *Prenatal and postnatal sensitivity.* Qualitative evidence of increased susceptibility of fetuses to fluazinam was demonstrated in a developmental toxicity study in rats. 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 toxicity study in rabbits and in a 2-generation reproduction study in rats, neither quantitative nor qualitative evidence of increased susceptibility of fetuses or pups to fluazinam was observed. Because of the neurotoxic lesion observed in the white matter of the brain in mice, dogs and rats and the qualitative evidence of increased susceptibility of rat fetuses to fluazinam, a developmental neurotoxicity study will be required to be submitted to the Agency. Further, because of the lack of a developmental neurotoxicity study and the qualitative evidence of increased susceptibility of rat fetuses to fluazinam, the Food Quality Protection Act (FQPA) safety factor (SF) for protection of infants and children, as required by the FQPA of 1996, will be retained at 10X when assessing acute dietary exposure for "females 13–50 years of age" due to concern for the developing fetus. Additionally, the FQPA SF will be reduced to 3X when assessing exposures for all populations for all exposure durations (acute and chronic) because of uncertainty resulting from lack of a developmental neurotoxicity study.

iii. *Conclusion.* Because of the lack of a developmental neurotoxicity study and the qualitative evidence of increased susceptibility of rat fetuses to fluazinam, the Agency determined that the FQPA safety factor should be retained at 10X when assessing acute dietary exposure for "females 13–50 years of age" since, in addition to the need for a developmental neurotoxicity study, increased susceptibility of rat fetuses was observed following *in utero* exposure in the rat developmental toxicity study resulting in concern for the developing fetus. The Agency also determined that the FQPA safety factor should be reduced to 3X when assessing exposure for "all populations" for all exposure durations (acute and chronic) since there is uncertainty due to the lack of a developmental neurotoxicity study. This study will further characterize the toxicity of fluazinam and may provide endpoints and NOAELs that could be used in risk assessments for any subpopulation/exposure duration.

E. Aggregate Risks and Determination of Safety

To estimate total aggregate exposure to a pesticide from food, drinking water, and residential uses, the Agency calculates DWLOCs which are used as a point of comparison against the model estimates of a pesticide's concentration in water (EECs). DWLOC values are not regulatory standards for drinking water. DWLOCs are theoretical upper limits on a pesticide's concentration in drinking water in light of total aggregate exposure to a pesticide in food and residential uses. In calculating a DWLOC, the Agency determines how much of the acceptable exposure (i.e., the PAD) is available for exposure through drinking water e.g., allowable chronic water exposure (mg/kg/day) = cPAD - (average food + residential exposure). This allowable exposure through drinking water is used to calculate a DWLOC.

A DWLOC will vary depending on the toxic endpoint, drinking water consumption, and body weights. Default body weights and consumption values as used by the USEPA Office of Water are used to calculate DWLOCs: 2L/70 kg (adult male), 2L/60 kg (adult female), and 1L/10 kg (child). Default body weights and drinking water consumption values vary on an individual basis. This variation will be taken into account in more refined screening-level and quantitative drinking water exposure assessments. Different populations will have different DWLOCs. Generally, a DWLOC is calculated for each type of risk assessment used: acute, short-term, intermediate-term, chronic, and cancer.

When EECs for surface water and groundwater are less than the calculated DWLOCs, the Office of Pesticide Programs (OPP) concludes with reasonable certainty that exposures to the pesticide in drinking water (when considered along with other sources of exposure for which OPP has reliable data) would not result in unacceptable levels of aggregate human health risk at this time. Because OPP considers the aggregate risk resulting from multiple exposure pathways associated with a pesticide's uses, levels of comparison in drinking water may vary as those uses change. If new uses are added in the future, OPP will reassess the potential impacts of residues of the pesticide in drinking water as a part of the aggregate risk assessment process.

1. *Acute risk.* Using the exposure assumptions discussed in this unit for acute exposure, the acute dietary exposure to fluazinam from food will occupy <1% of the aPAD for the U.S. population, 2% of the aPAD for the

most highly exposed population subgroup, females 13–50 years old. All other population subgroups occupy <1% of the aPAD. In addition, there is

potential for acute dietary exposure to fluazinam in drinking water. After calculating DWLOCs and comparing them to the EECs for surface and ground

water, EPA does not expect the aggregate exposure to exceed 100% of the aPAD, as shown in the following Table 3:

TABLE 3.—AGGREGATE RISK ASSESSMENT FOR ACUTE EXPOSURE TO FLUAZINAM

Population Subgroup	aPAD (mg/kg)	% aPAD (Food)	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Acute DWLOC (ppb)
U.S. Population	0.17	<1%	18	0.10	5,900
Adult Male 20+ yrs	0.17	<1%	18	0.10	5,900
Adult Female 13–50 yrs	0.007	2%	18	0.10	210
Children 1–6 yr	0.17	<1%	18	0.10	1,700

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that exposure to fluazinam from food will utilize 8% of the cPAD for the U.S. population and 11% of the cPAD for the most highly exposed population

subgroup, females 13–50 years old. There are no residential uses for fluazinam that result in chronic residential exposure to fluazinam. There is potential for chronic dietary exposure to fluazinam in drinking water. After calculating DWLOCs and comparing

them to the EECs for surface and ground water, EPA does not expect the aggregate exposure to exceed 100% of the cPAD, as shown in the following Table 4:

TABLE 4.—AGGREGATE RISK ASSESSMENT FOR CHRONIC (NON-CANCER) EXPOSURE TO FLUAZINAM

Population Subgroup	cPAD mg/kg/day	%cPAD Food	Surface Water EEC (ppb)	Ground Water EEC (ppb)	Chronic DWLOC (ppb)
U.S. Population	0.0037	8	3.15	0.10	120
Adult Male 13–19 yrs	0.0037	<1	3.15	0.10	130
Adult Female 13–50 yrs	0.0037	11	3.15	0.10	99
Children 1–6 yrs	0.0037	1	3.15	0.10	37

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.* In accordance with the EPA Draft Guidelines for Carcinogen Risk Assessment (July, 1999), the Agency classified fluazinam into the category Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential based on the following weight-of-the-evidence considerations:

i. There was some evidence in that fluazinam induced an increase in thyroid gland follicular cell tumors in male rats, but not in female rats. In one study in mice, there was clear evidence that an increased incidence of hepatocellular tumors observed in the male mice was treatment-related. In another study in mice, there was equivocal/some evidence that fluazinam may have induced an increase in hepatocellular tumors in the male mice. Increases in hepatocellular tumors observed in the female mice in the latter study were not statistically significant and some occurred at an excessively toxic dose level. The thyroid gland follicular cell tumors of concern were seen only in male rats and the hepatocellular tumors of concern were seen only in male mice.

ii. Fluazinam was negative in mutagenicity assays.

Based on the 1999 draft Agency Cancer Risk Assessment Guidelines, the classification of suggestive evidence of carcinogenicity a dose-response assessment is not indicated (i.e. no Q*, no MOE) therefore, sufficient protection is afforded by the RFD approach so a risk assessment was not performed.

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, and to infants and children from aggregate exposure to fluazinam residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

For fluazinam, the gas chromatography/electron capture detection (GC/ECD) methods are adequate for collecting data on residues of fluazinam per se in/on peanuts and potatoes and have a validated limit of quantitation of 0.01 ppm in/on all associated plant matrices. The method has been adequately radiovalidated, and has undergone a successful ILV trial in conjunction with the time-limited tolerance petition for use on peanuts. The method has been forwarded to the Analytical Chemistry Branch (ACB) for a petition method validation to determine if it is suitable as an enforcement method. ACB has determined that the method is suitable for collecting pesticide residue monitoring data and food tolerance enforcement of fluazinam in/on peanut nutmeat.

This method is currently being validated by the Analytical Chemistry Branch Laboratories, BEAD (7503C),

Office of Pesticide Programs. Upon successful completion of the EPA validation and the granting of this registration, the method will be forwarded to FDA for publication in a future revision of the Pesticide Analytical Manual, Vol-II (PAM-II). Prior to publication and upon request, the method will be available prior to the harvest season from the Analytical Chemistry Branch (ACB), BEAD (7503C), Environmental Science Center, 701 Mapes Road, Ft. George C. Meade, MD 20755-5350. Contact Francis D. Griffith, Jr., telephone (410) 305-2905, e-mail: griffith.francis@epa.gov. The analytical standards are also available from the EPA National Pesticide Standard Repository at the same location.

B. International Residue Limits

There are currently no Codex maximum residue levels established for residues of fluazinam on any crop.

C. Conditions

1. *Toxicology.* The toxicological database for fluazinam is adequate at this time to support the requested registration and tolerances according to Subdivision F Guideline requirements and 40 CFR 158.690. The Agency has determined that there is a high degree of confidence in the hazard endpoints and dose-response assessments conducted for this chemical. However, the Agency is requiring that the following additional toxicology studies be performed and submitted within a reasonable period of time in order to more clearly and fully characterize the toxicity of this chemical.

- 870.3465 28-Day inhalation toxicity in rats.

- 870.6300 Developmental neurotoxicity study in rats. Test material to be technical grade fluazinam containing the maximum level of Impurity-5 permitted in the current specification for technical grade fluazinam. The protocol should be submitted to EPA for comment before the start of the study and should include full neurohistopathological examination of dams.

- 870.6200 Subchronic neurotoxicity screening battery in rats (conditional requirement). Based on a consideration of the results in the developmental neurotoxicity study in rats required above (870.6300), the Agency will subsequently recommend whether a repeat of the subchronic neurotoxicity study in rats (870.6200) should also be required to support the registration of fluazinam.

2. *Residue chemistry.* The submitted potato processing studies did not

include quantifiable residues in the RAC samples. However, the tests were conducted at only 2.6–2.8X the proposed maximum rate instead of the required 5X rate, the maximum theoretical concentration factor for potatoes. Despite these factors, the Agency has concluded that it is unlikely that residues in processed potatoes will exceed the 0.02 ppm RAC tolerance based on the level of parent compound in the raw tuber being about 0.001 ppm in the plant metabolism study. However, for confirmatory purposes, the Agency is requiring the registrant to submit the following study as a condition of registration:

- 860.1850 Residue Chemistry. Potato processed commodity study at a higher treatment level of 5X).

V. Conclusion

Therefore, the tolerance is established for residues of fluazinam, 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine, in or on peanuts and potatoes at 0.02 ppm.

VI. Objections and Hearing Requests

Under section 408(g) of the FFDCA, as amended by the FQPA, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. The EPA procedural regulations which govern the submission of objections and requests for hearings appear in 40 CFR part 178. Although the procedures in those regulations require some modification to reflect the amendments made to the FFDCA by the FQPA of 1996, EPA will continue to use those procedures, with appropriate adjustments, until the necessary modifications can be made. The new section 408(g) provides essentially the same process for persons to “object” to a regulation for an exemption from the requirement of a tolerance issued by EPA under new section 408(d), as was provided in the old FFDCA sections 408 and 409. However, the period for filing objections is now 60 days, rather than 30 days.

A. What Do I Need to Do to File an Objection or Request a Hearing?

You must file your objection or request a hearing on this regulation in accordance with the instructions provided in this unit and in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket control number OPP-301160 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 on or before November 6, 2001.

1. *Filing the request.* Your objection must specify the specific provisions in the regulation that you object to, and the grounds for the objections (40 CFR 178.25). If a hearing is requested, the objections must include a statement of the factual issues(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). Information submitted in connection with an objection or hearing request may be claimed confidential by marking any part or all of that information as CBI. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the information that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice.

Mail your written request to: Office of the Hearing Clerk (1900), Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. You may also deliver your request to the Office of the Hearing Clerk in Rm. C400, Waterside Mall, 401 M St., SW., Washington, DC 20460. The Office of the Hearing Clerk is open from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Office of the Hearing Clerk is (202) 260-4865.

2. *Tolerance fee payment.* If you file an objection or request a hearing, you must also pay the fee prescribed by 40 CFR 180.33(i) or request a waiver of that fee pursuant to 40 CFR 180.33(m). You must mail the fee to: EPA Headquarters Accounting Operations Branch, Office of Pesticide Programs, P.O. Box 360277M, Pittsburgh, PA 15251. Please identify the fee submission by labeling it “Tolerance Petition Fees.”

EPA is authorized to waive any fee requirement “when in the judgement of the Administrator such a waiver or refund is equitable and not contrary to the purpose of this subsection.” For additional information regarding the waiver of these fees, you may contact James Tompkins by phone at (703) 305-5697, by e-mail at tompkins.jim@epa.gov, or by mailing a request for information to Mr. Tompkins at Registration Division (7505C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

If you would like to request a waiver of the tolerance objection fees, you must mail your request for such a waiver to: James Hollins, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental

Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460.

3. *Copies for the Docket.* In addition to filing an objection or hearing request with the Hearing Clerk as described in Unit VI.A., you should also send a copy of your request to the PIRIB for its inclusion in the official record that is described in Unit I.B.2. Mail your copies, identified by docket control number OPP-301160, to: Public Information and Records Integrity Branch, Information Resources and Services Division (7502C), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460. In person or by courier, bring a copy to the location of the PIRIB described in Unit I.B.2. You may also send an electronic copy of your request via e-mail to: *opp-docket@epa.gov*. Please use an ASCII file format and avoid the use of special characters and any form of encryption. Copies of electronic objections and hearing requests will also be accepted on disks in WordPerfect 6.1/8.0 or ASCII file format. Do not include any CBI in your electronic copy. You may also submit an electronic copy of your request at many Federal Depository Libraries.

B. When Will the Agency Grant a Request for a Hearing?

A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issues(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

VII. Regulatory Assessment Requirements

This final rule establishes a tolerance under FFDC section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this rule has been exempted from review under Executive Order 12866 due to its lack of significance, 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). 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); or OMB review or any other Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). 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). Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply. In addition, the Agency has determined that this action will not have a substantial direct effect on States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999). Executive Order 13132 requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that have “substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.” This final rule directly regulates growers, food processors, food handlers and food retailers, not States. This action does not alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC section 408(n)(4).

For these same reasons, the Agency has determined that this rule does not have any tribal implications as described in Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 6, 2000). Executive Order 13175, requires EPA to develop an accountable process to ensure meaningful and timely input by tribal officials in the development of

regulatory policies that have tribal implications. Policies that have tribal implications is defined in the Executive Order to include regulations that have substantial direct effects on one or more Indian tribes, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. This rule will not have substantial direct effects on tribal governments, on the relationship between the Federal government and Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes, as specified in Executive Order 13175. Thus, Executive Order 13175 does not apply to this rule.

VIII. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: August 9, 2001.

Anne E. Linday,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346(a) and 371.

2. Section 180.574 is added to read as follows:

§ 180.574 Fluazinam; tolerances for residues.

(a) *General.* 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 the following commodities:

Commodity	Parts per million
Peanuts	0.02
Potatoes	0.02

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

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

(d) *Indirect or inadvertent residues.* [Reserved]

[FR Doc. 01-22525 Filed 9-6-01; 8:45 am]

BILLING CODE 6560-50-S

NATIONAL SCIENCE FOUNDATION**45 CFR Part 670****Conservation of Antarctic Animals and Plants**

AGENCY: National Science Foundation.

ACTION: Final rule.

SUMMARY: The National Science Foundation (NSF) is amending its regulations to designate two additional Antarctic Specially Protected Areas (ASPAs) and to correct some typographical errors. These regulations, pursuant to the Antarctic Conservation Act of 1978, as amended, are being revised to reflect recommendations adopted by the Antarctic Treaty parties at the 15th and 21st Antarctic Treaty Consultative Meeting.

DATES: Effective September 7, 2001.

FOR FURTHER INFORMATION CONTACT: Anita Eisenstadt, Office of the General Counsel, at 703-292-8060, National Science Foundation, 4201 Wilson Boulevard, Room 1265, Arlington, Virginia 22230.

SUPPLEMENTARY INFORMATION: The Antarctic Conservation Act of 1978, as amended, (“ACA”) (16 U.S.C. 2401 *et seq.*) implements the Protocol on Environmental Protection to the Antarctic Treaty (“the Protocol”). Annex II of the Protocol contains provisions for conservation of native Antarctic plants and animals. Annex V contains provisions for the protection of specially designated areas. Section 6 of the ACA, (16 U.S.C. 2405), as amended, directs the Director of the National Science Foundation to issue such regulations as are necessary and

appropriate to implement Annexes II and V to the Protocol.

The Antarctic Treaty Parties periodically adopt measures to establish additional specially protected areas. At the 15th Antarctic Treaty Consultative Meeting (ATCM) held in Rio de Janeiro in 1987, the Parties adopted Recommendation XIV-5 that added as a specially protected area the Summit of Mt. Melbourne, North Victoria Land. This site was previously included in the list of specially protected areas in 45 CFR part 670. However, in the 1998 amendments to 45 CFR part 670 [63 FR 50164 (September 21, 1998)], the site was inadvertently omitted from the list. At the 21st ATCM in Christchurch, New Zealand in 1997, the Parties adopted Measure 3 (1997) that added as a specially protected area Botany Bay, Cape Geology, Victoria Land. The rule is being revised to add these two specially protected areas. No public comment is needed because the addition of these two sites merely implements measures adopted at the ATCM.

Finally, these amendments correct typographical errors in the names of several species designated as native birds in § 670.20, and one species designated as a specially protected species in § 670.25.

Determinations

NSF has determined, under the criteria set forth in Executive Order 12866, that this rule is not a significant regulatory action requiring review by the Office of Management and Budget. This rule involves a foreign affairs function of the United States and is, therefore, exempt from the notice requirements of section 553 of the Administrative Procedures Act and from regulatory flexibility analysis requirements of the Regulatory Flexibility Act, 5 U.S.C. 601-612. Although this rule is exempt from the Regulatory Flexibility Act, it has nonetheless been determined that this rule will not have a significant impact on a substantial number of small businesses. For purposes of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), these amendments to the existing regulations do not change the collection of information requirements contained in NSF’s existing regulations, which have already have been approved by the Office of Management and Budget (OMB No. 3145-0034). Finally, NSF has reviewed this rule in light of section 2 of Executive Order 12778 and certifies that this rule meets the applicable standards provided in sections 2(a) and 2(b) of that order.

List of Subjects in 45 CFR Part 670

Administrative practice and procedure, Antarctica, Exports, Imports, Plants, Reporting and recordkeeping requirements, Wildlife.

Dated: August 29, 2001.

Lawrence Rudolph,

General Counsel, National Science Foundation.

Pursuant to the authority granted by 16 U.S.C. 2405(a)(1), NSF hereby amends 45 CFR part 670 as set forth below:

PART 670—[AMENDED]

1. The authority citation for Part 670 continues to read as follows:

Authority: 16 U.S.C. 2405, as amended.

2. Section 670.20 is revised to read as follows:

§ 670.20 Designation of native birds.

The following are designated native birds:

Albatross

Black-browed—*Diomedea melanophris.*

Gray-headed—*Diomedea chrysostoma.*

Light-mantled sooty—*Phoebetria palpebrata.*

Wandering—*Diomedea exulans.*

Fulmar

Northern Giant—*Macronectes halli.*

Southern—*Fulmarus glacialisoides.*

Southern Giant—*Macronectes giganteus.*

Gull

Southern Black-backed—*Larus dominicanus.*

Jaeger

Parasitic—*Stercorarius parasiticus.*

Pomarine—*Stercorarius pomarinus*

Penguin

Adelie—*Pygoscelis adeliae.*

Chinstrap—*Pygoscelis antarctica.*

Emperor—*Aptenodytes forsteri.*

Gentoo—*Pygoscelis papua.*

King—*Aptenodytes patagonicus.*

Macaroni—*Eudyptes chrysolophus.*

Rockhopper—*Eudyptes crestatus.*

Petrel

Antarctic—*Thalassoica antarctica.*

Black-bellied Storm—*Fregatta tropica.*

Blue—*Halobaena caerulea.*

Gray—*Procellaria cinerea.*

Great-winged—*Pterodroma macroptera.*

Kerguelen—*Pterodroma brevirostris.*

Mottled—*Pterodroma inexpectata.*

Snow—*Pagodroma nivea.*

Soft-plumaged—*Pterodroma mollis.*

South-Georgia Diving—*Pelecanoides georgicus.*