



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460**

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

**MEMORANDUM**

**DATE:** 22 August 2007

**SUBJECT:** Fluazinam. Tolerance Petitions Requesting the Establishment of Permanent Tolerances (Associated with Section 3 Registration) for Food Use of the Herbicide on Edible-Podded Beans (Subgroup 6-A, Except Peas), Shelled Succulent Beans (Subgroup 6-B, Except Peas), Shelled Dried Beans (Subgroup 6-C, Except Peas), *Brassica* (Cole) Vegetables (Group 5), Bushberries (Subgroup 13-B), and Ginseng. Summary of Analytical Chemistry and Residue Data.

**Petition Numbers:** 6E7137, 6E7139  
**PC Code:** 129098  
**DP Number:** 335640  
**Decision Numbers:** 372193, 372348  
**Regulatory Citation:** 40CFR §180.574  
**Chemical Class:** Phenyl-pyridinamine Fungicide  
**Trade Name:** Omega 500F  
**MRID Numbers:** 46986701 & -02, 46986705 to -07,  
46990501 to -03, 46996601 & -02

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### Executive Summary

Fluazinam (with CAS registry number 79622-59-6, and CAS name 3-chloro-*N*-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine) is a non-systemic phenyl-pyridinamine fungicide currently registered for use on peanuts and potatoes. There is also a tolerance established for fluazinam in imported wine grapes (without US registration). Permanent tolerances are established for residues of fluazinam in peanuts and potatoes at 0.02 ppm (40CFR §180.574[a][1]), and in imported wine grapes at 3.0 ppm (40CFR §180.574[a][2]).

Interregional Research Project #4 (IR-4) has submitted petitions (PPs#6E7137, 6E7139) proposing the use of a formulation containing 4.17 pounds per gallon (lb/gal) of fluazinam (Omega 500F Agricultural Fungicide; EPA Registration #71512-1) on various crops. This end-use product (EP) is formulated as a flowable-suspension (F) concentrate. ISK Biosciences Corporation is the data submitter and registrant for the active ingredient (ai), fluazinam, in the US.

In PP#6E7139, IR-4 has requested registration of fluazinam for use on shelled succulent beans (Subgroup 6-B, except peas), shelled dried beans (Subgroup 6-C, except peas), and ginseng. In conjunction with these uses, IR-4 and ISK Biosciences have proposed the establishment of permanent tolerances for fluazinam in various crops, as listed below.

Ginseng.....	3.00 ppm
Bean, dry.....	0.01 ppm
Succulent-shelled legume vegetables subgroup 6-B, except peas.....	0.02 ppm

In PP#6E7137, IR-4 has requested registration of fluazinam for use on edible-podded beans (Subgroup 6-A, except peas), *Brassica* vegetables (Group 5), and bushberries (Subgroup 13-B). In conjunction with these uses, IR-4 and ISK Biosciences have proposed the establishment of permanent tolerances for fluazinam in various crops, as listed below. Individual tolerances were also requested for fluazinam in turnip leaves, a future member of the leafy *Brassica* greens subgroup 5-B, and for fluazinam in the future members of the bushberries subgroup 13-B, as approved by ChemSAC.

Edible-podded legume vegetables subgroup 6-A, except peas.....	0.15 ppm
Leafy <i>Brassica</i> greens subgroup.....	0.02 ppm
Turnip, leaves.....	0.02 ppm
Head and stem <i>Brassica</i> subgroup.....	0.01 ppm
Bushberry subgroup 13-B.....	4.5 ppm
Aronia berry.....	4.5 ppm
Blueberry, lowbush.....	4.5 ppm
Buffalo currant.....	4.5 ppm
Chilean guava.....	4.5 ppm
European barberry.....	4.5 ppm
Highbush cranberry.....	4.5 ppm
Honeysuckle.....	4.5 ppm
Jostaberry.....	4.5 ppm

Juneberry.....	4.5 ppm
Lingonberry.....	4.5 ppm
Native currant.....	4.5 ppm
Salal.....	4.5 ppm
Sea buckthorn.....	4.5 ppm

The nature of the residue in plants has been adequately delineated, based on acceptable potato, peanut, and grape metabolism studies reviewed previously (D257115; William Cutchin; 5/21/2001), along with an acceptable apple metabolism study submitted recently (MRID #46991301). At a meeting held on 11/28/2000, HED concluded that the residue of concern (ROC) in potatoes and peanuts (for both tolerance expression and dietary risk assessment purposes) was the parent compound only (D272624; William Cutchin; 4/23/2001). In wine grapes, both parent and AMGT were included in the ROC for tolerance expression and risk assessment. Additionally, HED determined that data generated for potential new uses on other crops (with the exception of root and tuber, and bulb vegetables) should include analyses for both parent and AMGT.

The nature of the residue in livestock is also understood, based on adequate goat and hen metabolism studies (D257115; William Cutchin; 5/21/2001). The fluazinam residues of regulatory interest in animals were determined by HED to be parent plus the metabolites AMPA and DAPA, and their sulfamate conjugates.

The submitted gas chromatography with electron-capture detection (GC/ECD) methods (modifications of the tolerance-enforcement method) are adequate for collecting data and enforcing tolerances for residues of fluazinam *per se* in the various crop commodities associated with this petition. The lowest level of method validation (LLMV) and/or limit of quantitation (LOQ) for residues of fluazinam *per se* were 0.010 ppm in all plant matrices except snap beans and lima beans, in which the LLMV/LOQ were 0.020 ppm. The tolerance-enforcement method, *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016), was adequately radiovalidated, and underwent a successful independent laboratory validation (ILV) trial. The method was forwarded to BEAD's Analytical Chemistry Branch (ACB) for a petition method validation (PMV) trial, and was subsequently determined to be suitable as a tolerance-enforcement method (D266802; Paul Golden; 6/22/2001).

The submitted high performance liquid chromatography with ultraviolet detection (HPLC/UV) method (a working method based on *Method Evaluation for the Analysis of AMGT in Grapes*, MRID #45593101) is adequate for collecting data and enforcing tolerances for AMGT residues in blueberries. The LLMV, limit of detection (LOD), and LOQ were 0.020, 0.013, and 0.038 ppm, respectively, for residues of AMGT in blueberries. HED has previously determined that residues of AMGT are to be regulated in wine grapes (D272624; William Cutchin; 4/23/2001). The Agency therefore requested that this method undergo an ILV trial, and, potentially, a PMV trial by the ACB. An ILV study has not yet been submitted.

The multiresidue method (MRM) testing data indicate that fluazinam is partially recovered through Sections 302, 303, and 304 of PAM Volume I, with its recovery being dependent on which Florisil elution system is used. The MRMs can serve as a confirmatory

procedure for residues of fluazinam. Data should also be provided for the metabolite AMGT, since it is included in the tolerance expression for grapes.

Adequate storage stability data were collected indicating that fluazinam residues were stable under frozen storage in blueberries, snap beans, and broccoli for the storage durations and conditions of the samples from the respective crop field trials. In blueberries, AMGT residues were stable under frozen storage for the storage durations and conditions of the samples from the blueberry field trials. However, storage stability studies indicated that there was significant dissipation of fluazinam residues under frozen storage in ginseng, lima beans, dried beans, cabbage, and mustard greens. Correction factors were therefore incorporated into the recommended tolerances for fluazinam in ginseng, shelled succulent beans, and shelled dried beans to account for dissipation during storage. A correction factor was not utilized when setting the recommended tolerance in *Brassica* leafy vegetables, because fluazinam applications made to cabbage and mustard greens were essentially identical to the treatment of broccoli (which had acceptable storage stability), and all residues in treated samples from the *Brassica* field trials were  $\leq$ LOQ ( $\leq$ 0.010 ppm).

The available crop field trial data are adequate, and support the proposed uses. Following treatment with fluazinam (F) at total seasonal rates ranging from 3.83 to 4.22 pounds ai per acre (lb ai/A), residues of fluazinam in treated blueberry samples ranged from 0.064 to 2.0 ppm, and residues of AMGT ranged from 0.025 to 0.13 ppm (with combined residues of 0.166-2.094 ppm) at the target pre-harvest interval (PHI) of 30 days (23-32 days). Following treatment with fluazinam (F) at total seasonal rates ranging from 0.881 to 0.921 lb ai/A, residues of fluazinam in treated snap bean samples ranged from  $<0.020$  to 0.109 ppm at the target PHI of 14 days (11-15 days). Residues of fluazinam were either less than or equal to the LLMV/LOQ (0.010 ppm) in all samples of broccoli, cabbage, or mustard greens harvested at PHIs ranging from 22 to 113 days after a single root-drench application of fluazinam (F) at a rate of 0.055 lb ai per 1000 plants. Following treatment with fluazinam (F) at total seasonal rates ranging from 3.13 to 3.39 lb ai/A, residues of fluazinam in treated ginseng samples ranged from 0.28 to 1.4 ppm at the target PHI of 30 days (29-31 days). Following treatment with fluazinam (F) at total seasonal rates ranging from 0.871 to 0.960 lb ai/A, residues of fluazinam in treated dried bean samples ranged from  $<0.010$  to 0.011 ppm at the target PHI of 30 days (31-57 days). Following treatment with fluazinam (F) at total seasonal rates ranging from 0.885 to 0.912 lb ai/A, residues of fluazinam in treated lima bean samples were all less than the LLMV (0.020 ppm) at the target PHI of 30 days (28-71 days). However, it was noted that residue data for AMGT were provided only for blueberries; AMGT data should also have been included with the field trial studies for edible-podded beans, shelled succulent and dried beans, and *Brassica* vegetables.

There are no processed commodities for which residue data are required associated with the proposed uses on the crops requested in the subject petitions under review.

There are no significant livestock feed items associated with the proposed uses on the crops requested in the subject petitions under review.

Regulatory requirements pertaining to fluazinam residues in rotational crops have been fulfilled, and the rotational crop restrictions on the proposed label are adequate.

There are no established or proposed Canadian or Codex Maximum Residue Limits (MRLs) for residues of fluazinam in plant or animal commodities. There are Mexican MRLs

established for residues of fluazinam in potato at 0.05 ppm, and in beans at 0.1 ppm. The International Residue Limit Status sheet is shown in Appendix 1.

### **Regulatory Recommendations and Residue Chemistry Deficiencies**

No major deficiencies were noted in the subject petition that would preclude the establishment of permanent tolerances for fluazinam residues in the requested crops. Revised Sections F should be submitted, so that the proposed tolerances reflect the recommended tolerance levels, and correct commodity definitions, as specified in Table 12. Issues pertaining to residue chemistry deficiencies should be resolved (see below).

**1. As a condition of registration, results of an ILV trial for the AMGT analytical method (with wine grapes) should be submitted by the registrant. If the registrant agrees with the modifications made by Ricerca to the original method (in MRID #45593101), these modifications should be incorporated into a revised method for the ILV. Sample sets should include, at the minimum, 2 control (untreated) samples of wine grapes, 2 samples fortified at the tolerance level (3.0 ppm), and 2 samples fortified at the LOQ (0.010 ppm).**

**2. As a condition of registration, MRM recovery data should be provided for the metabolite AMGT, since it is included in the tolerance expression for wine grapes.**

**3. The product label for Omega 500F should be amended to include a restriction, stating that turnip roots from turnip plants treated with this EP must not be used for human nor livestock consumption.**

**4. The Agency has previously determined, and the registrant is hereby advised again, that residue data for AMGT should be provided in the crop field trial studies for all future requested plant commodities, except root and tuber, and bulb vegetables.**

HED recommends in favor of establishing permanent tolerances for fluazinam in the requested crops, at the levels specified in Table 12.

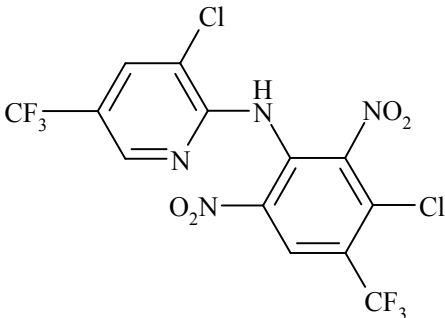
### **Background**

Fluazinam (Omega 500F Agricultural Fungicide) is a non-systemic, preventive, contact fungicide of the phenyl-pyridinamine class, with a multi-site mode of action. It disrupts the production of energy at several metabolic sites within the fungal cell. Fluazinam is a protectant fungicide; when applied to plants, it remains primarily on the plant surface, is not taken up to any extent by the plant, and is not translocated within the plant.

Fluazinam is currently registered for use on peanuts and potatoes. There is also a tolerance established for fluazinam in imported wine grapes (without US registration). Permanent tolerances have been established for residues of fluazinam in peanuts and potatoes at 0.02 ppm, and in imported wine grapes at 3.0 ppm.

IR-4 has submitted petitions (PPs#6E7137, 6E7139) proposing the use of a formulation containing 4.17 lb/gal of fluazinam (Omega 500F Agricultural Fungicide; EPA Registration #71512-1) on various crops. This EP is formulated as a flowable suspension concentrate. ISK

Biosciences Corporation is the data submitter and registrant for the ai, fluazinam, in the US. The nomenclature of fluazinam is summarized in Table 1 (below), and the physicochemical properties of fluazinam are summarized in Table 2 (below).

<b>TABLE 1. Test Compound Nomenclature.</b>	
Compound	Chemical Structure 
Empirical Formula	C <sub>13</sub> H <sub>4</sub> Cl <sub>2</sub> F <sub>6</sub> N <sub>4</sub> O <sub>4</sub>
Molecular Weight	465.1
Common Name	Fluazinam
Company Experimental Names	Fluazinam, IKF-1216
IUPAC Name	3-chloro- <i>N</i> -(3-chloro-5-trifluoromethyl-2-pyridyl)- $\alpha,\alpha,\alpha$ -trifluoro-2,6-dinitro- <i>p</i> -toluidine
CAS Name	3-chloro- <i>N</i> -[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine
CAS Number	79622-59-6
End-use Product/(EP)	Omega® 500F (USA); Allegro® 500F (Canada)

<b>TABLE 2. Physicochemical Properties of Fluazinam</b>		
Parameter	Value	Reference
Melting Point/Range	115-117°C	The e-Pesticide Manual (13 <sup>th</sup> Edition) Version 3.1
pH	5.85	MRID #43521001
Density (25°C)	1.02 g/cm <sup>3</sup> *	LSS 2000_1973_2LS_rev
Water Solubility (25°C)	(pH buffered to 5) 0.131 mg/L (pH buffered to 7) 0.157 mg/L (pH buffered to 9) 3.384 mg/L	LSS 2000_1973_2LS_rev

Parameter	Value		Reference
Solvent Solubility (25°C)	Solvent	Solubility (mg/mL)	LSS 2000_1973_2LS_rev
	acetone	853	
	dichloromethane	675	
	ethyl acetate	722	
	ethyl ether	231	
	hexane	8	
	methanol	192	
	octanol	41	
toluene	451		
Vapor Pressure	Temp (°C)	Vap. Press. (Pa)	LSS 2000_1973_2LS_rev
	25	$2.3 \times 10^{-5}$	
	35	$1.3 \times 10^{-4}$	
	45	$6.7 \times 10^{-5}$	
Dissociation Constant (pK <sub>a</sub> )	Average pK <sub>a</sub> = 7.22 in 50% ethanol/water (v/v)		LSS 2000_1973_2LS_rev
Octanol/Water Partition Coefficient (Log [K <sub>ow</sub> ])	1.08 x 10 <sup>4</sup> (Log K <sub>ow</sub> = 4.03)		LSS 2000_1973_2LS_rev
UV/Visible Absorption Spectrum	pH	λ <sub>max</sub> (nm)	Regulatory Note REG2003-12
	5	238	
	7	239, 342	
	>10	260, 343, 482	

\*REG2003-12 states the relative density as 1.76 g/cm<sup>3</sup>, temperature not stated.

### 860.1200 Directions for Use

IR-4 and ISK Biosciences are proposing the use of a flowable-suspension concentrate formulation containing 4.17 lb/gal of fluazinam (Omega 500F Agricultural Fungicide; EPA Registration #71512-1) on various crops. Copies of the proposed labels were provided, and the proposed uses on the requested crops are summarized in Table 3 (below).

In PP#6E7139, IR-4 has requested registration of fluazinam for use on shelled succulent beans (Subgroup 6-B, except peas), shelled dried beans (Subgroup 6-C, except peas), and ginseng. The proposed use pattern for Omega 500F to control white mold (*Sclerotinia sclerotiorum*) and gray mold (*Botrytis cinerea*) in shelled succulent and dried beans is up to two foliar applications (with the first made when 10-30% of plants have at least one open bloom) at rates of 0.26-0.45 lb ai/A per application (in water volume adequate to provide coverage of foliage and flowers). If need be, a second application may be made at a 7- to 10-day re-treatment interval (RTI), for a maximum total seasonal application rate of 0.90 lb ai/A, with a minimum PHI of 30 days. The proposed use pattern to control Rhizoctonia root rot (*Rhizoctonia solani*) in ginseng is up to 6 broadcast applications (with the first made at transplant) at a rate of 0.52 lb ai/A, with subsequent applications repeated at 14-day RTIs. The proposed use pattern to control *alternaria* blight (*Alternaria panax*), *botrytis* blight (*Botrytis cinerea*), and white mold (*Sclerotinia spp.*) in ginseng is up to 4-6 broadcast applications (with the first made when disease

first appears, or when conditions are favorable for disease development) at rates of 0.52-0.78 lb ai/A, with subsequent applications repeated (as needed) at 7- to 14-day RTIs. Applications should be made in a minimum spray volume of 100 gal/A. The proposed maximum total seasonal use rate is 3.1 lb ai/A, and the proposed minimum PHI is 30 days.

In PP#6E7137, IR-4 has requested registration of fluazinam for use on edible-podded beans (Subgroup 6-A, except peas), *Brassica* vegetables (Group 5), and bushberries (Subgroup 13-B). The proposed use pattern for Omega 500F to control white mold (*Sclerotinia sclerotiorum*) and gray mold (*Botrytis cinerea*) in edible-podded beans is up to two foliar applications (with the first made when 10-30% of plants have at least one open bloom) at rates of 0.26-0.45 lb ai/A per application (in water volume adequate to provide coverage of foliage and flowers). If need be, a second application may be made at a 7- to 10-day RTI, for a maximum total seasonal application rate of 0.90 lb ai/A, with a minimum PHI of 14 days. The proposed use pattern to control clubroot (*Plasmodiophora Brassicae*) in Crop Group 5, *Brassica* (Cole) leafy vegetables, is either:

1. a single soil-drench application (immediately after transplanting seedlings), made at a rate of 0.055 lb ai/1000 plants, prepared as a solution of 6.45 fluid ounces of the EP in 100 gal of water, with 3.4 fluid ounces (100 mL) of solution applied per plant; or
2. if desired, and for soil with low infiltration rates, a single soil-incorporation application (immediately prior to transplanting seedlings), made at a rate of 1.35 lb ai/A in a minimum bandwidth of 9 inches along the planting row, and incorporated to a soil depth of 6-8 inches, in a minimum water volume of 50 gal/A. If planting into a bed, a broadcast application may be made prior to forming the bed.

The proposed maximum total seasonal use rate is 2.0 lb ai/A, and the proposed minimum PHI is 20 days for leafy greens, and 50 days for heading vegetables. The proposed use pattern to control twig blight/fruit rot (*Phomopsis vaccinii*), anthracnose ripe rot (*Colletotrichum acutatum* and *Colletotrichum gloeosporiaoides*), and *botrytis* fruit rot (*Botrytis cinerea*) in bushberries is up to 6 foliar applications at a rate of 0.65 lb ai/A per application (in water volume adequate to provide coverage of foliage, flowers, and fruit). The first application should be made at the green tip stage, with subsequent applications repeated at 7- to 10-day RTIs (roughly corresponding to applications at pink tip, early bloom, full bloom, blossom drop, and small green fruit to some blue fruit). The proposed maximum total seasonal use rate is 3.9 lb ai/A, and the proposed minimum PHI is 30 days.

Applications of Omega 500F are to be made using ground equipment or chemigation (application via irrigation equipment) only. Aerial application of this EP is prohibited.



TABLE 3. Summary of Directions for Use of Fluazinam.						
Application Timing; Type; and Equipment <sup>1</sup>	Formulation <sup>2</sup>	Use Rate (lb ai/A)	Maximum # of Uses per Season	Maximum Seasonal Use Rate (lb ai/A)	PHI (Days)	Use Directions and Limitations
<b>Shelled Succulent and Dried Beans</b>						
At 10-30% bloom; foliar; spray.	Omega 500F	0.26-0.45	2	0.90	30	RTI = 7-10 days. Volume adequate to cover foliage and flowers.
<b>Ginseng</b>						
At transplant (for root rot); broadcast; spray.	Omega 500F	0.52	6	3.1	30	RTI = 14 days. Spray volume ≥ 100 gal/A.
At disease appearance or favorable conditions (for blight/white mold); broadcast; spray.		0.52-0.78	4-6			RTI = 7-14 days. Spray volume ≥ 100 gal/A.
<b>Edible-Podded Beans</b>						
At 10-30% bloom; foliar; spray.	Omega 500F	0.26-0.45	2	0.90	14	RTI = 7-10 days. Volume adequate to cover foliage and flowers.
<b>Brassica (Cole) Vegetables</b>						
At transplant; soil drench; spray.	Omega 500F	0.055 lb ai/1000 plants	1	2.0	20/50 <sup>3</sup>	6.45 oz EP/100 gal water, 3.4 oz (100 mL)/plant
Prior to transplant; soil incorporation; precision incorporator.		1.35				Band width ≥9", soil depth 6-8". Spray volume ≥ 50 gal/A.
Prior to forming bed; broadcast; spray.		2.0				Spray volume ≥ 50 gal/A.
<b>Bushberries</b>						
1Green tip, 2pink tip, 3early bloom, 4full bloom, 5blossom drop, 6small green fruit/some blue fruit; foliar; spray.	Omega 500F	0.65	6	3.9	30	RTI = 7-10 days. Volume adequate to cover foliage, flowers, and fruit.

1. Applications of Omega 500F are to be made using ground equipment or chemigation (application via irrigation equipment) only. Aerial application of this EP is prohibited.
2. Omega 500F is a flowable suspension concentrate containing 4.17 lb/gal of fluazinam.
3. PHI = 20 days for *Brassica* leafy greens, and 50 days for *Brassica* heading vegetables.

**Conclusion:** The proposed label directions are adequate, and are supported by the available field trial data. **The product label for Omega 500F should be amended to include a restriction, stating that turnip roots from turnip plants treated with this EP must not be used for human nor livestock consumption.**

#### 860.1300 Nature of the Residue – Plants

**MARC Decision Memo D272624; William Cutchin; 4/23/2001****Residue Chemistry Memo D257115; William Cutchin; 5/21/2001**

The nature of the residue in plants has been adequately delineated, based on acceptable potato, peanut, and grape metabolism studies reviewed previously (D257115; William Cutchin; 5/21/2001), along with an acceptable apple metabolism study submitted recently (MRID #46991301). The metabolism of fluazinam appears to be similar in potatoes, peanuts, grapes, and apples. Fluazinam undergoes reduction of one of the nitro groups to an amine, forming AMPA. AMPA may then be conjugated with glutathione, with subsequent degradation of the glutathione moiety to cysteine. The AMPA-cysteine conjugate then undergoes transamination, reduction, and conjugation with glucose to form AMGT. In addition, both rings of fluazinam appear to be labile to ring cleavage, and subsequent degradation of the rings into small fragments that may then be incorporated into a variety of natural plant components. At a meeting held on 11/28/2000, HED concluded that the ROC in potatoes and peanuts (for both tolerance expression and dietary risk assessment purposes) was the parent compound only (D272624; William Cutchin; 4/23/2001). In wine grapes, both parent and AMGT were included in the ROC for tolerance expression and risk assessment. Additionally, HED determined that data generated for potential new uses on other crops (with the exception of root and tuber, and bulb vegetables) should include analyses for both parent and AMGT.

**860.1300 Nature of the Residue - Livestock****MARC Decision Memo D272624; William Cutchin; 4/23/2001****Residue Chemistry Memo D257115; William Cutchin; 5/21/2001**

The nature of the residue in livestock is also understood, based on adequate goat and hen metabolism studies (D257115; William Cutchin; 5/21/2001). The metabolism of [<sup>14</sup>C]-fluazinam in ruminants and poultry is similar, and involves reduction of one or both nitro groups on the phenyl ring to form AMPA, MAPA, or DAPA. Fluazinam also undergoes dehalogenation and hydroxylation of the chlorine on the phenyl ring to form HYPA. These compounds may then undergo conjugation with glutathione, and subsequent degradation of the glutathione component yields a variety of polar compounds. Although the ring structure of the parent molecule remains intact, fluazinam *per se* was only a minor component ( $\leq 2.7\%$  TRR) of the [<sup>14</sup>C]-residues in poultry tissues and eggs, and was not detected in ruminant tissues or milk. The fluazinam residues of regulatory interest in animals were determined by HED to be parent plus the metabolites AMPA and DAPA, and their sulfamate conjugates.

**860.1340 Residue Analytical Methods – Plants****PMV Results Memo D266802; Paul Golden; 6/22/2001**

**Fluazinam:** The tolerance-enforcement method, *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016), was adequately radiovalidated. This GC/ECD method for determining residues of fluazinam *per se* was originally reviewed in conjunction with the time-limited tolerance petition for peanuts (D177127 and D177137; George Herndon; 6/19/1992). In brief, residues of fluazinam are extracted from crop samples with MeOH/acetic acid (HOAc) (50:1, v/v), filtered, acidified with 0.2N HCl, and partitioned into hexane. Residues are then partitioned into 0.5N NaOH, the aqueous phase is acidified, and residues are partitioned back into hexane. The resulting hexane fraction is concentrated, and residues are purified using a

Florisil column, then analyzed by GC/ECD. The petitioner achieved adequate recoveries of fluazinam from peanut nutmeat samples fortified with fluazinam at 0.010-1.00 ppm.

This method has undergone a successful ILV trial (D212612, D216941, and D217467; George Herndon; 9/5/1995) using peanut nutmeats fortified with fluazinam at 0.010, 0.020, and 0.050 ppm. Recoveries at the 0.010 ppm level were low (56% and 68%) owing to an interference peak; therefore, the validated LOQ would be 0.020 ppm. However, the independent laboratory noted that the method could possibly be improved in the Florisil clean-up step. The method was forwarded to ACB for a PMV trial, and was subsequently determined to be suitable as a tolerance-enforcement method (D266802; Paul Golden; 6/22/2001).

The submitted GC/ECD methods (modifications of the tolerance-enforcement method) are adequate for collecting data on residues of fluazinam *per se* in the various crop commodities associated with this petition. The LLMV and/or LOQ for residues of fluazinam *per se* were 0.010 ppm in all plant matrices except snap beans and lima beans, in which the LLMV and LOQ were 0.020 ppm.

**AMGT:** The submitted HPLC/UV method (a working method based on *Method Evaluation for the Analysis of AMGT in Grapes*, MRID #45593101) is adequate for collecting data on AMGT residues in blueberries. Blueberries were blended with acetonitrile (ACN)/water (4:1, v:v), and filtered. The filter paper with contents was extracted a second time. The combined solvent extract was then concentrated by evaporation. The sample was partitioned with 2% aqueous Na<sub>2</sub>SO<sub>4</sub> and methylene chloride. The aqueous layer was acidified to a pH of <1 with 6N HCl, then partitioned twice with EtOAc, and the organic phase was evaporated to dryness. The aqueous sample was applied to a C<sub>18</sub> SPE column, and AMGT was eluted with ACN/water (3:7; v:v). After evaporation to dryness, the sample was taken up in ACN/H<sub>2</sub>O/HOAc, and filtered through a 0.45 µm PTFE disc prior to analysis by HPLC/UV at 256 nm. The LLMV, LOD, and LOQ were 0.020, 0.013, and 0.038 ppm, respectively, for residues of AMGT in blueberries. HED has previously determined that residues of AMGT are to be regulated in wine grapes (D272624; William Cutchin; 4/23/2001). The Agency therefore requested that this method undergo an ILV trial, and, potentially, a PMV trial by the ACB. An ILV study has not yet been submitted.

**Conclusion:** The CG/ECD methods, based on the tolerance-enforcement method, are adequate for collecting data and enforcing tolerances for fluazinam residues in the various crop commodities associated with this petition. The submitted HPLC/UV method is adequate for collecting data and enforcing tolerances for AMGT residues in blueberries. **As a condition of registration, an ILV for the AMGT analytical method (with wine grapes) should be submitted by the registrant. If the registrant agrees with the modifications made by Ricerca to the original method (in MRID #45593101), these modifications should be incorporated into a revised method for the ILV. Sample sets should include, at minimum, 2 control (untreated) samples of wine grapes, 2 samples fortified at the tolerance level (3.0 ppm), and 2 samples fortified at the LOQ (0.010 ppm).**

#### 860.1340 Residue Analytical Methods – Livestock

As there are currently no tolerances established in livestock commodities, and none are needed as a result of the requested uses, residue analytical methods for livestock commodities are not required.

#### 860.1360 Multiresidue Methods

Data depicting the analysis of fluazinam through FDA MRM Protocols were submitted, and have been forwarded to FDA for review (Letter from William Cutchin to Mark Wirtz; 8/16/2000). The MRM testing data indicate that fluazinam is partially recovered through Sections 302, 303, and 304 of PAM Volume I, with its recovery being dependent on which Florisil elution system is used. The MRMs can serve as a confirmatory procedure for residues of fluazinam. **As a condition of registration, MRM data should also be provided for the metabolite AMGT, since it is included in the tolerance expression for grapes.**

#### 860.1380 Storage Stability

Adequate storage stability data were collected indicating that fluazinam residues were stable under frozen storage in blueberries, snap beans, and broccoli for the storage durations and conditions of the samples from the respective crop field trials. In blueberries, AMGT residues were stable under frozen storage for the storage durations and conditions of the samples from the blueberry field trials (see Table 4, below). However, storage stability studies indicated that there was significant dissipation of fluazinam residues under frozen storage in ginseng, lima beans, dried beans, cabbage, and mustard greens. Correction factors were therefore incorporated into the recommended tolerances for fluazinam in ginseng, shelled succulent beans, and shelled dried beans to account for dissipation during storage (see Table 5, below). A correction factor was not utilized when setting the recommended tolerance in *Brassica* leafy vegetables, because fluazinam applications made to cabbage and mustard greens were essentially identical to the treatment of broccoli (which had acceptable storage stability), and all residues in treated samples from the *Brassica* field trials were  $\leq$ LOQ ( $\leq$ 0.010 ppm). At the time of submission, the freezer storage stability analyses were not completed for the AAFC cabbage field trial. A final report is expected shortly. Pending submission of the final report for AAFC Project AAFC03-066R, the storage stability data generated for IR-4 Project 08796 are adequate to support the storage conditions and durations of the cabbage samples from the AAFC field trial.

Crop [Matrix]	Analyte	Storage Temperature (°C)	Actual Storage Duration (Days)	Interval of Demonstrated Storage Stability (Days)
Blueberry [Berry]	Fluazinam	-21 ± 7	162	203
	AMGT		229	251

Crop [Matrix]	Storage Temperature (°C)	Actual Storage Duration (Days)	Interval of Demonstrated Storage Stability (Days)
Snap Bean [Succulent Seed with Pod]	-38 to -1 <sup>1</sup>	377	377

<b>Crop [Matrix]</b>	<b>Storage Temperature (°C)</b>	<b>Actual Storage Duration (Days)</b>	<b>Interval of Demonstrated Storage Stability (Days)</b>
Broccoli [Flower Head & Stem] (IR-4 Project 08795)	-21 ± 7	146	205
Broccoli [Flower Head & Stem] (AAFC Project AAFC03-018)	-26.3 to -10.2	179	232
Cabbage [Head with Wrapper Leaves] (IR-4 Project 08796)	-23 to -4	560	560 <sup>2</sup>
Cabbage [Head with Wrapper Leaves] (AAFC Project AAFC03-066R)	<-16.7	180	Interim report only; refer to SS data for IR-4 Project 08796.
Mustard Greens [Leaves] (IR-4 Project 08797)	-23 to -4	621	580 <sup>3</sup>
Ginseng [Dried Root]	-21 ± 7	332	347 <sup>4</sup>
Dried Bean [Shelled Dried Seed]	-38 to -1	245	307 <sup>5</sup>
Lima Bean [Shelled Succulent Seed]	-38 to -1	254	455 <sup>6</sup>

1. Except for one 6-hour period at 6°C, owing to compressor failure.
2. Results from the concurrent freezer storage stability studies indicated that significant dissipation of residues occurred (~70%) during the storage interval.
3. Results from the concurrent freezer storage stability studies indicated that significant dissipation of residues occurred (~55%) during the storage interval.
4. Results from the concurrent freezer storage stability studies indicated that significant dissipation of residues occurred (~30%) during the storage interval.
5. Results from the concurrent freezer storage stability studies indicated that significant dissipation of residues occurred (~45%) during the storage interval.
6. Results from the concurrent freezer storage stability studies indicated that significant dissipation of residues occurred (~40%) during the storage interval.

**Conclusion:** The available data adequately support the storage durations and conditions for the current blueberry, snap bean, and *Brassica* field trials. To account for dissipation during frozen storage, correction factors have been incorporated into the recommended tolerances for fluazinam residues in ginseng, shelled succulent beans, and shelled dried beans.

#### **860.1400 Water, Fish, and Irrigated Crops**

This guideline requirement is not relevant to the current petitions, as the proposed uses are non-aquatic.

#### **860.1460 Food Handling**

This guideline requirement is not relevant to the current petitions, as no uses are being proposed for food/feed handling establishments.

#### **860.1480 Meat, Milk, Poultry, and Eggs**

This guideline requirement is not relevant to the current petitions, as there are currently no tolerances established in livestock commodities, and there are no significant livestock feed items associated with the proposed uses.

#### **860.1500 Crop Field Trials**

**DER for MRID #46986701 (Blueberry)**

**Blueberry:** Thirteen magnitude of the residue trials were conducted in Canadian and US growing regions (in 2003-2004) for fluazinam on blueberries. Four trials were located in Canada in Region 1A (2 in Prince Edward Island, 1 in Nova Scotia), and Region 5A (1 in Quebec). Nine trials were located in the US in Region 1 (1 in Maine), Region 2 (2 in New Jersey, 1 in North Carolina), Region 5 (US)/5A (Canada) (3 in Michigan), Region 11 (1 in Washington), and Region 12 (1 in Oregon). Fluazinam was applied as six foliar applications (at rates of 0.62 to 0.72 lb ai/A per application) to blueberries with RTIs of 3-9 days, for total seasonal use rates ranging from 3.83 to 4.05 lb ai/A. There were 2 treated plots at each site (except in NS), with the applications in one plot timed to harvest at a 30-day PHI, and the applications in the second plot timed to harvest at a 50-day PHI. At the NS trial, only the 30-day PHI regime was conducted. Applications were made using ground equipment, in spray volumes of 30.2 to 61.4 gallons per acre (GPA); spray adjuvants were not used at any of the trial sites.

Residue analysis for fluazinam in blueberries was conducted using an analytical method entitled *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016). Residue analysis for the metabolite AMGT was conducted using *Method Evaluation for the Analysis of AMGT in Grapes* (MRID #45593101). Concurrent recoveries were measured in samples fortified with fluazinam at 0.010 ppm, 0.100 ppm, 1.00 ppm, and 3.00 ppm (1X, 10X, 100X, and 300X the LLMV), and in samples fortified with AMGT at 0.020 ppm, 0.100 ppm, 0.200 ppm, and 1.00 ppm (1X, 5X, 10X, and 50X the LLMV). Individual recoveries of fluazinam (n = 31) ranged from 60-140% across all spike levels, while recoveries of AMGT (n = 35) ranged from 58-125%. At each fortification level, average recoveries were within the generally recognized acceptable range (70-120%) except for 4 samples spiked with 0.010 ppm fluazinam (140, 60, 66, and 140% recovery), 1 sample spiked with 1.00 ppm fluazinam (140% recovery), 2 samples spiked with 0.020 ppm AMGT (125 and 65% recovery), and 3 samples spiked with 0.100 ppm AMGT (58, 68, and 68% recovery). Overall, peaks were well-defined and symmetrical in all chromatograms. Untreated control sample chromatograms for fluazinam were free from interference above the chromatographic background. Three untreated control samples showed identifiable peaks at or near the retention time for AMGT (ranging from 0.0333 to 0.1307 ppm). Treated sample chromatograms showed analyte peaks within the area of analytical interest; no carryover was observed in control samples. Detector linearity for fluazinam was demonstrated across the range of residues ( $r^2 > 0.9834$ ). Calibration curves were not provided for AMGT.

The number and geographical distribution of the blueberry field trials were in accordance with OPPTS Residue Chemistry Test Guideline 860.1500. Since the petitioner is also seeking registration of fluazinam for use on bushberries in Canada, additional field trials were conducted in the Canadian provinces of Prince Edward Island, Nova Scotia, and Quebec.

Treated and control blueberry samples were stored frozen (at  $-21 \pm 7^\circ\text{C}$ ) for durations of up to 162 days (fluazinam) and 229 days (AMGT). A concurrent freezer storage stability study was conducted in blueberry samples fortified with fluazinam (at 0.10 ppm) and AMGT (at 0.15 ppm). Residues in the concurrent freezer storage stability samples remained stable for intervals of 203 days (fluazinam) and 251 days (AMGT). Therefore, there are no concerns with the stability of residues over time in this study.

Residues of fluazinam (summarized in Table 6, below) in treated blueberry samples ranged from 0.064 to 2.0 ppm, and residues of AMGT ranged from 0.025 to 0.13 ppm (with combined residues of 0.166-2.094 ppm) at the target PHI of 30 days (23-32 days). Residues of fluazinam ranged from 0.017-1.1 ppm, and residues of AMGT ranged from <0.020-0.12 ppm (with combined residues of 0.054-1.164 ppm) at the target PHI of 50 days (43-51 days). At three of the trial sites, residue behaviour was also assessed 7 or 8 days after the initial samples were harvested (PHI of 38 or 39 days). At two of the three sites (03-NJ32, 03-NJ33), residues declined with longer PHIs, but residues increased with the longer PHI at the third site (03-MI34).

TABLE 6. Summary of Residue Data from Blueberry Field Trials with Fluazinam.									
Crop [Matrix]	Total Use Rate (lb ai/A)	PHI (Days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT <sup>1</sup>	Median	Mean	Std. Dev.
<b>Fluazinam</b>									
Blueberry [Berry]	3.79-4.07	23-32	23 <sup>2</sup>	0.064	2.0	1.8	0.55	0.740	0.61
	3.83-4.22	38-39	6	0.22	0.42	0.38	0.28	0.30	0.070
	3.83-4.03	43-51	23	0.017	1.1	0.98	0.16	0.272	0.279
<b>AMGT</b>									
Blueberry [Berry]	3.79-4.07	23-32	23 <sup>2</sup>	0.025	0.13	0.125	0.084	0.08	0.032
	3.83-4.22	38-39	6	0.032	0.17	0.165	0.04	0.080	0.066
	3.83-4.03	43-51	23	<0.020 <sup>3</sup>	0.12	0.11	0.056	0.055	0.030
<b>Combined Residues (Fluazinam and AMGT)</b>									
Blueberry [Berry]	3.79-4.07	23-32	23 <sup>2</sup>	0.166	2.094	1.902	0.622	0.820	0.600
	3.83-4.22	38-39	6	0.296	0.463	0.42	0.379	0.380	0.069
	3.83-4.03	43-51	23	0.054	1.164	1.047	0.214	0.327	0.284

1. HAFT = Highest Average Field Trial.

2. Values from NS01 trial were not included because the application rate was 1.5X the target rate.

3. Residue results of <LOQ were assigned a value of the LOQ for the purpose of calculating the mean, median, and standard deviation.

#### DER for MRID #46986702 (Snap Bean)

**Snap Bean:** Eleven supervised magnitude of the residue trials were conducted with fluazinam on snap beans in Canada and the US during the 2003 and 2004 growing seasons. Beans were grown and harvested according to common agricultural practices. Details of trial site history and plot maintenance were provided. Each trial site consisted of two treated plots. The first treated plot received a single foliar application of fluazinam, formulated as a flowable suspension concentrate, at rates of 0.444 to 0.495 lb ai/A, and mature beans were harvested at PHIs ranging from 14-28 days. The second treated plot received two foliar applications at 2- to 6-day RTIs, at rates of 0.422 to 0.469 lb ai/A per application, for total seasonal use rates of 0.881 to 0.921 lb ai/A. Mature beans from these plots were harvested at PHIs of 10-22 days. At two trial sites, samples were harvested at two additional PHIs around the target PHI of 14 days (10-11 days and 20 days). Applications were made using ground equipment, in spray volumes of

19.8 to 46.7 GPA; spray adjuvants were not used at any of the field trial sites.

It was noted that at one trial site (03-NY18), the second treatment protocol (involving two applications) was discontinued, as the second application was made well beyond the study protocol target. No further details were provided. According to IR-4 Protocol #07602, “timing for application in this study is critical and is based on % plants with open blooms.” The protocol specified that, for a single treatment, application was to occur “at first bloom to 30% bloom,” while for two treatments, the first application was to occur “at first bloom to 10% bloom,” and the second application 4-7 days later, but “no later than 50% bloom.” Field data summaries provided for the trial sites (specifically 03-MI39, 03-MI40, 03-WA20, and 03-QC12) indicated that several applications were not conducted according to this timing protocol. However, as the majority of these trials had mature samples harvested at or near the target PHI of 14 days, with residue results consistent with those from other trials which were treated according to the study protocol, the reviewer concluded that these discrepancies in application timing did not affect the residue results reported.

Residues of fluazinam were determined using a working method based on the GC/ECD Ricerca method, *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016). Minor modifications were made to the method to improve performance. The LLMV was reported as 0.020 ppm for fluazinam. Based on the standard deviation observed in 18 snap bean samples fortified with fluazinam at the LLMV, the LOD and LOQ of the modified method were calculated to be 0.0065 ppm and 0.020 ppm, respectively. The modified method was successfully validated in snap beans at the method LLMV/LOQ of 0.020 ppm, with a mean recovery of 110%, and a standard deviation of 7%. Concurrent recoveries ranged from 71% to 122% (n = 12) in snap beans fortified with fluazinam at 0.020 ppm, indicating that the modified method is reliable for the determination of fluazinam residues in this matrix. Representative chromatograms were provided for control samples (including calibration standards), fortified control samples, and treated samples. Standard peaks were generally symmetrical and well defined. Calibration curves and representative chromatograms were provided for fluazinam over the range of 0.0010 to 0.0100 µg/mL. The detector response was linear, with  $r^2$  values reported as 0.972 or greater.

The number and geographical distribution of the snap bean field trials were in accordance with OPPTS Residue Chemistry Test Guideline 860.1500. Since the petitioner is also seeking registration of fluazinam for use on edible-podded beans in Canada, additional field trials were conducted in the Canadian provinces of Prince Edward Island and Quebec.

Harvested beans were stored frozen for a maximum duration of 377 days prior to extraction and analysis. A concurrent freezer storage stability study was conducted with snap beans fortified with fluazinam at 1.00 ppm. Uncorrected recoveries in these samples ranged from 58% to 69% after 377 days storage (n = 3; mean recovery 62%). When recoveries were corrected for concurrent recovery (75%; n = 1), the mean recovery was 83% (77% to 92%), indicating that residues of fluazinam in snap beans did not decline significantly over the storage interval. Therefore, there are no concerns associated with the stability of fluazinam residues over time in this study.

Residues of fluazinam determined in snap beans are summarized in Table 7 (below). The maximum residue observed in snap beans treated with a single application of fluazinam at 0.444



to 0.495 lb ai/A, and harvested at PHIs of 14-28 days, was 0.029 ppm, detected in a single sample. All remaining samples had residues below the LOQ (<0.020 ppm). The maximum residue observed in snap beans treated with two applications of fluazinam, at total application rates of 0.881 to 0.921 lb ai/A, and harvested at PHIs of 10-22 days, was 0.109 ppm. At two trial sites, samples were harvested at two additional PHIs surrounding the target PHI of 14 days (10-11 days and 20 days). Results from these trials indicated that residues of fluazinam in snap beans decreased with increasing PHIs, reaching levels <LOQ (<0.020 ppm) by 20 days.

Crop [Matrix]	Total Use Rate (lb ai/A)	PHI (Days)	Residue Levels <sup>1</sup> (ppm)						
			n	Min.	Max.	HAFT <sup>2</sup>	Median	Mean	Std. Dev.
Snap Bean [Succulent Seed with Pod]	0.444-0.495	14-17	8	<0.020	0.029	0.025	0.020	0.021	0.003
		18-28	14	<0.020	<0.020	<0.020	<0.020	<0.020	0
	0.881-0.921	10	2	0.046	0.072	0.059	0.059	0.059	--
		11-15	16	<0.020	0.109	0.080	0.021	0.038	0.030
		20-22	10	<0.020	<0.020	<0.020	<0.020	<0.020	0

1. Residue results of <LOQ were assigned a value of the LOQ for the purpose of calculating the mean, median, and standard deviation.

2. HAFT = Highest Average Field Trial.

**DER for MRIDs #46996601 & -02, 46986705 to -07 (Broccoli, Cabbage, Mustard Greens)**

**Broccoli, Cabbage, Mustard Greens, Turnip Leaves:** Thirteen supervised magnitude of the residue trials were conducted with fluazinam on broccoli, 12 trials were conducted with fluazinam on cabbage, and 11 trials were conducted with fluazinam on mustard greens in Canada and the US during the 2003, 2004, and 2005 growing seasons. As discussed below, it was not necessary to conduct field trials with turnip leaves. *Brassica* crops were grown and harvested according to common agricultural practices. Details of trial site history and plot maintenance were provided. Each trial site consisted of a single untreated (control) plot, and a single treated plot. Broccoli, cabbage, and mustard green transplants were treated with a single root-drench application of fluazinam, formulated as a flowable suspension concentrate, at a rate of 0.055 lb ai per 1000 plants, and mature crops were harvested at PHIs ranging from 50-113 days (broccoli), 58-104 days (cabbage), and 22-78 days (mustard greens).

Residues of fluazinam from all field trials were determined using working methods based on the GC/ECD Ricerca method *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016). Minor modifications were made to the method to improve method performance. These modifications did not appear to affect the validity of the analytical method. The LLMVs (IR-4 studies) and LOQs (AAFC studies) were reported as 0.010 ppm fluazinam in all matrices. In the IR-4 studies, LODs were calculated based on the recoveries observed in crop samples fortified with fluazinam at the method LLMV. LODs were reported as 0.0038 ppm for broccoli, 0.0033 ppm for cabbage, and 0.0037 ppm for mustard greens. LODs in the AAFC trials were reported as 0.003 ppm for broccoli, and ~0.005 ppm for cabbage. LOQs in these studies (calculated as 3x the LODs) were reported as ~0.010 ppm fluazinam in all matrices. For all studies, representative chromatograms for standards, untreated (control), treated, and fortification samples were provided in the accompanying analytical reports. Standard peaks

were generally symmetrical and well-defined. Little or no interference was noted in control samples. Standard curves were provided for all studies demonstrating linearity (all  $r^2$  values were  $\geq 0.9674$  for broccoli,  $\geq 0.9710$  for cabbage, and  $\geq 0.9690$  for mustard greens).

The number and geographical distribution of the *Brassica* field trials were in accordance with OPPTS Residue Chemistry Test Guideline 860.1500. Since the petitioner is also seeking registration of fluazinam for use on *Brassica* vegetables in Canada, additional field trials were conducted in the Canadian provinces of Ontario, British Columbia, and Quebec.

**Broccoli:** The working methods were successfully validated in broccoli at fortification levels ranging from 0.010 ppm to 0.100 ppm. In samples fortified at 0.010 ppm, method validation recoveries ranged from 72% to 90% (IR-4,  $n = 6$ ,  $SD = 6\%$ ), and from 91% to 99% (AAFC,  $n = 3$ ,  $SD = 4\%$ ). Method validation recoveries ranged from 68% to 92%, with all  $SDs \leq 10\%$ , from control samples fortified at levels ranging from 0.020 to 0.100 ppm. Concurrent recoveries ranged from 57% to 110% (IR-4,  $n = 9$ ,  $SD = 18\%$ ), and from 75% to 95% (AAFC,  $n = 6$ ,  $SD = 8$ ) in samples fortified at 0.010 ppm (LLMV or LOQ). In samples fortified with fluazinam at 0.100 ppm, concurrent recoveries ranged from 62% to 90% across both studies. As recoveries were usually within the generally recognized acceptable range of 70% to 120%, and all  $SDs \leq 20\%$ , the working methods are considered reliable for the determination of fluazinam residues in broccoli.

In IR-4 Study #08795, poor recoveries were initially obtained in method validation samples fortified with 0.100 ppm fluazinam. According to the study report, it was thought that poor recoveries at this fortification level were due to a matrix “quenching” effect. When samples were diluted 10-fold, recoveries improved on average by 26%. Subsequently, all 0.100 ppm fortified samples in this trial (method validation and concurrent validation samples) were diluted prior to extraction and analysis.

Treated broccoli samples were stored frozen for durations of up to 146 days in the IR-4 trials, and 179 days in the AAFC trials. Freezer storage stability of residues in broccoli was determined concurrently in both trials, using samples fortified with fluazinam at 0.100 ppm. In IR-4 Study #08795, initial analysis of the storage stability samples (182 days after storage) indicated that residues had significantly dissipated during storage (recoveries ranged from 20% to 34%). However, it was also noted that concurrent recoveries for these analyses were not acceptable ( $\leq 49\%$ ). Following approval from the study director, the storage stability samples were diluted 10-fold, which significantly improved concurrent recoveries. The storage stability samples were reanalyzed following dilution, and recoveries ranged from 39% to 68%. When corrected for mean concurrent recoveries (74% and 81% across both days of analysis), freezer storage stability recoveries ranged from 53% to 84%, indicating that residues of fluazinam did not degrade significantly throughout the storage interval (205 days after initial storage). Storage stability samples from the AAFC trial were analyzed 232 days after initial storage. Recoveries in these samples were low, ranging from 50% to 52%. Concurrent recoveries were also below the generally recognized acceptable range of 70% (67%), but were considered valid because recoveries within this range were also noted with treated samples. When adjusted for concurrent recoveries, storage stability recoveries were acceptable (74% to 76%), indicating that residues of fluazinam did not degrade significantly throughout the storage interval. Therefore, there are no concerns with the stability of residues of fluazinam in broccoli throughout these trials.

Residues of fluazinam determined in broccoli are summarized in Table 8 (below). No quantifiable (<LOQ; <0.010 ppm) or detectable (<LOD; <0.003 ppm) residues of fluazinam were reported in any broccoli sample harvested 50 to 113 days after a single root-drench application of fluazinam at the time of transplant, at a rate of 0.055 lb ai per 1000 plants. Residue decline was not assessed in these trials.

**Cabbage:** The working methods were successfully validated in cabbage at fortification levels ranging from 0.010 ppm to 0.100 ppm. In samples fortified at 0.010 ppm, method validation recoveries ranged from 50% to 85% (IR-4, n = 5, SD = 16%), and from 74% to 81% (AAFC, n = 3, SD = 4%). Method validation recoveries at fortification levels ranging from 0.020 to 0.100 ppm ranged from 76% to 113%, with all SDs  $\leq 6$ . Concurrent recoveries ranged from 78% to 103% in samples fortified at 0.010 ppm (IR-4, n = 11, SD = 16). Concurrent recoveries at additional fortification levels (0.050 ppm and 0.100 ppm) ranged from 66% to 125% across both studies. As recoveries were usually within the generally recognized acceptable range of 70% to 120%, and all SDs were  $\leq 20\%$ , the working methods are considered reliable for the determination of fluazinam residues in cabbage.

Treated cabbage samples were stored frozen for maximum durations of 560 days (IR-4 trials), and 180 days (AAFC trials). The freezer storage stability of residues in cabbage was determined concurrently in both trials, using samples fortified with fluazinam at 0.100 ppm. In IR-4 Study #08796, storage stability samples analyzed 560 days after initial storage had recoveries ranging from 26% to 33%. When corrected for concurrent recovery (81%), recoveries ranged from 32% to 40%, indicating that residues had dissipated significantly within the noted storage interval. At the time of submission, the freezer storage stability analyses were not completed for the AAFC trial. A final report is expected shortly. Pending submission of the final report for AAFC Project AAFC03-066R, the storage stability data generated for IR-4 Project 08796 are adequate to support the storage conditions and durations of the cabbage samples from the AAFC field trial.

Residues of fluazinam determined in cabbage are summarized in Table 8 (below). No quantifiable (<LOQ; <0.010 ppm) or detectable (<LOD; <0.005 ppm) residues of fluazinam were reported in any cabbage sample harvested 58 to 104 days after a single root-drench application of fluazinam at the time of transplant, at a rate of 0.055 lb ai per 1000 plants. Residue decline was not assessed in these trials.

**Mustard Greens:** The working method was successfully validated in mustard greens at fortification levels ranging from 0.010 ppm to 0.100 ppm. In samples fortified at 0.010 ppm, method validation recoveries ranged from 70% to 93% (n = 3, SD = 12%). Method validations at fortification levels of 0.100 ppm ranged from 80% to 109% with an SD of 15%. Concurrent recoveries ranged from 64% to 109% (n = 12, SD = 15) in samples fortified at 0.010 ppm, and from 71% to 118% in samples fortified at 0.100 ppm. As recoveries were usually within the generally recognized acceptable range of 70% to 120%, and all SDs were  $\leq 20\%$ , the working method is considered reliable for the determination of fluazinam residues in mustard greens.

Treated mustard green samples were stored frozen for durations of up to 621 days. The freezer storage stability of residues in mustard greens was determined concurrently, in samples fortified with fluazinam at 0.100 ppm. After 580 days, the storage stability samples showed recoveries ranging from 40 to 52%. Concurrent recoveries for the freezer storage stability

analyses were ~100%, so no correction was applied to the freezer storage stability recoveries. The low recoveries in the freezer storage stability samples indicate that residues of fluazinam degraded over the storage interval of the study. While the analysis interval (580 days) is somewhat shorter than the actual storage duration for treated samples (621 days), it is within  $\pm 7\%$  of the maximum duration, and it is not expected that significantly greater dissipation will have occurred during the additional ~40 days.

Residues of fluazinam determined in mustard greens are summarized in Table 8 (below). No residues above the LLMV (the maximum residue observed was 0.010 ppm) were reported in any mustard greens sample harvested 22 to 78 days after a single root-drench application of fluazinam at the time of transplant, at a rate of 0.055 lb ai per 1000 plants. Residue decline was not assessed in these trials.

**Turnip Leaves:** Turnip field trials were not conducted because the Agency will be including turnip leaves with the *Brassica* leafy vegetables group in the near future. Field trial data were submitted for all the representative commodities of this group. Therefore, field trial data are not needed for turnip leaves.

Crop [Matrix]	Total Use Rate (lb ai/1000 plants)	PHI (Days)	Residue Levels <sup>1</sup> (ppm)						
			n	Min.	Max.	HAFT <sup>2</sup>	Median	Mean	Std. Dev.
Broccoli [Flower Head & Stem]	0.055	55-113	26	<0.010	<0.010	<0.010	0.010	0.010	0
Cabbage [Head + Wrapper Leaves]	0.055-0.056	60-104	24	<0.010	<0.010	<0.010	0.010	0.010	0
Mustard Greens [Leaves]	0.055	22-78	22	<0.010	0.010	0.010	0.010	0.010	0

- Residues of fluazinam from the AAFC trials in broccoli and cabbage were reported as <LOD (0.003 ppm in broccoli, and 0.005 ppm in cabbage). However, these residue results, along with those of <0.010 ppm from all other trials, were assigned a value of the LOQ (0.010 ppm in all crops) for the purpose of calculating the mean, median, and standard deviation.
- HAFT = Highest Average Field Trial.

#### **DER for MRID #46990501 (Ginseng)**

**Ginseng:** Four magnitude of the residue trials were conducted for fluazinam on ginseng during the 2003 growing season. The trials were conducted in Michigan and Wisconsin (Region 5). Each trial consisted of one untreated control plot, and one treated plot. At each trial, four broadcast applications of fluazinam, formulated as a flowable suspension concentrate, were made, with an RTI of 9-14 days. The 1X rates ranged from 0.756 to 0.936 lb ai/A per application, for total seasonal use rates of 3.13 to 3.39 lb ai/A. All 1X applications were made using appropriate ground equipment in spray volumes of 175-251 GPA; spray adjuvants were not used at any of the field trial sites. The 2X rates ranged from 1.58 to 1.73 lb ai/A per application, for a total seasonal use rate of 6.61 lb ai/A. All 2X applications were made using appropriate ground equipment in spray volumes of 177-194 GPA; spray adjuvants were not used. At all field trials, mature ginseng was harvested at a PHI of 29-31 days.

Four applications of fluazinam were made, instead of the maximum of six as allowed by the supplemental label use directions. Although the number of applications performed in the field trials was two fewer than the supplemental label allowed, the proposed label's maximum total seasonal rate was applied.

The samples were analyzed using a Cornell Analytical Laboratory Method, entitled *Residue Analysis of Fluazinam on Ginseng by GCEC Detection. Version #2*. This method is very similar to the Ricerca method *Fluazinam: Method for the Analysis in Peanut Nut Meat* (MRID #43521016). Minor modifications were made to improve the performance of the method. The validated LOQ was 0.009 ppm. This method is adequate for data collection, based on acceptable method recoveries. Overall method validation recoveries ranged from 62-110% from ginseng fortified with fluazinam at 0.010-2.00 ppm. Recoveries of samples fortified at the LLMV (0.010 ppm) averaged 99% with a standard deviation of 10% (n = 9). One recovery spike at the LLMV of 0.010 ppm was 150%, and was considered a statistical outlier after performing a "Q" Test (statistical rejection of values test), and discussions with the Study Director. Recoveries of method validation samples fortified at 0.050 ppm averaged 69% with a standard deviation of 6% (n = 9), and one sample spiked at 0.050 ppm had a concurrent recovery result of 64%. The low recoveries of the 0.050 ppm fortifications might be due to some quenching of the fluazinam by the matrix. Detector linearity was satisfactory. Chromatograms of control (untreated) ginseng samples were uncontaminated, and free from interferences (baseline detector response was flat) at the retention time for fluazinam.

The total number of field trials exceeded EPA recommendations; four trials were performed, whereas only 3 are recommended. All 4 trials were performed in Region 5. OPPTS Residue Test Chemistry Guideline 860.1500 does not specify where the trials should be performed.

Fluazinam residues were relatively unstable in ginseng over the storage durations of the field trial studies. Storage stability samples were extracted and analyzed after intervals of up to 339 days of freezer storage. The fluazinam recoveries from the storage stability samples ranged from 42% to 49%. After correction for concurrent recoveries, these storage stability recoveries ranged from 65% to 72%. Ginseng samples from the field trials were stored for a maximum duration of 332 days.

A summary of the residue data for ginseng is presented in Table 9 (below). In the trials performed at the 1X and 2X application rates, the residues of fluazinam in ginseng ranged from 0.28 to 1.4 ppm, and 2.1 to 2.2 ppm, respectively. The storage stability study, however, raises the possibility that actual residues in ginseng (at harvest) were up to 50% greater than the quantitated results, based on in-storage dissipation of fluazinam.

Crop [Matrix]	Total Use Rate (lb ai/A)	PHI (Days)	Residue Levels (ppm)					
			n	Min.	Max.	HAFT*	Mean	Std. Dev.
Ginseng [Dried Root]	3.13-3.39	29-31	8	0.28	1.4	1.3	0.82	0.38
	6.61	29	2	2.1	2.2	2.15	2.2	0.071

\* HAFT = Highest Average Field Trial.

**DER for MRID #46990502 (Dried Beans)**

**Dried Beans:** Thirteen magnitude of the residue trials were conducted for fluazinam on dried beans, 12 during the 2003 growing season, and 1 during the 2004 growing season. The trials were conducted in Region 1 (New York), Region 5 (MI, WI, SD, ND) Region 7 (ND), Region 8 (CO), Region 9 (CO), Region 10 (CA), and Region 11 (ID and WA). At each trial, one foliar application of fluazinam, formulated as a flowable suspension concentrate, was made at early bloom, and a second application was made about 14 days later. The applications were made at rates of 0.432-0.481 lb ai/A per application, for total seasonal use rates of 0.871-0.960 lb ai/A. Applications were made using ground equipment, in spray volumes of 18-35 GPA; spray adjuvants were not used at any of the field trial sites. Mature dried beans were harvested at a PHI of 31-57 days.

Samples were analyzed for fluazinam using a procedure derived from the Ricerca method (MRID #43521016), *Fluazinam: Method for the Analysis in Peanut Nut Meat*. Minor modifications were made to improve the performance of the method. The validated LOQ was 0.009 ppm. This method is adequate for data collection, based on acceptable method recoveries. Overall recoveries ranged 71-108% from dried beans fortified with fluazinam at 0.010-1.04 ppm. Recoveries at the LLMV (0.010 ppm) averaged 84% with a standard deviation of 11% (n = 16). Recoveries at fortifications of 0.010-1.04 ppm averaged 88% with a standard deviation of 11% (n = 23). Detector linearity was satisfactory. Chromatograms of control (untreated) dried bean samples were uncontaminated, and free from interferences (baseline detector response was flat) at the retention time for fluazinam.

The total number of field trials exceeded EPA recommendations, but the geographical distribution of the dried bean field trials was, technically, not in accordance with the guidance (OPPTS Residue Test Chemistry Guideline 860.1500). One additional dried bean field trial was performed in both Regions 5 and 11, but one fewer trial was performed in Region 7 than recommended by the Guidelines.

Fluazinam residues were relatively unstable in dried beans over the storage durations of the field trial studies. After a storage interval of 307 days, fluazinam residues in fortified dried bean samples declined to 52% of the fortification level. Recoveries from method validation and concurrent recovery samples averaged 88%. Dried bean samples from the field trials were stored for a maximum duration of 245 days.

A summary of residue data for dried beans is presented in Table 10 (below). Fluazinam residues were less than the LLMV (<0.010 ppm) in all dried bean samples from the field trials, except for one sample at 0.0114 ppm. The storage stability study, however, raises the possibility that actual residues in dried beans (at harvest) were up to 50% greater than the quantitated results, based on in-storage dissipation of fluazinam.

Crop [Matrix]	Total Use Rate (lb ai/A)	PHI (Days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
Bean [Shelled Dried Seed]	0.871-0.960	31-57	26	<0.010	0.0114	0.0107	0.010	0.0101	0.00027

\* HAFT = Highest Average Field Trial.

**DER for MRID #46990503 (Lima Bean)**

**Lima Bean:** Seven magnitude of the residue trials were conducted for fluazinam on lima beans during the 2003 and 2004 growing seasons. The trials were conducted in New Jersey, Maryland, and Georgia (Region 2), California (Region 10; 2 trials), and Idaho (Region 11; 2 trials). Each trial consisted of one control (untreated) plot, and one treated plot. At each trial, two foliar applications of fluazinam, formulated as a flowable suspension concentrate, were made. The first application was made at first bloom to 10% bloom, and the second was made about 3-7 days later, but no later than 55% bloom. Applications were made at rates of 0.441-0.459 lb ai/A per application, for total seasonal use rates of 0.885-0.912 lb ai/A. All applications were made using ground equipment, in spray volumes of 19.7-48.9 GPA; spray adjuvants were not used at any of the field trial sites. Mature lima beans were harvested at a PHI of 28-71 days.

Samples were analyzed for fluazinam using a procedure derived from the Ricerca method (MRID #43521016), *Fluazinam: Method for the Analysis in Peanut Nut Meat*. Minor modifications were made to improve the performance of the method. The validated LOQ was 0.020 ppm. This method is adequate for data collection, based on acceptable method validation and concurrent recoveries.

Overall recoveries ranged 71-107% from lima beans fortified with fluazinam at 0.020-1.00 ppm. Recoveries from samples fortified at the LLMV (0.020 ppm) averaged 83% with a standard deviation of 13% (n = 11). The average recovery of all fortifications was 82% with a standard deviation of 11% (n = 18). Detector linearity was satisfactory. Chromatograms of control (untreated) lima bean samples were uncontaminated, and free from interferences (baseline detector response was flat) at the retention time for fluazinam.

The total number of field trials exceeded EPA recommendations, but the geographical distribution of the lima bean field trials was, technically, not in accordance with the guidance (OPPTS Residue Test Chemistry Guideline 860.1500). One additional lima bean field trial was performed in both Regions 10 and 11, but one fewer trial was performed in Region 5 than recommended by the Guidelines.

Fluazinam residues were relatively unstable in lima beans over the storage durations of the field trial studies. After a storage interval of 455 days, fluazinam residues in fortified lima bean samples had been reduced to 51% of the fortification level. Recoveries from method validation and concurrent recovery samples averaged 82%. Lima bean samples from the field trials were stored for a maximum duration of 254 days.

A summary of residue data for lima beans is presented in Table 11 (below). Fluazinam residues were less than the LOQ (<0.020 ppm) in all lima bean samples from the field trials. The storage stability study, however, raises the possibility that actual residues in lima beans (at harvest) were up to 50% greater than the quantitated results, based on in-storage dissipation of fluazinam.

Crop [Matrix]	Total Use Rate (lb ai/A)	PHI (Days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT*	Median	Mean	Std. Dev.
Lima Bean [Shelled Succulent Seed]	0.885-0.912	28-71	14	<0.020	<0.020	<0.020	<0.020	<0.020	0

\* HAFT = Highest Average Field Trial.

**Conclusions:** The field trial data are adequate, and support the proposed use patterns. Adequate numbers of trials were conducted in the appropriate geographical regions, and samples were analyzed for the ROC using adequate methods. The sample storage conditions and durations are supported by the available storage stability data. However, residue data for AMGT were provided only for blueberries; AMGT data should also have been included with the field trial studies for edible-podded beans, shelled succulent and dried beans, and *Brassica* vegetables. **The Agency has previously determined, and the registrant is hereby advised again, that residue data for AMGT should be provided in the crop field trial studies for all future requested plant commodities, except root and tuber, and bulb vegetables.**

#### **860.1520 Processed Food and Feed**

This guideline requirement is not relevant to the current petitions, as there are no processed commodities for which residue data are required associated with the proposed uses on the crops requested in the subject petitions under review.

#### **860.1650 Submittal of Analytical Reference Standards**

An analytical reference standard for fluazinam is available (as of 7/2/2007) in the inventory at the EPA National Pesticide Standards Repository. However, the certificate of analysis (COA) expired on 4/17/2007. NPSR will request another fluazinam standard, or request a new COA (for the current standard) from the manufacturer.

#### **860.1850 Confined Accumulation in Rotational Crops**

Regulatory requirements pertaining to fluazinam residues in rotational crops have been fulfilled, and the rotational crop restrictions on the proposed label are adequate.

#### **860.1900 Field Accumulation in Rotational Crops**

Regulatory requirements pertaining to fluazinam residues in rotational crops have been fulfilled, and the rotational crop restrictions on the proposed label are adequate.

#### **860.1550 Proposed/Recommended Tolerances**

For the purpose of setting tolerances, the Agency has determined that, apart from wine grapes, fluazinam is the ROC in both primary and rotational crops. The proposed and recommended tolerances for the various commodities requested in the current petitions are listed in Table 12 (below).

**Bushberries (Subgroup 13-B):** The representative commodity of the bushberry crop subgroup is highbush blueberry. Residue data inputs from the blueberry field trials (for samples with 23- to 32-day PHIs) resulted in an MRL/tolerance calculator recommendation of a 7.0 ppm tolerance for fluazinam on bushberries. Separate individual tolerances are also listed for fluazinam in the future members of the bushberries subgroup 13-B, as approved by ChemSAC.

**Edible-Podded Beans (Subgroup 6-A, Except Peas):** The representative bean commodity of subgroup 6-A is one succulent cultivar of edible-podded bean which, in this case,



was snap bean. Approximately 80% of fluazinam residues were <LOQ (<0.010 ppm), so the MRL/tolerance calculator was not used. Based on the maximum residue (at an 11-day PHI) of 0.109 ppm (HAFT = 0.080), and a proposed minimum 14-day PHI, HED recommends that the tolerance for fluazinam in Subgroup 6-A (except peas) be set at 0.10 ppm.

**Brassica (Cole) Vegetables (Group 5):** The representative commodities of the *Brassica* crop group are broccoli, cabbage, and mustard greens. Fluazinam residues in broccoli were stable under frozen storage, and residues in all samples of all 3 crops were ≤LOQ (≤0.010 ppm). Therefore, despite the poor storage stability recoveries from cabbage and mustard greens (both of which have the same use pattern as broccoli), HED recommends that the tolerance for fluazinam in Group 5 be set at the LOQ (0.01 ppm), based on the weight of evidence provided by the broccoli field trials and storage stability studies. A separate individual tolerance was also listed for fluazinam in turnip leaves, a future member of the leafy *Brassica* greens subgroup 5-B.

**Ginseng:** Residue data inputs resulted in an MRL/tolerance calculator recommendation of a 3.0 ppm tolerance for fluazinam on ginseng. Because of 65-72% recoveries from storage stability samples (corrected for concurrent recovery), HED recommends that the tolerance be increased by 50%, to 4.5 ppm.

**Dried Shelled Beans (Subgroup 6-C, Except Peas):** The representative bean commodity of subgroup 6-C is one dried cultivar of bean which, in this case, was a variety of dried beans (primarily navy and kidney beans). All residues, except for one at 0.0114 ppm, were <LOQ (<0.010 ppm) but, based on fluazinam dissipation during frozen storage of roughly 50%, HED recommends that the tolerance in Subgroup 6-C (except peas) be double the LOQ (0.01 ppm), or 0.02 ppm.

**Succulent Shelled Beans (Subgroup 6-B, Except Peas):** The representative bean commodity of subgroup 6-B is one succulent shelled cultivar of bean which, in this case, was lima bean. All fluazinam residues in succulent shelled beans were <LOQ (<0.020 ppm) but, based on fluazinam dissipation during frozen storage of roughly 50%, HED recommends that the tolerances in Subgroup 6-B (except peas) be double the LOQ (0.02 ppm), or 0.04 ppm.

There are no established or proposed Canadian or Codex MRLs for residues of fluazinam in plant or animal commodities. There are Mexican MRLs established for residues of fluazinam in potato at 0.05 ppm, and in beans at 0.1 ppm. The International Residue Limit Status sheet is shown in Appendix 1. Residue data sets for blueberries and ginseng, utilized as inputs in the MRL/tolerance calculator, are shown in Appendix 2.

<b>Commodity</b>	<b>Proposed Tolerance (ppm)</b>	<b>Recommended Tolerance (ppm)</b>	<b>Comments [Correct Commodity Definition]</b>
Ginseng	3.00	4.5	
Bean, dry	0.01	0.02	[Pea and bean, dried shelled, except soybean, subgroup 6-C (except peas)]
Succulent-shelled legume vegetables subgroup 6B, except pea	0.02	0.04	[Pea and bean, succulent shelled, subgroup 6-B (except peas)]
Edible-podded legume vegetables subgroup 6A, except peas	0.15	0.10	[Vegetable, legume, edible-podded, subgroup 6-A (except peas)]
Leafy <i>Brassica</i> greens subgroup	0.02	0.01	Crop group tolerance is appropriate. [Vegetable, <i>Brassica</i> leafy, group 5]
Head and stem <i>Brassica</i> subgroup	0.01		
Turnip, leaves	0.02	0.01	[Turnip, tops]
Bushberry subgroup 13B	4.5	7.0	[Bushberry subgroup 13-B]
Aronia berry	4.5	7.0	
Blueberry, lowbush	4.5	Not needed.	Lowbush blueberry is already a member of the bushberries subgroup, 13-B.
Buffalo currant	4.5	7.0	
Chilean guava	4.5	7.0	
European barberry	4.5	7.0	
Highbush cranberry	4.5	7.0	
Honeysuckle	4.5	7.0	
Jostaberry	4.5	7.0	
Juneberry	4.5	7.0	
Lingonberry	4.5	7.0	
Native currant	4.5	7.0	
Salal	4.5	7.0	
Sea Buckthorn	4.5	7.0	

**REFERENCES**

*Temporary Tolerance Petition and Experimental Use Permit for Use of Fluazinam on Peanuts; 050534-EUP-E.; D177127 and D177137; George Herndon; 6/19/1992.*

*Temporary Tolerance Petition and Experimental Use Permit for Use of Fluazinam on Peanuts; 050534-EUP-E. Submission Dated 1/23/95 in Response to the Memo of G.J. Herndon Dated 6/19/92.; D212612, D216941, and D217467; George Herndon; 9/5/1995.*

*Fluazinam. Decision by Metabolism Assessment Review Committee (MARC).; D272624; William Cutchin; 4/23/2001.*

*PP#9F5079. Request for the Use of Fluazinam on Peanuts, Potatoes, and Wine Grapes. Evaluation of Analytical Chemistry and Residue Data.; D257115; William Cutchin; 5/21/2001.*

*PP#9F5079. Fluazinam in/on Peanuts and Grapes. Tolerance Method Validation Report.; D266802; Paul Golden; 6/22/2001.*

**ATTACHMENTS**

Appendix 1 - International Residue Limits.

Appendix 2 - Tolerance Assessment Data Sets.

**APPENDIX 1 - International Tolerances.**

<b>INTERNATIONAL RESIDUE LIMIT STATUS</b>			
<b>Chemical Name:</b> 3-chloro- <i>N</i> -[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine	<b>Common Name:</b> Fluazinam	<b>X Recommended tolerances</b> <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	<b>Date:</b> 6/20/2007
<b>Codex Status (Maximum Residue Limits)</b>		<b>US Tolerances</b>	
X No Codex proposal step 6 or above <input type="checkbox"/> No Codex proposal step 6 or above for the crops requested		<b>Petition Number:</b> 6E7139, 6E7139 <b>DP Number:</b> 335640 <b>Other Identifier:</b> PC Code 129098	
Residue definition (step 8/CXL): NA		<b>Reviewer/Branch:</b> William T. Drew/RAB2	
		<b>Residue definition:</b> Fluazinam	
<b>Crop(s)</b>	<b>MRL (mg/kg)</b>	<b>Crops</b>	<b>Tolerance (ppm)</b>
		Ginseng	4.5
		Dried shelled pea and bean (except soybean) subgroup 6-C, except peas	0.02
		Succulent shelled pea and bean subgroup 6-B, except peas	0.04
		Edible-podded legume vegetables subgroup 6-A, except peas	0.10
		<i>Brassica</i> (Cole) leafy vegetables group 5	0.01
		Turnip, tops (leaves)	0.01
		Bushberry subgroup 13-B	7.0
		Aronia berry	7.0
		Blueberry, lowbush	7.0
		Buffalo currant	7.0
		Chilean guava	7.0
		European barberry	7.0
		Highbush cranberry	7.0
		Honeysuckle	7.0
		Jostaberry	7.0
		Juneberry	7.0
		Lingonberry	7.0
		Native currant	7.0
		Salal	7.0
		Sea Buckthorn	7.0

Limits for Canada		Limits for Mexico	
<input checked="" type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested		<input type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested	
Residue definition: NA		Residue definition: Fluazinam	
Crop(s)	MRL (mg/kg)	Crops	MRL (mg/kg)
		Potato	0.05
		Beans	0.1
<b>Notes:</b> per Steve Funk (6/20/2007). NA = Not Applicable.			

**APPENDIX 2 - Tolerance Assessment Data Sets.**

EPA  
 Fluazinam  
 Blueberry  
 23-32 Days  
 3.8-4.1 lb ai/A  
 IR-4

<b>Residues</b>
0.450
0.490
0.420
0.680
1.200
1.000
0.500
0.550
0.160
0.120
0.064
0.074
0.170
0.130
1.500
1.200
0.700
0.640
1.600
1.700
1.600
2.000
0.070

EPA  
 Fluazinam  
 Ginseng  
 29-31 Days  
 3.1-3.4 lb ai/A  
 IR-4

<b>Residues</b>
1.200
1.400
0.730
0.940
0.580
0.960
0.460
0.280