UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 20/NOV/2007

Subject: Flumioxazin. Petitions for Tolerances on Alfalfa, Asparagus, Dry Beans, Fruiting Vegetables (Group 8, including Okra), Melons (subgroup 9A), Bushberries (subgroup 13B), and Tree Nuts (group 14), and a Request for an Amended Use on Garlic. Summary of Analytical Chemistry and Residue Data. PP#s: 6F7092 and 6E7151.

DP Number:	342963	Decision Number:	372752
PC Code:	129034	MRID Numbers::	46889603, 46889604, 47005101, 47005102, 47005103, 47005104, 47005105, 47005106, 47005107
40 CFR §180.	568		
Chemical Class:	N-phenylpthalimide derivative herbicide		

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This document was originally prepared under contract by Dynamac Corporation (submitted 25/MAY/2007). The document has been reviewed by the ARIA team of the RIMUERB/RD and revised to reflect current Office of Pesticide Programs (OPP) policies.

Executive Summary

Flumioxazin is an N-phenylphthalimide class herbicide (Group 14) that is currently used for pre- and post-emergence control of susceptible weeds in a variety of fruit, vegetable and field crops. Tolerances are currently established for residues of flumioxazin, with CAS number 103361-09-7, and IUPAC name *N*-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2*H*-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboxamide, in/on various plant commodities at levels ranging from 0.02 to 0.70 ppm (40 CFR §180.568[a]). Additionally, temporary tolerances are established on alfalfa forage and hay at 0.13 and 0.45 ppm, respectively (Expiration date 31/DEC/2009).

Valent U.S.A Corporation (Valent) and Interregional Research Project No. 4 (IR-4) have submitted petitions supporting the use of flumioxazin, formulated as two 51% water-dispersible granular (WDG) formulations, on alfalfa, asparagus, dry beans, assorted bushberries, fruiting vegetables (including okra), melons, and tree nuts. The proposed use on alfalfa is for a broadcast application within 7 days after cutting at 0.125 lb ai/A. A total of two applications are proposed per season, and a 25-day preharvest interval (PHI) is specified. For asparagus, the proposed use is for a single broadcast application prior to spear emergence at up to 0.375 lb ai/A, with a 14-day PHI. For fruiting vegetables and okra, the proposed use is for up to two soil applications, directed to row middles at up to 0.125 lb ai/A, following transplanting or seedling emergence and again ~21 days prior to harvest, for a maximum of 0.25 lb ai/A/season. A 21-day PHI is specified for fruiting vegetables, and applications may include use of a crop oil concentrate (COC) at 1% v/v. For melons, the proposed use is for up to two soil applications directed to row middles at up to 0.125 lb ai/A; the applications are made either preplant or preemergence and again 21-28 days later, for a maximum of 0.25 lb ai/A/season. No PHI is specified for melons. For dry beans, the proposed use is for a single broadcast application at up to 0.093 lb ai/A, as either a preemergence application (weed control), or as a late-season broadcast foliar application (harvest aid). A 5-day PHI is specified for dry beans, and the late-season use may include a COC at 1% v/v. For tree nuts, the proposed use is for up to two soil-directed applications at 0.375 lb ai/A at retreatment intervals (RTIs) of 60 days, for a maximum use rate of 0.75 lb ai/A/season with a PHI of 60 days. For bushberries, the proposed use is for up to two soil-directed applications at 0.375 lb ai/A, during early spring and again during the later stages of berry development, for a maximum use rate of 0.75 lb ai/A/season. A 7-day PHI is specified, and only the single early season application is allowed on lowbush blueberries. In addition to these new uses, IR-4 is also requesting that the current use directions for garlic be amended to increase the maximum use rate to 0.38 lb ai/A for the preemergence application. In conjunction with the above uses, the petitioners are proposing the following permanent tolerances for flumioxazin:

Alfalfa, forage	1.0 ppm
Alfalfa, hay	2.0 ppm
Asparagus	0.02 ppm
Fruiting Vegetables, Group 8	0.02 ppm
Okra	0.02 ppm
Melon, subgroup 9A	0.02 ppm
Bean, dry, seed	0.06 ppm
Tree Nuts, Group 14	0.02 ppm
Bushberry, subgroup 13B	0.02 ppm
Aronia berry	0.02 ppm

Blueberry, lowbush ..... 0.02 ppm
Blueberry, highbush ..... 0.02 ppm
Buffalo currant ..... 0.02 ppm
Chilean guava ..... 0.02 ppm
Currant, black ..... 0.02 ppm
Currant, red ..... 0.02 ppm
Elderberry ..... 0.02 ppm
European barberry ..... 0.02 ppm
Gooseberry ..... 0.02 ppm
Highbush cranberry ..... 0.02 ppm
Honeysuckle ..... 0.02 ppm
Jostaberry ..... 0.02 ppm
Juneberry, including Saskatoon berry ..... 0.02 ppm
Lingonberry ..... 0.02 ppm
Native currant ..... 0.02 ppm
Salal ..... 0.02 ppm
Sea buckthorn ..... 0.02 ppm

Based on adequate corn, sugarcane, grape, hen and goat metabolism data, the nature of flumioxazin residues in plants and animals is understood. In primary and rotated crops, the residue of concern is only the parent compound. For ruminants, the residues of concern are parent, 3-OH-flumioxazin, 4-OH-flumioxazin, plus Metabolites B, C, and F. For poultry, the residues of concern are parent, 3-OH-flumioxazin, 4-OH-flumioxazin, and 4-OH-S-53482-SA.

An adequate gas chromatography/nitrogen-phosphorus detection (GC/NPD) method is available for enforcing tolerances of flumioxazin in/on plant commodities (Valent Method RM-30-A-1). The reported method limits of quantitation and detection (LOQ and LOD) for flumioxazin in plant commodities are 0.02 and 0.01 ppm, respectively. Residues of flumioxazin in samples of raw agricultural commodities (RACs) from the current field trials were determined using an adequate GC/NPD method (Method RM-30A-3), which is a more recent version of the enforcement method. The validated method LOQ for flumioxazin in/on all plant commodities is 0.02 ppm, and the LODs range from 0.005 to 0.01 ppm.

Adequate liquid chromatography with tandem mass spectroscopy detection (LC/MS/MS) methods are also available for collecting data on residues of flumioxazin, 3-OH-flumioxazin and 4-OH-flumioxazin in milk (Method RM-30MK) and cattle tissues (Method RM-30T). The validated method LOQ is 0.02 ppm for each analyte in milk and tissues, and the reported LOD is 0.01 ppm.

New storage stability data were provided in conjunction with the field trials. These studies indicate that flumioxazin is stable in frozen storage (≤-15°C) for intervals of up to 30 months in alfalfa forage and hay, 22 months in dry beans, 7 months in tomatoes and asparagus, 5.8 months in blueberries, and up to 4.4 months in cantaloupes and pecans. Some apparent decline (19%) was observed in frozen peppers after 26 months of storage; however, this level of decline could not be verified as only one storage interval was tested. In addition, any correction of residue levels in peppers would not alter the recommended tolerance in fruiting vegetables. Together with earlier storage stability data on a wide variety of plant commodities, the new storage

stability data support the sample storage durations and conditions used in the submitted field trials.

The new field trials on cantaloupes, tomatoes, peppers, dry beans, asparagus, blueberries, and pecans are adequate, and together with the previously submitted almond data, these field trials support the proposed uses. An adequate number of tests were conducted on each crop in the appropriate regions, and samples were analyzed for the residue of concern using an adequate method.

In the eight cantaloupe field trials conducted during 2003, flumioxazin (WDG) was applied as two soil applications directed to row middles at 0.121-0.130 lb ai/A/application, for a total use rate of 0.245-0.256 lb ai/A (1x rate). The initial application was made either preplant or preemergence, and the second application was made during later vegetative development or at blooming, at RTIs of 30-47 days. Flumioxazin residues were <LOD (<0.008 ppm) in/on all samples of cantaloupes harvested at maturity, following a PHI of 36-69 days.

In the 12 tomato and 9 pepper field trials conducted during 2003, flumioxazin (WDG) was applied as two soil applications directed to row middles at 0.120-0.134 lb ai/A/application, for a total use rate of 0.244-0.259 lb ai/A (1x rate). The initial application was made to seedlings or transplants during early vegetative development, and the second application was made approximately 21 days prior to crop maturity, for RTIs of 42-103 days. All applications included the use of a COC as an adjuvant at 1% v/v. At crop maturity (15-21 day PHI), flumioxazin residues were <LOD (<0.007 ppm) in/on all pepper samples and <LOQ (<0.02 ppm) in/on all tomato samples.

In the 12 dry bean field trials conducted during 2003, flumioxazin (WDG) was applied as a single pre-harvest, broadcast application at 0.091-0.096 lb ai/A (1x rate), and all applications included the use of a COC at 0.6-2.5%. At normal crop maturity (4-6 day PHI), flumioxazin residues were <0.02-0.05 ppm in/on 26 samples of dried beans, with 22 samples having residues <LOQ (<0.02 ppm).

In the eight asparagus field trials conducted during 2003/2004, flumioxazin (WDG) was applied as a single broadcast application to dormant or recently cut asparagus at approximately 2 weeks prior to harvest. Each test site included two plots treated at either 0.190-0.197 lb ai/A or 0.380-0.404 lb ai/A (0.5x and 1x rates). For both application rates, flumioxazin residues were <LOQ in/on all samples harvested at an 8-20 day PHI.

In the lowbush (1 trial) and highbush (5 trials) blueberry field trials conducted during 2003, flumioxazin (WDG) was applied as either as single broadcast application to dormant lowbush blueberries at 0.40 lb ai/A (1x rate), or as two soil-directed applications to highbush blueberries at 0.370-0.405 lb ai/A/application, for a total use rate of 0.744-0.797 lb ai/A (1x rate). The first application to highbush blueberries was made around bud break/flowering and the second application was made 50-113 days later during fruit development. At normal crop maturity, flumioxazin residues were <LOD (<0.006 ppm) in/on two samples of lowbush blueberries (99 DAT) and <LOQ (<0.02 ppm) in/on 10 samples of highbush blueberries collected at a PHI of 6-8 days.

In the four almond field trials conducted during 1999 and the five pecan field trials conducted during 2003, flumioxazin (WDG) was applied to trees as two soil-directed applications during nut development at rates of 0.375 lb ai/A/application and RTIs of 58-61 days, for a total use rate of 0.75-0.76 lb ai/A/season (1x rate). At normal nut maturity (42-61 DAT), flumioxazin residues were <LOQ in/on eight samples of almonds (<0.01 ppm) and 10 samples of pecans (<0.02 ppm). Residues in/on eight samples of almond hulls from the 1x application were <0.01-0.066 ppm.

The 12 alfalfa field trials conducted from 2003-2005 are also adequate to support the proposed use of two applications per season. However, the recommended tolerance will be based on the highest subset or combination of residue data. In six trials, flumioxazin (WDG) was applied to alfalfa as a single broadcast application within 7-9 days after the 1st cutting at 0.12-0.13 lb ai/A, and in the other six trials, flumioxazin (WDG) was applied as two broadcast applications at 0.12-0.13 lb ai/A, to dormant alfalfa and again following the 1st cutting, for a total use rate of 0.24-0.26 lb ai/A. Applications included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.25% v/v. Although half of the trials included an extra application to dormant alfalfa at the start of the season, residues in/on forage and hay from the 2nd, 3rd and 4th cutting were similar across all 12 trials. Flumioxazin residues in/on forage and hay were respectively <0.02-1.70 ppm and 0.06-5.50 ppm from the 2nd cutting (24-26 day PHI), <0.02-0.19 ppm and <0.02-0.09 ppm from the 3rd cutting (45-70 day PHI), and <0.02-0.06 ppm and <0.02-0.15 ppm from the 4th cutting (71-128 day PHI). Residue decline data from one field trial also indicated that residues in/on both forage and hay decline at longer post-treatment intervals.

In addition, the previously reviewed bulb onion field trial data will support the requested increase in the use rate for garlic to 0.38 lb ai/A. Following two postemergence, broadcast applications of flumioxazin (WDG) to onions in nine tests at rates totaling 0.185-0.200 lb ai/A, flumioxazin residues were <LOQ (<0.02 ppm) in/on all samples of bulb onions harvested at a 42-49 day PHI. Although the bulb onion data were conducted at only ~0.5x the proposed maximum use rate for garlic, the postemergence applications to onions occurred at a much later growth stage than allowed for garlic (preemergence), and the typical harvest interval for garlic would be >200 days, compared to the 45-day PHI for bulb onions.

No processing studies were submitted with the current petitions. Although a tomato processing study is typically required to support uses on fruiting vegetables, the available tomato field trial data indicated that flumioxazin residues in/on tomatoes were <LOQ following applications at 5x the maximum proposed use rate. Therefore, a tomato processing study is not required, and separate tolerances are not required for processed tomato commodities.

Based on the established and recommended tolerances for flumioxazin residues in feedstuffs, and recent Agency guidance on calculating reasonably balanced livestock diets, the theoretical dietary burden (TDB) of flumioxazin residues to livestock was calculated to be 0.96 ppm for beef cattle, 3.19 ppm for dairy cattle, 0.005 ppm for poultry and 0.004 ppm for swine.

An adequate cattle feeding study is available in which lactating dairy cows (3/group) were dosed orally with flumioxazin at levels equivalent to 2, 6 and 20 ppm in their diet for 28 consecutive days (0.6, 1.9 and 6.3x the TDB). Composited samples of milk were collected throughout the study, and subsamples of milk from Day 24 were used to generate cream and skim milk samples. Samples of liver, kidney, composited muscle, and composited fat were also collected from each animal within 24 hours of the final dose. Milk and tissue samples were analyzed using the

adequate data collection methods discussed above, and no supporting storage stability data were required as all frozen samples were analyzed within 30 days of collection. For the 20 ppm dose group, residues of flumioxazin, 3-OH-flumioxazin and 4-OH-flumioxazin were each non-detectable (<0.01 ppm) in all samples of milk, skim milk, cream, and tissues from all three cows.

As residues of flumioxazin and its two hydroxy metabolites were <LOD in milk and tissues from cattle dosed at 6.3x TDB, quantifiable residues are unlikely to occur in cattle commodities. Therefore, tolerances for flumioxazin residues are not required for commodities from cattle, goats, hogs, horses or sheep (40 CFR §180.6[a][3]). In addition, results from the available poultry metabolism study, in which hens were dosed for 14 days at levels equivalent to >1,800x TDB, indicate that quantifiable residues are unlikely to occur in eggs or poultry tissues. Therefore, tolerances for flumioxazin residues are also not required in eggs or poultry tissues.

An adequate confined rotational crop study is available to support the uses on the proposed crops that can be rotated (alfalfa, dry beans, fruiting vegetables, melon and garlic). Based on the results of the confined accumulation study, ARIA concludes that the current rotational crop plant-back intervals (PBIs) are acceptable, and that field trials for, and tolerances in, rotated crops are not necessary.

Regulatory Recommendations and Residue Chemistry Deficiencies

No major deficiencies were noted in the subject petitions that would preclude establishing permanent tolerances for flumioxazin on the proposed commodities; however, the petitioner should address the deficiencies noted below. The available residue data support establishing permanent tolerances for flumioxazin residues at 0.02 ppm in/on asparagus, fruiting vegetables, melons, okra, tree nuts and assorted bushberries, at 0.05 ppm in/on dry beans, and at 3.0 and 8.0 ppm respectively in/on alfalfa forage and hay. A summary of the proposed and recommended tolerances, along with the correct commodity definitions for the requested commodities, are presented in Table 7.

- Use directions for the proposed crops should be revised as indicated under the conclusions for the Use Directions Section.

- Section F of both petitions should be revised to reflect the recommended tolerance levels and correct commodity definitions listed in Table 7.

Background

Flumioxazin is an herbicide of the N-phenylphthalimide class that is currently used for pre- and post-emergence control of susceptible weeds in a variety of fruit, vegetable and other field crops. Its mode of action is as an inhibitor of protoporphyrinogen oxidase (PPO); it is active against certain grasses, broadleaf weeds, and sedges. Tolerances are currently established for residues of flumioxazin in/on various plant commodities, at levels ranging from 0.02 to 0.70 ppm (40 CFR §180.568[a]). Tolerances associated with a Section 18 emergency exemption have also been established on alfalfa forage and hay at 0.13 and 0.45 ppm, respectively (40 CFR 180.568[b]) (Expiration date 31/DEC/2009).

Valent has submitted a petition (PP# 6F7092) proposing the use of flumioxazin formulated as a 51% WDG on alfalfa, and IR-4 has submitted a separate petition (PP# 6E7151) proposing new uses of flumioxazin on tree nuts, melons, dry beans, bushberries, fruiting vegetables (including okra), and asparagus. The nomenclature and physicochemical properties of flumioxazin are presented below in Tables 1 and 2.

Table 1. Flumioxazin Nomenclature.

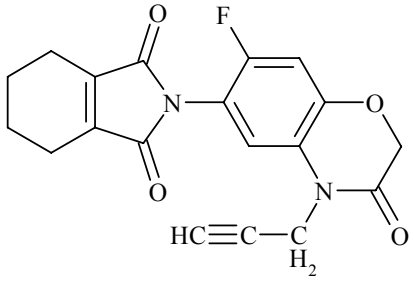
Compound	
Common name	Flumioxazin
Company experimental name	VC-1152
IUPAC name	*N*-(7-fluoro-3,4-dihydro-3-oxo-4-prop-2-ynyl-2*H*-1,4-benzoxazin-6-yl)cyclohex-1-ene-1,2-dicarboxamide
CAS name	2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione
CAS registry number	103361-09-7
End-use product (EP)	51% WDG, Valor Herbicide and Chateau ™ WDG Herbicide

Table 2. Physicochemical Properties of Flumioxazin.

Parameter	Value	Reference
Melting point/range	202-204 °C	EPA Pesticide Fact Sheet for flumioxazin issued on April 12, 2001 for conditional registration (http://www.epa.gov/opprd001/factsheets/flumioxazin.pdf)
pH	7.29 at 25 °C	
Density	1.51 g/ml at 20 °C	
Water solubility (25°C)	1079 mg/L	
Solvent solubility	Not available	
Vapor pressure	2.41 x10^{-6} mm Hg	
Dissociation constant, pK_a	None	
Octanol/water partition coefficient, Log(K_{OW})	2.55 at 20 °C	
UV/visible absorption spectrum	λ_{218}, ϵ = 14700 (pH 1.9) λ_{216}, ϵ = 43600 (pH 6.8) λ_{216}, ϵ = 51200 (pH 10.0)	

Directions for Use

Valent and IR-4 are proposing new uses of flumioxazin for weed control in alfalfa, dry beans, fruiting vegetables (including okra), melons, bushberries, and asparagus and for use as a harvest

aid on dry beans. IR-4 has also proposed expanding the existing use on almonds to include all tree nuts and amending the existing use on garlic to increase the use rate. The formulations being proposed for these uses include two 51% WDG formulations (VALOR® Herbicide, EPA Reg. No. 59639-99; CHATEAU® WDG Herbicide, EPA Reg. No. 59639-119). These formulations are currently registered to Valent for use on a wide variety of fruit, vegetable and other field crops at maximum seasonal use rates of 0.05-0.75 lb ai/A.

Valent provided example labels containing the proposed use directions for alfalfa, and IR-4 provided example labels containing the use directions for the other crops. IR-4 also provided summaries of the proposed use directions in Section B of their petition. With the exception of alfalfa, the use directions summarized in Table 3 were obtained from the summaries provided by IR-4.

Table 3. Summary of Directions for Use of Flumioxazin. [1]

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [2]
Alfalfa (established plantings)						
Broadcast foliar application within 7 days after cutting; ground or aerial equipment	51% WDG [59639-99] [59639-119]	0.125	2	0.25	25	A minimum RTI of 60 days is specified. Do not apply with any adjuvants or tank mix with EC formulations. Do not use on mixed stands of alfalfa and grass.
Dry Beans						
Weed control: Preemergence broadcast application; ground equipment	51% WDG [59639-99] [59639-119]	0.093 (0.05)	1	0.093 (0.05)	NA	Apply in a minimum of 10 gal/A. Use is restricted to areas west of US Hwy 83 in CO and NE
Harvest aid: Broadcast foliar application to mature beans; ground equipment		0.093 (0.05)	1	0.093 (0.05)	5	Application may include a COC at 1% v/v. Apply in a minimum of 10 gal/A (15 gal/A).
Fruiting Vegetables (including okra)						
Directed soil applications to row middles after transplanting or emergence and approximately 21 days prior to harvest; ground equipment	51% WDG [59639-99] [59639-119]	0.125 (0.096)	2 (1)	0.25 (0.096)	21 (NS)	Applications may include a COC at 1% v/v. Apply in a minimum of 10 gal/A (15 gal/A). Use directed for shielded sprayers for all applications.
Melons						
Directed soil applications to row middles, preplant or preemergence, and post-emergence 21-28 days later; ground equipment	51% WDG [59639-99] [59639-119]	0.125 (0.096)	2 (1)	0.25 (0.096)	NS	Minimum RTIs of 21-28 days. Use directed for shielded sprayers for all applications. Apply in a minimum of 10 gal/A (15 gal/A).

Table 3. Summary of Directions for Use of Flumioxazin. [1]						
Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations [2]
Bushberries						
Lowbush blueberry: Directed soil application in early spring; ground equipment	51% WDG [59639-99] [59639-119]	0.375	1	0.375	NS	Apply in a minimum of 20 gal/A (15 gal/A). The minimum RTI is 30 days.
Other bushberries: Directed soil application in early spring and during the later stages of berry development.		0.375	2	0.75	7	
Tree Nuts (including pistachios)						
Soil directed applications; ground equipment	51% WDG [59639-99] [59639-119]	0.375	2	0.75	60	The minimum RTI is 60 days (30 days). Apply in a minimum of 20 gal/A (15 gal/A).
Asparagus						
Broadcast soil application prior to spear emergence	51% WDG [59639-99] [59639-119]	0.375 (0.255)	1	0.375 (0.255)	14	Apply in a minimum of 20 gal/A (or 15 gal/A).
Garlic						
Preemergence broadcast application within 3 days of planting; ground equipment	51% WDG [59639-99] [59639-119]	0.38	1	0.38	NS	Apply in a minimum of 10 gal/A.

[1] Where there is a difference in information between the summarized use directions and the example labels, the information from the example labels is indicated by shading.

[2] Rotational crop restriction: Do not plant any crop except cotton, peanut, soybean and sugarcane earlier than 30 days after application of flumioxazin.

NS = not specified.

Conclusions: The available labels and summaries of the proposed use directions are adequate for evaluation of the field trial data. However, discrepancies were noted in the maximum use rates and the minimum application volumes listed on example labels when compared to those in the use summaries provided by IR-4. For purposes of this review, the use summaries provided by IR-4 were considered to represent the intended 1x use rate. For each crop, the use directions on the proposed labels must be reconciled with the directions listed in the use summaries, and new labels should be submitted. Based on the available field trial data, the following revisions should also be made to the proposed labels for the 51% WDG formulations.

- For dry beans, the labels may specify a maximum single and seasonal use rate of up to 0.093 lb ai/A, including both the preemergence and pre-harvest uses.
- For fruiting vegetables (including okra) and melons, labels may allow for up to two directed applications per season at up to 0.125 lb ai/A/application.
- For melons, applications after blooming should be prohibited.
- For tree nuts, the labels should specify a minimum RTI of 60 days rather than 30 days.
- For asparagus, a maximum single application rate of up to 0.375 lb ai/A may be specified.

860/1300 Nature of the Residue – Plants

MARC Decision Memo, DP Num: 272652, R. Loranger, 12/MAR/2001

Adequate plant metabolism studies are available depicting the uptake and metabolism of [^{14}C]-flumioxazin following pre-emergence or soil-directed applications to soybeans, peanuts, corn, sugarcane, and grapes (DP Num: 259493, D. Dotson; 12/MAR/2001; and 45375504.der, 45888501.der, and 45375503.der, M. Doherty). Based on these studies, the HED has determined that the parent compound only is the residue of concern to be used in risk assessments and the tolerance expression for primary and rotated crops. The crops and use patterns utilized in the available metabolism studies adequately cover the proposed uses.

860.1300 Nature of the Residue – Livestock

MARC Decision Memo; DP Num: 272652; R. Loranger; 12/MAR/2001

Adequate ruminant and poultry metabolism studies are available depicting the metabolism of flumioxazin radiolabeled in either the phenyl or tetrahydrophthaloyl (THP) ring (DP Num: 194594, J. Garbus, 22/SEP/1994; and DP Num: 259493, D. Dotson, 12/MAR/2001). In the ruminant studies, dairy goats were dosed orally for 5 days with phenyl-[^{14}C]- flumioxazin or THP-[^{14}C]-flumioxazin at levels equivalent to 7.2 and 11.8 ppm in the diet, which represent approximately 4.7x and 7.8x the TDB. Levels of total radioactive residues (TRR) in tissues were similar for the two [^{14}C]-labels, at 0.012 to 0.028 ppm in muscle, 0.004 to 0.010 ppm in fat, 0.110 to 0.330 ppm in liver and kidney, and 0.005 to 0.055 ppm in milk.

In the poultry studies, laying hens were dosed orally for 14 days with phenyl-[^{14}C]- flumioxazin or THP-[^{14}C]-flumioxazin at levels equivalent to 9.0 and 9.9 ppm in the diet, which represent approximately 2250x and 2475x the TDB. For the phenyl-[^{14}C]-label, TRR were 0.040 to 0.074 ppm in muscle and fat, 0.237 ppm in liver, 0.437 ppm in egg yolks, and 0.018 ppm in egg whites. For the THP-[^{14}C]-label, TRR were 0.138 to 0.226 ppm in muscle and fat, 1.137 ppm in liver, 0.531 to 0.760 ppm in egg yolks (Days 9 to 14), and 0.024 to 0.041 ppm in egg whites.

The metabolism of flumioxazin is similar in both ruminants and poultry, involving the hydroxylation and reduction of the cyclohexene ring in the THP moiety, hydrolytic cleavage of the imide and amide linkages, and incorporation of sulfonic acid into the THP moiety. After reviewing the available studies, the MARC determined that the residues of concern for ruminants should include parent, 3-OH-flumioxazin, 4-OH-flumioxazin, and Metabolites B, C, and F. For poultry, the residues of concern are parent, 3-OH-flumioxazin, 4-OH-flumioxazin, and 4-OH-S-53482-SA.

860.1340 Residue Analytical Methods

Plant Commodities An adequate GC/NPD method is available for enforcing tolerances of flumioxazin in plant commodities (MRID No. 43935509, Valent Residue Method #RM-30A-1, *Determination of Flumioxazin Residues in Crops,* J. Garbus, 08/JAN/1996). This method has undergone a successful independent laboratory validation (ILV) trial and a successful petition method validation (PMV) trial by the Agency. The reported method LOQ and LOD for flumioxazin are 0.020 and 0.010 ppm, respectively. However, the validated LOQ was 0.010 ppm for residues in soybean seed, forage, and hay in the PMV trial, and the LOD was 0.005 ppm.

In the crop field trials submitted in support of the current petitions, residues of flumioxazin were determined in plant commodities using a GC/NPD method (Valent Method RM-30A-3), which is

a more recent version of the tolerance enforcement method. For Method RM-30A-3, residues are extracted with acetone/water (4:1, v/v) and then partitioned into DCM. After evaporation of the DCM, residues are purified by partitioning between hexane/ACN. The residues in the ACN phase are then concentrated, re-dissolved in hexane/ethyl acetate, and purified using a Florisil column eluted with hexane/ethyl acetate (2:1 v/v). Residues in the eluate were concentrated, reconstituted in acetone, and then analyzed by GC/NPD, using external standards.

Method RM-30A-3 was adequately validated in conjunction with the analysis for samples from each of the field trials. The validated method LOQ for flumioxazin in/on all plant commodities is 0.02 ppm, and the LODs range from 0.005 ppm (asparagus) to 0.01 ppm (pecans and alfalfa).

Livestock Commodities As tolerances for livestock commodities are not required, an enforcement method for livestock commodities is not necessary. However, adequate data collection methods were submitted in conjunction with the cattle feeding study (46889603.der, D. Rate, 10/SEP/2007). Residues of flumioxazin and its two hydroxy metabolites (3-OH-flumioxazin and 4-OH-flumioxazin) were determined in milk and tissues using two related LC/MS/MS methods, Valent Methods RM-30MK for milk and RM-30T for tissues.

For Method RM-30MK, milk samples are diluted with acetone and centrifuged. The resulting supernatant is diluted with 5% sodium chloride solution, and residues are partitioned into DCM. Residues are then concentrated to dryness, and re-dissolved and partitioned in hexane/ACN. Residues in the resulting ACN phase are concentrated to dryness, and re-dissolved in methanol/water (1:1, v/v). Residues are determined by LC/MS/MS using a high performance liquid chromatography (HPLC) system consisting of a C_8 column with a mobile phase gradient of water to methanol, each containing 0.05% formic acid. Residues were quantified by MS/MS using external standards and the m/z 355→299 transition for parent, m/z 371→299/107 transitions for 3-OH-flumioxazin, and the m/z 371→299/107 transitions for 4-OH-flumioxazin.

For Method RM-30T, residues in tissue samples are extracted sequentially with ACN and ACN/water (1:1, v/v) containing 1% acetic acid. The extracts are combined and concentrated to remove the ACN, and diluted with 5% sodium chloride solution. Residues are then partitioned into DCM, concentrated to dryness, and re-dissolved and partitioned in hexane/ACN. Residues in the resulting ACN phase are concentrated to dryness, and re-dissolved in methanol/water (1:1, v/v). Residues are determined by LC/MS/MS using an HPLC system consisting of a C_8 column with a mobile phase gradient of water to methanol, each containing 0.05% formic acid. Residues were quantified by MS/MS using external standards and the m/z 355→299 transition for parent, m/z 371→299/107 transitions for 3-OH-flumioxazin, and the m/z 371→299/107 transitions for 4-OH-flumioxazin.

The above methods were adequately validated in conjunction with the analysis of the feeding study samples using control samples of milk and tissues fortified with each analyte at 0.02 and 0.10 ppm. Recoveries from milk, cream and skim milk averaged 84-92% (± 1-9%) for flumioxazin, 89-95% (± 8-11%) for 3-OH-flumioxazin, and 84-93% (± 6-10%) for 4-OH-flumioxazin. Recoveries from tissues averaged 77-88% (± 3-12%) for flumioxazin, 85-102% (± 12-25%) for 3-OH-flumioxazin, and 96-102% (± 17-20%) for 4-OH-flumioxazin. For both methods, the validated LOQ is 0.02 ppm for each analyte, and the reported LOD is 0.01 ppm.

860.1360 Multiresidue Methods

DP Num: 259493, D. Dotson, 12/MAR/2001

Data depicting the analysis of flumioxazin through FDA Multiresidue Protocols were submitted and will be forwarded to FDA for review. The multiresidue method testing data indicate that flumioxazin is not recovered through Sections 304 and 402 of PAM, Vol. I.

860.1380 Storage Stability

Storage stability data for flumioxazin residues in various plant commodities are available from several earlier petitions (DP Num: 259493, D. Dotson, 12/MAR/2001; DP Num: 298647, W. Drew, 17/FEB/2004; DP Num: 301247, W. Drew; 23/JUL/2004; and DP Num: 310408, W. Drew; 15/MAR/2006). Data from these petitions indicate that flumioxazin is stable in frozen (-20ºC) storage for at least the following intervals: 13 months in sugarcane; 12 months in cherries and soybean forage, hay, and seed; 10 months in peanut forage, hay, hulls, and nutmeats; 9 to 11 months in mint tops and oil; 9 months in prunes, wet apple pomace, potatoes, and potato processed fractions; 6 months in apple juice, grapes, raisins, and almond nutmeats and hulls; 4 months in dry bulb onions; 3 months in cotton seed, gin byproducts, hulls, and meal; and 2 to 3 months in grape juice, and sugarcane molasses and refined sugar.

In conjunction with each of the new field trials, concurrent storage stability studies were also conducted using control samples of each commodity fortified with flumioxazin at 0.10 or 0.20 ppm and stored under conditions similar to the field trial samples (≤-15ºC). These studies indicated that flumioxazin is stable at -20ºC for at least the following intervals: 30 months in alfalfa forage and hay; 22 months in dry beans; 7 months in tomatoes and asparagus; 5.8 months in blueberries; and 4 months in cantaloupes and pecans. The actual durations of sample storage from the new crop field trials are presented in Table 4.

Residue decline was observed only in the pepper storage stability study. Following 786 days (25.8 months) of frozen storage, there was an apparent 19% decline in flumioxazin residues in peppers. However, the validity of the decline could not be confirmed as only one storage interval was tested. In addition, the correction of residue levels in peppers would have no impact on the conclusions regarding the tolerance level in fruiting vegetables. Residues were non-detectable (<0.007 ppm) in/on all 18 pepper samples, and even if a 19% correction factor is applied for decline during storage, the resulting residues on peppers (0.009 ppm) would still be well below the method LOQ of 0.02 ppm.

Table 4. Summary of Storage Conditions and Intervals of Samples from Crop Field Trials.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (Days)	Interval of Demonstrated Storage Stability (Days)
Alfalfa forage and hay	-20	455	929
Pecan, nutmeat	-20 to -15	55-97	135
Cantaloupes	-25 to -15	58-125	125
Dry Bean, seeds	-25 to-15	309	684
Blueberries	-25 to-15	128-176	176
Asparagus	-25 to -15	29-110	217
Tomato	-25 to -15	204	212
Pepper	-25 to -15	807	786 [1]

[1] An apparent 19% decline in residues was noted in peppers after 26 months of frozen storage.

Conclusions The available storage stability data are adequate and support the sample storage durations incurred in the alfalfa, pecan, cantaloupe, dry bean, blueberry, asparagus, tomato and pepper field trials. As frozen samples of whole milk, cream, skim milk and tissues from the cattle feeding study were analyzed within 30 days of collection, no storage stability data are required to support the feeding study.

860.1400 Water, Fish, and Irrigated Crops

This guideline requirement is not relevant to the current petition as no aquatic uses are being proposed.

860.1460 Food Handling

This guideline requirement is not relevant to the current petition as no food handling uses are being proposed for flumioxazin.

860.1480 Meat, Milk, Poultry, and Eggs

46889603.der, D. Rate, 20/JUN/2007 (Cattle Feeding Study)

The potential dietary exposure of livestock to flumioxazin residues was previously calculated to be 0.25 ppm for beef and dairy cattle, 0.008 ppm for poultry, and 0.15 ppm for swine under an earlier petition (DP Num: 310408, W. Drew, 15/MAR/2006). However, the addition of uses on alfalfa will increase the potential dietary burden of flumioxazin residues for cattle. In addition, the Agency has recently revised its guidance on calculating potential residues in livestock diets and updated the types and percentages of feedstuffs listed in Table 1 of OPPTS Guideline 860.1000 (Memo, ChemSAC, OCT/25/2006). Therefore, the potential TDB of flumioxazin residues to livestock was recalculated using the recent guidance on constructing a reasonably balanced diet for livestock. The dietary exposure was calculated to be 0.96 ppm for beef cattle, 3.19 ppm for dairy cattle, 0.005 ppm for poultry and 0.004 ppm for swine (Table 5).

Table 5. Calculation of Maximum Dietary Burdens of Flumioxazin Residues to Livestock.					
Feedstuff	Type	% Dry Matter	% Diet	Recommended Tolerance (ppm)	Dietary Contribution (ppm)
Beef Cattle R: 15%; CC: 75 %; PC: 10%					
Alfalfa, hay	R	89	10	8.0	0.90
Cotton, gin byproducts	R	90	5	0.6	0.034
Sugarcane , molasses	CC	75	10	0.2	0.027
Untreated	CC	NA	70	NA	-0-
Soybean, seed (meal)	PC	89	5	0.02	0.001
Total			**100**		**0.961**
Dairy Cattle R: 45%; CC: 45 %; PC: 10%					
Alfalfa, hay	R	89	20	8.0	1.80
Alfalfa, forage/silage	R	35	15	3.0	1.29
Almond, hulls	R	90	10	0.7	0.08
Sugarcane , molasses	CC	75	10	0.2	0.027
Untreated	CC	NA	35	NA	-0-
Cotton, undelinted seed	PC	90	10	0.02	0.002
Total			**100**		**3.19**
Poultry CC: 75-80 %; PC: 20-25% (normally no R, some exceptions)					
Untreated	CC	NA	75	NA	-0-
Peanut, meal/soybean seed/meal	PC	N/A	25	0.02	0.005
Total			**100**		**0.005**
Swine CC: 80-85 %; PC: 15-20%					
Untreated	CC	NA	80	NA	-0-
Peanut, meal/soybean seed/meal	PC	N/A	20	0.02	0.004
Total			**100**		**0.004**

All data are based on Table 1 Feedstuffs (October 2006), a revision of feedstuffs data found in Table 1 (OPPTS Residue Chemistry Test Guideline 180.1000). Residue levels for beef and dairy cattle are corrected for moisture content and are determined by formula: tolerance / % dry matter (DM) x % in diet. Residue levels for poultry and swine are considered "as-is" and are determined by formula: tolerance x % in diet. R = roughage; CC = carbohydrate concentrate; PC = protein concentrate.

Cattle: In the submitted cattle feeding study, lactating Holstein dairy cows (3 cows/dose group) were dosed orally with flumioxazin (TGAI, 99.1% ai) via capsules at levels equivalent to 2, 6 and 20 ppm in their diet for 28 consecutive days. These dose levels are respectively equivalent to 0.6x, 1.9x, and 6.3x the TDB for dairy cattle. Cows were dosed once a day following the a.m. milking, and the actual dose for each cow was based on their average feed consumption (dry wt. basis) during the acclimation period. Composited samples of milk were collected from each cow on Study Days: -1 (pre-dosing), 1, 2, 4, 7, 10, 14, 17, 21, 24 and 28, and subsamples of whole milk from Day 24 were centrifuged to obtain cream and skim milk samples. Within 24 hours of receiving the final dose, cows were sacrificed and samples of liver, kidney, composited muscle, and composited fat were collected from each animal and stored at -20ºC. As all samples were analyzed within 30 days of collection, supporting storage stability data are not required.

Residues of flumioxazin and its two hydroxy metabolites (3-OH-flumioxazin and 4-OH-flumioxazin) were determined in milk and tissues using two related LC/MS/MS methods, Valent

Methods RM-30MK for milk and RM-30T for tissues. These methods were adequately validated in conjunction with the analysis of feed study samples. Recoveries from milk, cream and skim milk averaged 84-92% (± 1-9%) for flumioxazin, 89-95% (± 8-11%) for 3-OH-flumioxazin, and 84-93% (± 6-10%) for 4-OH-flumioxazin. Recoveries from tissues averaged 77-88% (± 3-12%) for flumioxazin, 85-102% (± 12-25%) for 3-OH-flumioxazin, and 96-102% (± 17-20%) for 4-OH-flumioxazin. For each analyte, the validated LOQ in milk and tissues is 0.02 ppm, and the reported LOD is 0.01 ppm.

Following oral dosing with flumioxazin at a level equivalent to 20 ppm in the diet (6.3x TDB), residues of flumioxazin, 3-OH-flumioxazin and 4-OH-flumioxazin were each non-detectable (<0.01 ppm) in all samples of milk, skim milk, cream, liver, kidneys, muscle and fat from all three cows. As residues were <LOD in the 20 ppm dose group, samples of milk and tissues from the 2 and 6 ppm dose groups were not analyzed.

Conclusions The submitted cattle feeding study is adequate. As residues of flumioxazin and its two hydroxy metabolites were <LOD in all samples of milk and tissues from cattle dosed for 28 days at levels equivalent to 20 ppm in their diet (6.3x TDB), quantifiable residues are unlikely to occur in cattle, goats, horse, or sheep. Therefore, tolerances for flumioxazin residues are not required in commodities from cattle, goats, hogs, horses or sheep (40 CFR §180.6[a][3]).

In addition, results from the available poultry metabolism study, in which hens were dosed for 14 days at 9.0 ppm (1,800x TDB), indicate that quantifiable residues are unlikely to occur in eggs or poultry tissues. Therefore, tolerances for flumioxazin residues are also not required in eggs or poultry tissues (40 CFR §180.6[a][3]).

860.1500 Crop Field Trials

45375505.der, W. Drew (Almond)
46133901.der, W. Drew (dry bulb onion)
46889604.der, D. Rate, 19/SEP/2007 (Alfalfa)
47005101.der, D. Rate, 10/SEP/2007 (Pecan)
47005102.der, D. Rate, 07/SEP/2007 (Cantaloupe)
47005103.der, D. Rate, 07/SEP/2007 (Dry beans)
47005104.der, D. Rate, 10/SEP/2007 (Blueberry)
47005105.der, D. Rate, 07/SEP/2007 (Asparagus)
47005106.der, D. Rate, 07/SEP/2007 (Tomato)
47005107.der, D. Rate, 07/SEP/2007 (Pepper)

Valent has submitted new field trail data on alfalfa and IR-4 has submitted new field trial data on pecans, cantaloupes, dry beans, blueberries, asparagus, tomatoes and peppers. The pecan data will be used in conjunction with data from the previously reviewed almond field trials (DP Num: 301247, W. Drew, 23/JUL/2004) to support a use on the tree nuts crop group. The results from these studies are discussed below and summarized in Table 6. In addition, data from the previously reviewed bulb onion field trials (DP Num: 301247, W. Drew, 23/JUL/2004) will be used to evaluate the proposed label amendment for garlic.

Table 6. Summary of Residue Data from Crop Field Trials with Flumioxazin (WDG).

Crop matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
Alfalfa (proposed use = 0.25 lb ai/A total application rate, 25-day PHI)									
Forage	0.12-0.26 [3]	25	2	24	0.02	0.80	0.80	0.12	0.18

Table 6. Summary of Residue Data from Crop Field Trials with Flumioxazin (WDG).									
Crop matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm) [1]						
			n	Min.	Max.	HAFT	Median	Mean	Std. Dev.
		60	3	26	<0.01	0.19	0.14	0.02	0.03
		113	4	26	<0.01	0.09	0.04	0.01	0.02
Hay	0.12-0.26 [3]	25	2	24	0.06	1.60	1.50	0.27	0.48
		60	3	26	<0.01	0.09	0.08	0.03	0.03
		113	4	22	<0.01	0.15	0.13	0.01	0.03
Tree nuts (proposed use = 0.75 lb ai/A total application rate, 60-day PHI)									
Pecan	0.751-0.769	42-61 [4]	10	<0.02	<0.02	<0.02	0.02	0.02	--
Almond	0.749-0.758	60-61	8	<0.01	<0.01	<0.01	0.01	0.01	--
Almond, hulls			8	<0.01	0.066	0.064	0.034	0.034	0.022
Melons (proposed use = 0.25 lb ai/A total application rate, No PHI)									
Cantaloupe	0.245-0.256	36-69	16	<0.02	<0.02	<0.02	0.02	0.02	--
Dry Beans (proposed use = 0.093 lb ai/A total application rate, 5-day PHI)									
Beans, dry	0.091-0.096	4-6	26	<0.02	0.05	0.05	0.02	0.02	0.01
Bushberries: Lowbush, proposed use = 0.40 lb ai/A total application rate, No PHI Highbush, proposed use =0.75 lb ai/A total application rate, 7-day PHI									
Blueberry, lowbush	0.400	99	2	<0.02	<0.02	<0.02	0.02	0.02	--
Blueberry, highbush	0.744-0.797	6-8	10	<0.02	<0.02	<0.02	0.02	0.02	--
Asparagus (proposed use =0.375 lb ai/A total application rate, 14-day PHI)									
Asparagus	0.190-0.197	8-20 [5]	16	<0.02	<0.02	<0.02	0.02	0.02	--
	0.380-0.404		16	<0.02	<0.02	<0.02	0.02	0.02	--
Fruiting vegetables, including okra (proposed use = 0.25 lb ai/A total, 21-day PHI)									
Tomato	0.244-0.259	15-21 [6]	24	<0.02	<0.02	<0.02	0.02	0.02	--
Peppers (Bell and Non-Bell)	0.246-0.259	15-21 [6]	18	<0.02	<0.02	<0.02	0.02	0.02	--

[1] With the exception of the almond field trials, the validated method LOQ is 0.02 ppm. For almond nutmeats and hulls, the LOQ was 0.01 ppm. For calculation of the median, mean, and standard deviation, the LOQ was used for samples with residues <LOQ.

[2] HAFT = Highest Average Field Trial.

[3] All 12 alfalfa field trials included a single application at 0.12-0.13 lb ai/A following the 1st cutting, and six of the field trials also included an earlier application to dormant alfalfa at 0.12-0.13 lb ai/A for a total of 0.24-0.26 lb ai/A.

[4] Pecan samples were collected at a 59-61 day PHI, with the exception of one site (42 day PHI).

[5] Samples were collected at a 19-21 day PHI, with the exception of one site (15 day PHI) each for tomatoes and peppers.

[6] For asparagus, 12 out of 16 samples were harvested at a 14-15 day PHI.

Bulb Vegetables (Group 3)

Garlic For the currently registered preemergence use of flumioxazin on garlic, IR-4 is requesting that the use directions be amended to increase the maximum application rate to 0.38 lb ai/A. The current use on garlic is supported by bulb onion field trial data, which were previously reviewed under an earlier petition (DP Num: 301247, W. Drew, 23/JUL/2004).

In 9 bulb onion trials conducted during 2001-2002 in EPA growing Regions 1, 2, 5, 6, 9, 10 and 11, flumioxazin (51% WDG) was applied to bulb onions as a two postemergence broadcast applications at 0.09-0.10 lb ai/A, for a total use rate of 0.185-0.200 lb ai/A. The first application was made at the 2nd leaf stage and the second application was made during vegetative development at RTIs of 29-78 days. The applications were made using ground equipment at spray volumes of 16-42 gal/A, and each application included the use of NIS adjuvant at 0.25% of the spray volume. Control and duplicate treated samples of bulb onions were harvested at normal maturity at a 42-49 day PHI. Samples were stored frozen up to 124 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-1) used for determining flumioxazin residues in/on onions was adequately validated in conjunction with the field trials. The validated LOQ for flumioxazin was 0.02 ppm in/on bulb onions, and the stated LOD was 0.009 ppm.

Following two postemergence applications totaling 0.185-0.200 lb ai/A, residues were <0.02 ppm in/on 18 samples of bulb onions harvested at a 42-to 49-day PHI.

Although the bulb onion data are from field trials that were conducted at only 0.5x the proposed maximum use rate for garlic, the bulb onion data will adequately support the requested increase in the use rate for garlic because the applications to onions occurred at a much later growth stage than allowed for garlic, and residues in/on all onion samples were <LOQ. The residue data on onions reflect postemergence applications with PHIs of 42-49 days, whereas, the use on garlic is for a single preemergence application, and the typical planting to harvest interval for garlic is approximately 8 months (250 days).

Legume Vegetables (Group 6)

Dry Beans: IR-4 submitted field trial data for flumioxazin on dry beans. In 12 field trials conducted during 2003 in EPA growing Regions 1 (one trial; NY), 5 (3 trials; OH, ND), 7 (4 trials; NE, ND), 8 (2 trials; CO), 10 (one trial; CA) and 11 (one trial; ID), flumioxazin (51% WDG) was applied to dry bean varieties as a single pre-harvest, broadcast application at 0.091-0.096 lb ai/A (1x rate). The applications were made using ground equipment at volumes of 10-35 gal/A, and each application included the use of a COC at 0.6-2.5% of the spray volume. The beans were cut at normal commercial maturity following a 4- to 6-day PHI, and dried prior to shelling. Beans were shelled either by hand or mechanically, and duplicate control and treated samples of dry beans were collected. Samples were stored frozen up to 309 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on dry beans was adequately validated in conjunction with the field trials. The average concurrent recovery of flumioxazin was 107% with a standard deviation of 11%. The validated method LOQ for flumioxazin was 0.02 ppm in/on dry beans, and the statistically calculated LOD was 0.007 ppm.

Following a single pre-harvest broadcast application of flumioxazin (WDG) at 0.091-0.096 lb ai/A, residues were ND-0.05 ppm in/on 26 samples of dried beans harvested at a 4- to 6-day PHI. Residues were <LOQ (<0.02 ppm) in/on 22 of the 26 samples. Average residues were 0.02 ppm and the HAFT residues were 0.05 ppm.

Fruiting Vegetables, except Cucurbits (Group 8)

Tomatoes: IR-4 submitted field trial data for flumioxazin on the representative crop of tomatoes. In 12 field trials conducted during the 2003 growing season in EPA growing Regions 1 (one trial; NY), 2 (one trial; SC), 3 (2 trials; FL), 5 (one trial; WI) and 10 (7 trials; CA), flumioxazin (51% WDG) was applied to tomatoes as two soil applications directed to row middles at 0.120-0.134 lb ai/A/application, for a total use rate of 0.244-0.259 lb ai/A (1x rate).

The initial application was made at seedling emergence, transplanting, or during early vegetative development, and the second application was made approximately 21 days prior to crop maturity, for RTIs of 45-103 days. At one field site, an additional plot was treated at an exaggerated rate of 0.621-0.689 lb ai/A, for a total of 1.25 lb ai/A (5x rate). Applications were made using ground equipment at volumes of 16-32 gal/A, and each application included the use of a COC at 1% v/v of the spray volume. Single control and duplicate treated samples were harvested at a 19- to 21-day PHI, with the exception of one test where samples were harvested at a 15-day PHI due to weather conditions. Samples were stored frozen up to 204 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on tomatoes was adequately validated in conjunction with the field trials. The validated method LOQ for flumioxazin in/on tomatoes was 0.02 ppm, and the statistically calculated LOD was 0.01 ppm.

Following two soil-directed applications of flumioxazin (WDG) totaling 0.244-0.259 lb ai/A (1x rate), residues were <LOQ in/on all samples of tomatoes harvested at 15-21 DAT. Based on an LOQ of 0.02 ppm, average and median residues were 0.02 ppm. Residues were also <LOQ in/on the two tomato samples harvested from the plot treated at 1.25 lb ai/A (5x rate).

Peppers: IR-4 submitted field trial data for flumioxazin on the representative crop of peppers. In 9 field trials conducted during 2003 growing season in EPA growing Regions 2 (2 trials; NC, GA), 3 (one trial; FL), 6 (2 trials; TX), 8 (one trial; CO) and 10 (3 trials; CA, NM), flumioxazin (51% WDG) was applied to bell and non-bell peppers as two soil applications directed to row middles at 0.121-0.131 lb ai/A/application, for a total use rate of 0.246-0.259 lb ai/A (1x rate). The initial application was made to seedlings or transplants during early vegetative development, and the second application was made approximately 21 days prior to crop maturity, for RTIs of 42-82 days. Applications were made using ground equipment at volumes of 12-26 gal/A, and each application included the use of a COC at 1% v/v of the spray volume. Duplicate control and treated samples were harvested at a 19- to 21-day PHI, with the exception of one test where samples were harvested at a 15-day PHI due to fruit rot. Pepper samples were stored frozen up to 807 days, and the storage durations are supported by the available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on peppers was adequately validated in conjunction with the field trials. The average method validation recovery of flumioxazin from peppers was 87% with a standard deviation of 19%. The validated LOQ for flumioxazin in/on peppers was 0.02 ppm, and the statistically calculated LOD was 0.007 ppm.

Following two soil-directed applications of flumioxazin (WDG) to peppers at rates totaling 0.246-0.259 lb ai/A (1x rate), residues were non-detectable (<0.007 ppm) for in/on all samples harvested at a 15- to 21-day PHI. Even if residues are corrected to account for a 19% decline during storage, residues in/on all pepper samples would still be <0.009 ppm.

Melon (Subgroup 9A)

Cantaloupes: IR-4 submitted field trial data for flumioxazin on the representative crop cantaloupes. In eight field trials conducted during 2003 in EPA growing Regions 2 (one trial;

NC), 5 (one trial; MI), 6 (2 trials; TX) and 10 (4 trials; CA, NM), flumioxazin (51% WDG) was applied to cantaloupes as two soil applications directed to row middles at 0.121-0.130 lb ai/A/application, for a total use rate of 0.245-0.256 lb ai/A (1x rate). The initial application was made either preplant or preemergence, and the second application was made during later vegetative development or at blooming, for RTIs of 30-47 days. Applications were made using ground equipment at volumes of 20-32 gal/A, and did not include the use of any adjuvant. Duplicate control and treated samples were harvested following a 36- to 69-day PHI. Samples were stored frozen up to 125 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on cantaloupes was adequately validated in conjunction with the analysis of field trial samples. The validated LOQ for flumioxazin was 0.02 ppm, and the statistically calculated LOD was 0.008 ppm.

Following two soil-directed applications of flumioxazin (WDG) totaling 0.245-0.256 lb ai/A, residues were non-detectable (<0.008 ppm) in/on all 16 samples of cantaloupes harvested at 36-69 DAT. Based on an LOQ of 0.02 ppm, average and median residues were 0.02 ppm.

Bushberries (Subgroup 13B).

Blueberries: IR-4 submitted field trial data for flumioxazin on the representative crop blueberries. A total of 6 field trials were conducted on lowbush (1 test) and highbush (5 tests) blueberries during 2003 in EPA growing Regions 1 (one trial; ME), 2 (2 trials; NJ,NC), 5 (2 trials; MI), and 12 (one trial; OR). In the lowbush blueberry test, flumioxazin (51% WDG) was applied to dormant plants as a single broadcast application at 0.40 lb ai/A. In the highbush blueberry tests, flumioxazin (51% WDG) was applied as two soil-directed applications at 0.370-0.405 lb ai/A/application, for a total use rate of 0.744-0.797 lb ai/A (1x rate). The first application was made around bud break and flowering and the second application was made 50-113 days later during fruit development. Applications were made using ground equipment at volumes of 20-32 gal/A and did not include the use of an adjuvant. Duplicate control and treated samples of blueberries were harvested at either a 99-day PHI in the lowbush test or at a 6- to 8-day PHI in the highbush tests. Samples were stored frozen up to 176 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on blueberries was adequately validated in conjunction with the analysis of field trial samples. The validated LOQ for flumioxazin in/on blueberries was 0.02 ppm, and the statistically calculated LOD was 0.006 ppm.

Following a single broadcast application to dormant plants at 0.40 lb ai/A, flumioxazin residues were non-detectable (ND) in/on two samples of lowbush blueberries harvested at a 99-day PHI. Residues were <LOQ (<0.02 ppm) in/on 10 samples of highbush blueberries harvested 6-8 days after the second of two soil-directed applications totaling 0.744-0.797 lb ai/A. Average flumioxazin residues were <0.02 ppm in/on both lowbush and highbush blueberries.

Tree Nuts (Group 14)

Almonds: The almond field trail data were previously reviewed under an earlier petition (DP Num: 301247, W. Drew, 23/JUL/2004). A total of 5 field trials were conducted on almonds during 1999 in CA (Zone 10). In four tests, flumioxazin (51% WDG) was applied to almond trees as two soil-directed applications during nut development at 0.375 lb ai/A/application, and RTIs of 60 days, for a total use rate of 0.75 lb ai/A/season (1x rate). In a fifth test, flumioxazin (51% WDG) was applied similarly at rates of 0.75 lb ai/A, for a total use rate of 1.5 lb ai/A/season (2x rate). Applications were made using ground equipment at spray volumes of 18-25 gal/A, and included the use of a COC as an adjuvant. Control and treated samples of nuts and hulls were harvested from four of the tests at a 60- to 61-day PHI. Samples were stored frozen up to 185 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-1) used for determining flumioxazin residues in/on almond nutmeats and hulls was adequately validated in conjunction with the field trials. The validated LOQ for flumioxazin in/on almond nutmeats and hulls was 0.01 ppm, and the reported LOD was 0.005 ppm.

Following two soil-directed applications of flumioxazin (WDG) during nut development at rates totaling 0.75 lb ai/A (1x rate), flumioxazin residues were <LOQ (ND-0.007 ppm) in/on 8 samples of nutmeats and ND-0.066 ppm in/on 8 samples of hulls. For the 2x-rate applications, residues were 0.006 and 0.007 ppm in/on two nutmeat samples and 0.487 and 0.617 ppm in/on 2 hull samples.

Pecans: IR-4 submitted additional field trial data for flumioxazin on pecans. In 5 field trials conducted during 2003 in EPA growing Regions 2 (2 trials; NC), 4 (one trial; TX), 6 (one trial; LA) and 8 (one trial; NM), flumioxazin (51% WDG) was applied to pecan trees as two soil-directed applications during nut development at rates of 0.374-0.381 lb ai/A and RTIs of 58-61 days, for a total use rate of 0.751-0.760 lb ai/A (1x rate). Applications were made using ground equipment at volumes of 22-33 gal/A, and did not include the use of any spray adjuvant. Duplicate control and treated samples of nuts were harvested from four of the tests at a 59- to 61-day PHI, and from one site at a 42-day PHI to prevent predation. Samples were stored frozen up to 97 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on pecans was adequately validated in conjunction with the field trials. The validated LOQ for flumioxazin in/on pecans was 0.02 ppm, and the statistically calculated LOD was 0.01 ppm.

Following two soil-directed applications of flumioxazin (WDG) during nut development at rates totaling 0.751-0.760 lb ai/A, flumioxazin residues were non-detectable (ND, <0.01 ppm) in/on all samples of nutmeats harvested at a 42-61 day PHI.

Nongrass Animal Feeds (Group 18)

Alfalfa: Valent Corporation submitted field trial data for flumioxazin on alfalfa from 12 field trials conducted during 2003, 2004 and 2005 in EPA growing Regions 1 (one trial; PA), 2 (one trial; GA), 5 (6 trials; MO, NE, SD, OH, IL), 7 (one trial; ND), 9 (one trial; AZ), 10 (one trial; CA) and 11 (one trial; ID). In the six field trials conducted during 2003 and 2004 (Trials A-G), flumioxazin (51% WDG) was applied to alfalfa as two broadcast foliar applications at 0.12-0.13

lb ai/A/application, for a total use rate of 0.24-0.26 lb ai/A. One test site (Trial A) also include a plot using exaggerated application rates of 0.25 lb ai/A, for a total use rate of 0.5 lb ai/A/season. The initial application in the 2003/2004 trials was made to dormant or immature alfalfa approximately 25 days prior to the 1st cutting, and the second application was made to stubble and new growth, 6-8 days following the 1st cutting, for RTIs of 31-41 days. Owing to the excessive phytotoxicity noted in the 2003/2004 tests, the application regime was changed for the six field trails conducted in 2005. In these tests, flumioxazin (51% WDG) was applied to the new growth 7-9 days after the 1st cutting as a single broadcast foliar application at 0.12-0.13 lb ai/A. Two test sites during 2005 (Trials H and J) also include plots using an exaggerated application of 0.25 lb ai/A. All applications were made using ground equipment at volumes of 15-26 gal/A. The initial application in the 2003/2004 tests and the single application in the 2005 tests included the use of a non-ionic surfactant (NIS) as an adjuvant at 0.25% v/v.

Following the application of flumioxazin to alfalfa stubble/new growth after the 1st cutting, three additional cuttings of alfalfa were obtained from each test at normal harvest intervals. The 2nd, 3rd, and 4th cuttings were made following a 24- to 26-day PHI, 45- to 70-day PHI, and a 71- to 128-day PHI, respectively. At each of these cuttings, single control and duplicate treated samples of forage and hay were collected. Duplicate treated samples of forage and hay were also collected at 3, 15, 24, 35, 65 and 107 DAT from one test in 2003 to examine residue decline. In all tests, the forage samples were immediately frozen after collection, and the hay samples were field-dried for 1-9 days prior to collection. Forage and hay samples were stored frozen for up to 455 days prior to analysis, a duration supported by the submitted storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on alfalfa forage and hay was adequately validated in conjunction with the analysis of field trial samples. The validated method LOQ for flumioxazin in/on alfalfa forage and hay was 0.02 ppm, and the reported LOD was 0.01 ppm.

Although the 2003/2004 field trials included an extra application of flumioxazin to dormant or emergent alfalfa, all the field trials included an application at 0.12-0.13 lb ai/A to alfalfa approximately 7 days following the 1st cutting of the season. The resulting flumioxazin residues in/on forage and hay from the 2nd cutting (~25 day PHI), and from the subsequent 3rd and 4th cuttings were similar across all tests, regardless of whether or not an early-season application was made. Residues of flumioxazin in/on forage were <0.02-1.70 ppm from the 2nd cutting harvested at 24-26 DAT, <0.02-0.19 ppm from the 3rd cutting harvested at 45-70 DAT, and <0.02-0.06 ppm from the 4th cutting harvested at 71-128 DAT. Residues in/on hay from the three cuttings were 0.06-5.50 ppm at 24-26 DAT, <0.02-0.09 ppm at 45-70 DAT, and <0.02-0.15 ppm at 71-128 DAT. Average flumioxazin residues in/on alfalfa from the 2nd, 3rd, and 4th cuttings were respectively 0.18, 0.03, and 0.02 ppm for forage and 0.48, 0.04, and 0.03 ppm for hay.

Miscellaneous Crops

Asparagus: IR-4 submitted field trial data for flumioxazin on asparagus from 8 field trials conducted during the 2003 and 2004 growing seasons in EPA growing Regions 2 (one trial; NJ), 5 (2 trials; MI), 10 (3 trials; CA) and 11 (2 trials; WA). In each test, flumioxazin (51% WDG) was applied as a single broadcast application to dormant or recently cut asparagus at

approximately 14-15 days prior to the anticipated harvest. Two plots were treated at each test site at rates of either 0.190-0.197 lb ai/A or 0.380-0.404 lb ai/A. Applications were made using ground equipment at volumes of 20-37 gal/A, and an adjuvant was not used for any application. Single control and duplicate treated samples were harvested following an 8- to 20-day PHI, with most samples being harvested at a 14- to 15-day PHI. Samples were stored frozen up to 110 days, a duration supported by available storage stability data.

The GC/NPD method (RM-30A-3) used for determining flumioxazin residues in/on asparagus was adequately validated in conjunction with the field trials. The validated LOQ for flumioxazin in/on asparagus was 0.02 ppm, and the statistically calculated LOD was 0.005 ppm.

Following a single early-season application of flumioxazin (WDG) to dormant or freshly cut asparagus at either 0.190-0.197 lb ai/A or 0.380-0.404 lb ai/A (0.5x and 1x rates), flumioxazin residues were <LOQ in/on all samples of asparagus from both the low and high application rates.

Conclusions: The available almond, pecan, cantaloupe, dry bean, blueberry, asparagus, tomato, and pepper field trials are adequate and support the proposed use patterns. An adequate number of tests were conducted on each crop in the appropriate geographical regions. Samples were analyzed for the residue of concern using an adequate method, and sample storage conditions and durations were supported by the available/submitted storage stability data. As residues were <LOQ (0.02 ppm) in/on all commodities, except dry beans and almond hulls, the data support the proposed 0.02 ppm tolerances in the following commodities: tree nuts (group 14), melons (subgroup 9A), asparagus, fruiting vegetables (group 8), okra, and assorted types of bushberries.

Utilizing the tolerance harmonization spreadsheet, the available residue data on dry beans does not conform to lognormality; thus, lognormality is rejected. Based on the CA method ($\mu + 3\sigma$), the residue data will support a tolerance of 0.05 ppm.

The alfalfa field trial data are also adequate. A sufficient number of field trials are available. However, the tolerance harmonization spreadsheet will be used and the highest residue calculated from each set or combination will represent the recommended tolerance. Utilizing the tolerance harmonization spreadsheet in this way, the available residue data on alfalfa supports tolerances of 3.0 ppm for forage and 8.0 ppm for hay.

In addition, the available bulb onion field trial data will support the requested increase in the use rate for garlic up to 0.38 lb ai/A, and the existing 0.02 ppm tolerance in garlic is adequate.

A revised section F will be required for both petitions to correct commodity definitions and match the proposed tolerances with the recommended tolerances as listed in Table 7.

860.1520 Processed Food and Feed

Tomato is the only crop associated with the current petitions for which a processing study is required. No tomato processing study was submitted with these petitions. However, in one of the tomato field trials, flumioxazin (WDG) was applied as two soil-directed applications at 0.621-0.689 lb ai/A, for a total use rate of 1.25 lb ai/A (5x rate). Both applications included the use of a COC at 1% v/v. Residues were <0.02 ppm in/on duplicate samples of tomatoes

harvested at 21 DAT. As residues were <LOQ following applications at a 5x rate, a tomato processing study is not required, and no tolerances are necessary in processed tomato commodities.

860.1650 Submittal of Analytical Reference Standards

An analytical reference standard for flumioxazin has been submitted to the EPA National Pesticide Standards Repository.

860.1850/860.1900 Confined and Field Accumulation in Rotational Crops

Current label directions for both 51% WDG formulations of flumioxazin specify the following general rotational crop restriction: do not plant any crop except cotton, peanut, soybean and sugarcane earlier than 30 days after application of flumioxazin. In addition, the labels also specify a variety of PBIs for different field crops depending on the application rate. For the highest use rate on any rotated crop (0.38 lb ai/A), the specified PBIs are 9 months for cotton, field corn, peanut, rice, sorghum, soybean, sunflower, tobacco and wheat, and 18 months for all other field crops.

An adequate confined rotational crop study is available reflecting application of [THP-^{14}C] flumioxazin at rates of 0.096 and 0.19 lb ai/A (DP Num: 259593, D. Dotson, 12/MAR/2001). Following an application of [^{14}C]flumioxazin at 0.96 lb ai/A, TRRs were 0.004-0.057 ppm in RACs from representative rotational crops planted 30 days post-treatment (60 days for lettuce, because of phytotoxicity). Extraction and analysis of plant samples with TRRs >0.01 ppm indicated that the majority of extractable ^{14}C-residues were comprised of unknown polar components each present at ≤0.015 ppm. Low levels of flumioxazin (≤0.003 ppm) were detected in carrot tops and wheat chaff and straw, along with trace amounts (<0.001 ppm) of the metabolites 482-HA, IMOXA, and 482-CA.

Following an application at 0.19 lb ai/A, TRRs were 0.003-0.072 ppm in RACs from representative rotational crops planted 30 days post-treatment (90 days for lettuce and 60 days for carrots, due to phytotoxicity). Although the highest TRR values were obtained at the 120-day PBI (0.131 ppm in wheat straw), ^{14}C-residues generally declined at longer PBIs. As with the 1x-treated plant samples, the majority of extractable ^{14}C-residues were comprised of unknown polar components. Flumioxazin was detected at ≤0.009 in sample extracts from carrot tops and roots, and wheat chaff and straw, with the exception of wheat straw (0.033 ppm) from the 120-day PBI. Other metabolites tentatively identified included: 482-HA (≤0.002 ppm), IMOXA (<0.001 ppm), 482-CA (<0.001) in carrot and wheat samples and SAT-1-OH-482 (0.008 ppm), 1-OH-HPA (0.004 ppm), THPA (0.004 ppm), and TPA (0.0004 ppm) in wheat straw from later PBIs. Based on the results from the confined study, HED has determined that the residue of concern in rotational crops is parent compound.

In the current petitions, the maximum seasonal use rates on melons and fruiting vegetables (0.25 lb ai/A) and on garlic and asparagus (0.38 lb ai/A) are higher than utilized in the confined study. However, HED has previously addressed the adequacy of the current rotational crop restrictions at these higher use rates under a petition for use on sugarcane (DP Num: 301247, W. Drew, 23/JUL/2004), which has a maximum seasonal use rate of 0.38 lb ai/A. The Agency concluded that the higher use rates (0.25 and 0.38 lb ai/A) are supported by the results from the confined

study conducted at 0.19 lb ai/A, and that field trials for, and tolerances in, rotational crops are not required.

860.1550 Proposed Tolerances

HED determined that the tolerance expression for primary and rotational crops should include only parent flumioxazin. Tolerances for flumioxazin residues are currently established on plant commodities at levels ranging from 0.02 ppm on various commodities to 0.70 ppm on almond hulls (40 CFR §180.568[a]). The tolerances currently being proposed by Valent and IR-4 are listed below in Table 7, along with the Agency's recommended tolerance levels.

The recommended tolerance levels for alfalfa forage and hay were determined using Agency Guidance (*Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP), as all the field trials were conducted at a ~1x rate and quantifiable residues were detected in >90% of the samples. The appropriate tolerances in alfalfa forage and hay were calculated to be 3.0 and 8.0 ppm, respectively (Appendix II).

Data from the available cattle feeding study, conducted at 20 ppm (6.3x TDB), indicate that quantifiable residues are unlikely to occur in cattle, goats, hogs, horses, or sheep. Likewise, the data from the available poultry metabolism studies, conducted at >1,800x TDB, indicate that quantifiable residues are also unlikely to occur in eggs and poultry tissues. Therefore, tolerances for flumioxazin residues in livestock commodities are not required for these petitions (40 CFR §180.6[a][3]).

No international harmonization issues are associated with these petitions, as there are no established or proposed Canadian, Mexican or Codex MRLs for residues of flumioxazin in plant commodities (Appendix I).

Table 7. Tolerance Summary for Flumioxazin.

Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Alfalfa, forage	1.0	3.0	Adequate residue data are available, and the tolerances were calculated using the tolerance harmonization spreadsheet. *Alfalfa, hay* *Alfalfa, forage*
Alfalfa, hay	2.0	8.0	
Tree Nut Crop Group 14	0.02	0.02	Adequate almond and pecan field trial data are available. *Nut, tree, group 14*
Melon subgroup 9A	0.02	0.02	Adequate cantaloupe field trial data are available. *Melon, subgroup 9A*
Asparagus	0.02	0.02	Adequate asparagus field trial data are available. *Asparagus*
Bean, dry, seed	0.06	0.05	Adequate dry bean field trial data are available. As residues were <LOQ in/on 22 out of 26 samples, the recommended tolerance was determined using the CA method (μ

Table 7. Tolerance Summary for Flumioxazin.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
			+ 3σ). *Bean, dry, seed*
Fruiting Vegetable Crop Group 8	0.02	0.02	Adequate tomato and pepper field trial data are available. *Vegetable, fruiting, except cucurbits, group 8*
Okra	0.02	0.02	The tolerance in okra is supported by the available tomato and pepper field trial data.
Bushberry subgroup 13B	0.02	0.02	Adequate lowbush and highbush blueberry field trial data are available and support establishing a tolerance in the *Bushberry, subgroup 13B.* In accordance with the Agency's proposed revisions to the Berry Crop Group, separate tolerances should be established in new members of the bushberry subgroup 13B, until the revised crop group is approved. However, separate tolerances are not required in the existing members of the bushberry subgroup.
Aronia berry	0.02	0.02	
Blueberry, lowbush	0.02	None [1]	
Blueberry, highbush	0.02	None [1]	
Buffalo currant	0.02	0.02	
Chilean guava	0.02	0.02	
Currant, black	0.02	None [1]	
Currant, red	0.02	None [1]	
Elderberry	0.02	None [1]	
European barberry	0.02	0.02	
Gooseberry	0.02	None [1]	
Highbush cranberry	0.02	0.02	
Honeysuckle	0.02	0.02	
Jostaberry	0.02	0.02	
Juneberry, including Saskatoon berry	0.02	0.02	
Lingonberry	0.02	0.02	
Native currant	0.02	0.02	
Salal	0.02	0.02	
Sea buckthorn	0.02	0.02	

[1] As a tolerance is being established in bushberry, subgroup 13B, separate tolerances are not required in the existing members of this subgroup, including: lowbush and highbush blueberries, currants, elderberry, gooseberry, and huckleberry.

References

DP Num: 194594
Subject: PP#3G4250: New Chemical EUP: V-53482, Flumioxazin on Soybeans. Evaluation of Analytical Methods and of Residue Data.
From: J. Garbus
To: J. Miller, D. Kenny and A. Koscialski
Dated: 21/SEP/1994
MRID(s): 42884011-42884014, 42884016-42884019

DP Num: None
Subject: PP#G4250: New Chemical EUP: Flumioxazin: Revised Tolerance Enforcement Method.

From: J. Garbus
To: J. Miller
Dated: 08/JAN/1996
MRID(s): 43935509

DP Num: 259493 and 268181
Subject: PP#s 7F4841 and 0F6171. Tolerance Petitions for the Use of Flumioxazin on Peanuts, Soybeans, and Sugarcane. Evaluation of Residue Chemistry and Analytical Methodology
From: D. Dotson
To: D. Kenny and J. Miller
Dated: 12/MAR/2001
MRID(s): 44013001, 44013002, 44295049 - 44295057

DP Num: 272652
Subject: PP#7F4841/0F6171; Flumioxazin in/on Peanuts, Soybeans and Sugarcane. Conclusions of the 12/20/2000 Meeting of the Metabolism Assessment Review Committee.
From: R. Loranger
To: Y. Donovan
Dated: 12/MAR/2001
MRID(s): None

DP Number: 301247

Subject: Flumioxazin. Tolerance Petition Requesting Section 3 Registration for Food Use of the Herbicide Flumioxazin on Sugarcane, Grape, Almond/Pistachio, Mint, Tuberous/Corm Vegetables (Crop Subgroup 1C), and Dry Bulb Onion/Garlic/Shallot. Summary of Analytical Chemistry and Residue Data. Petitions Numbered 0F06171, 1F06296, 3E06777, 3E06779, 3E6788.
From: W. Drew
To: Joanne Miller/James Stone
Dated: 23/JUL/2004
MRID(s): 45244801, 45375503, 45375504, 45375505, 45375507, 45888501, 46109201, 46114601, 46133901

DP Num: 310408, 313783
Subject: Flumioxazin. Tolerance Petitions Requesting Section 3 Registration for Food Use of the Herbicide Flumioxazin on Pome Fruit (Crop Group 11), Stone Fruit (Crop Group 12), and Strawberries. Summary of Analytical Chemistry and Residue Data.
From: W. Drew
To: J. Stone, J. Miller and D. Rosenblatt,
Dated: 15/MAR/2006
MRID(s): 46229401, 46229402, 46229403, 46229404, 46229405, 46229406, 46229407, 46229408, 46292501

DP Num: None

Subject: Crop Grouping – Part III: Analysis of the USDA IR-4 Petition to Amend the Crop Group Regulation 40 CFR §180.41 (c)(13) and Commodity Definitions [40 CFR §180.1(h)] Related to Crop Group Berry.
From: B. Schneider
To: B. Madden
Dated: 28/MAR/2006
MRID(s): None

Attachments:
Appendix I - International Residue Limits Status
Appendix II- Tolerance Spreadsheet Calculations.

Appendix I

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: 2-[7-fluoro-3,4-dihydro-3-oxo-4-(2-propynyl)-2*H*-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1*H*-isoindole-1,3(2*H*)-dione	Common Name: Flumioxazin	X Recommended tolerance □ Reevaluated tolerance □ Other	Date: 08/22/07
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
√ No Codex proposal step 6 or above □ No Codex proposal step 6 or above for the crops requested		Petition Numbers: 6F7092 and 6E7151 DP Numbers: 342963 Other Identifier: PC Code 129034	
Residue definition (step 8/CXL): N/A		Reviewer/Branch: D. Rate/ RIMUERB	
		Residue definition: Flumioxazin	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Alfalfa, forage	3.0
		Alfalfa, hay	8.0
		Bean, dry seed	0.05
		Nut, tree, group 14	0.02
		Melon, subgroup 9A	0.02
		Asparagus	0.02
		Vegetable, fruiting, group 8	0.02
		Okra	0.02
		Bushberry, subgroup 13B	0.02
		Aronia berry	0.02
		Buffalo currant	0.02
		Chilean guava	0.02
		European barberry	0.02
		Highbush cranberry	0.02
		Honeysuckle	0.02
		Jostaberry	0.02
		Juneberry, including Saskatoon berry	0.02
		Lingonberry	0.02
		Native currant	0.02
		Salal	0.02
		Sea buckthorn	0.02
Limits for Canada		Limits for Mexico	
√ No Limits □ No Limits for the crops requested		√ No Limits □ No Limits for the crops requested	
Residue definition: N/A		Residue definition: N/A	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
Notes/Special Instructions: S. Funk,09/07/2007			

Appendix II

Table II-1 Data used to Set Tolerances

Alfalfa, Hay	Alfalfa, Forage	Asparagus	Bean, dry seed	Tomatos	Peppers	Canteloupe	Blueberries	Pecans
Set 1	**Set 1**							
0.36	0.800	ND	ND	ND	ND	ND	ND	ND
0.34	0.790	0.005	ND	ND	ND	ND	ND	ND
0.27	0.030	0.010	ND	ND	ND	ND	ND	ND
0.27	0.020	0.010	ND	ND	ND	ND	ND	ND
0.27	0.130	0.006	ND	ND	ND	ND	ND	ND
0.17	0.070	0.005	ND	ND	ND	ND	ND	ND
0.07	0.060	0.009	0.04	ND	ND	ND	ND	ND
0.06	0.050	0.008	0.03	ND	ND	ND	ND	ND
0.23	0.240	ND	0.04	ND	ND	ND	ND	ND
0.18	0.220	ND	0.05	ND	ND	ND	0.008	ND
1.1	0.140	0.005	0.012	ND	ND	ND	ND	
1.3	0.120	ND	ND	ND	ND	ND	ND	
1.4	0.800	ND	0.017	ND	ND	ND		
1.6	0.790	ND	ND	ND	ND	ND		
0.11	0.030	0.012	ND	ND	ND	ND		
0.11	0.020	0.010	ND	ND	ND	ND		
0.23	0.130	0.006	0.010	ND	ND			
0.36	0.070	0.008	0.016	ND	ND			
0.22	0.060	0.010	0.019	ND				
0.25	0.050	0.009	0.015	ND				
0.47	0.240	ND	0.016	ND				
0.45	0.220	ND	0.011	ND				
0.88	0.140	0.007	0.012	ND				
0.84	0.120	0.006	0.012	ND				
Set 2	**Set 2**	0.008	0.014					
0.360	0.090	0.008	ND					
0.340	0.120	0.010						
0.270	0.080	0.013						
0.270	0.160	ND						
0.270	0.120	ND						
0.170	0.120	0.008						
0.070	0.030	0.009						
0.060	0.030							
0.230	0.090							
0.180	0.110							
1.100	0.430							
1.300	0.350							
5.500	1.700							
3.000	1.100							
0.940	0.260							
0.510	0.020							
0.360	0.090							
0.340	0.120							
0.270	0.080							

ND = non detectable; LOQ for each matrix is 0.02 ppm. LOQ was used in the calculation of tolerance when residue was ND. Set 1 = 0.125 lb ai/A; Set 2 = 0.250 lb ai/A; Set 3 = Set 1 + Set 2.

Tolerance assessment calculations.

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was utilized for determining appropriate tolerance levels on alfalfa forage and hay, as less than 10% of the residue values were below the LOQ in/on forage and hay. However, the tolerance spreadsheet was not used to calculate tolerances in tree nuts, fruit vegetables, melons, bushberries, asparagus, or dry beans as residues were <LOQ in/on >80% of the samples from these crops.

The datasets used to establish tolerances for flumioxazin residues on alfalfa forage and hay consisted of field trial data representing applications of the appropriate formulations at ~1x proposed use rates. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP, the field trial application rates were within 25% of the maximum application rates, and the PHIs are consistent with the appropriate stage of maturity and the proposed PHIs for each commodity. The residue values used to calculate the alfalfa tolerances are provided in Table II-1.

The datasets for flumioxazin residues in alfalfa forage and hay were entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plots indicated that the datasets are reasonably lognormal, and results from the approximate Shapiro-Francia test statistic (Figures II-1 and II-2) confirm this assumption. Therefore, the Log Normal method was used to calculate tolerances of 3.0 ppm in alfalfa forage and 8.0 ppm in alfalfa hay, based on data from Set 2.

Figure II-1. Data summary table for flumioxazin residues in/on alfalfa forage.

	Regulator:	EPA	
	Chemical:	Flumioxazin	
	Crop:	Alfalfa Forage	
	PHI:	25 days	
	App. Rate:	0.25	
	Submitter:		
	n:	16	
	min:	0.01	
	max:	1.70	
	median;	0.12	
	average:	0.30	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	1.1 (1.5)	1.4 (1.9)	1.8 (--)
EU Method I Log Normal	1.2 **(4.0)**	3.0 (13)	8.0 (--)
EU Method II Distribution-Free		0.70	
California Method μ + 3σ		**1.7**	
UPLMedian95th		**0.80**	
Approximate Shapiro-Francia Normality Test		0.9564 p-value > 0.05 : Do not reject lognormality assumption	

Figure II-2. Data summary table for residues of flumioxazin in/on alfalfa hay.

	Regulator:	EPA	
	Chemical:	Flumioxazin	
	Crop:	Alfalfa Hay	
	PHI:	25 days	
	App. Rate:	0.25	
	Submitter:		
	n:	16	
	min:	0.06	
	max:	5.50	
	median;	0.31	
	average:	0.91	
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	3.5 (5.0)	4.5 (6.0)	6.0 (--)
EU Method I Log Normal	3.5 **(10)**	8.0 (35)	19 (--)
EU Method II Distribution-Free		2.5	
California Method $\mu + 3\sigma$		**6.0**	
UPLMedian95th		**2.5**	
Approximate Shapiro-Francia Normality Test		0.9543 p-value > 0.05 : Do not reject lognormality assumption	