

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



OFFICE OF PREVENTION, PESTICIDE
AND TOXIC SUBSTANCES

MEMORANDUM

Date: 6/12/2008

SUBJECT: Ingredient: Fenbuconazole

Title: Petition for Registration for Use on Pepper, Bushberry Subgroup (13-B), and Cranberry. Summary of Analytical Chemistry and Residue Data.

PC Code: 129011

Decision No.: 354084, 354085, 383131, 383432

Petition Nos.: 9E5041, 1E6252, and 7E7256

Risk Assessment Type: None

TXR No.: None

MRID No.: 44690600, 44690601, 45268401,
45296000, 45296001, 47215801

DP #s: 313752, 313753, 345256, 351444

Registration No.: 62719-421

Regulatory Action: Section 3

Case No.: None

CAS No.: 114369-43-6

40 CFR: 180.480

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This document was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B, Durham NC 27713; submitted 1/23/2008). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

Executive Summary

Fenbuconazole [α -[2-(4-chlorophenyl)ethyl]- α -phenyl-1*H*-1,2,4-triazole-1-propanenitrile] is a broad spectrum, triazole-type fungicide that acts by inhibiting sterol biosynthesis in fungi. It is formulated as a flowable concentrate (FIC) or wettable powder (WP), and is currently registered for use on the following food/feed crops: cranberries, the Bushberry Subgroup (Crop Subgroup 13-B), almonds, apples, bananas, citrus fruits, pecans, peanuts, stone fruits, sugar beets, and wheat. Permanent tolerances are established for the combined residues of fenbuconazole and its lactone metabolites, RH-9129 and RH-9130 [trans- or cis-5-(4-chlorophenyl)dihydro-3-phenyl-3-(1*H*-1,2,4-triazol-1-ylmethyl)-2(3*H*)-furanone], expressed as parent in/on plant commodities at levels ranging from 0.05 ppm in/on almonds and pecans to 40 ppm in citrus oil [40 CFR §180.553(a)]. Permanent tolerances have also been established at 0.05 ppm for the combined residues in meat byproducts of cattle, goats, horses, and sheep.

A tolerance of 0.3 ppm is currently in effect for Crop Subgroup 13-B, the Bushberry Subgroup, and a tolerance of 0.5 ppm is in effect for cranberries. These tolerances were recommended by HED in a human health risk assessment performed for several commodities (Memo, D316607, M. Collantes, et al., 8/3/2006). Although the field trial data for blueberries and cranberries were reviewed and a residue chemistry summary document was prepared, the summary document was never finalized. The human health risk assessment referenced above was prepared, however. The bushberry registration was made conditional, and the registrant was asked to submit two additional field trials for blueberries. The blueberry and cranberry field trial data are being included in this document and the associated human health risk assessment (Memo, D344351, D. Dotson, 6/12/2008).

A 75% WP formulation of fenbuconazole (INDAR[®] 75WSP; EPA Reg, No 62719-421) is currently registered to Dow AgroSciences for use on a variety of fruit and nut crops, sugar beets, and wheat. Interregional Research Project No. 4 (IR-4) has submitted a petition proposing the use of this formulation on peppers for control of *Cercospora* leafspot and powdery mildew. The proposed use is for multiple broadcast foliar applications to peppers at up to 0.188 lb ai/A/application with a minimum retreatment interval (RTI) of 10 days, for a maximum of 0.75 lb ai/A/season. Applications may be made using either ground or aerial equipment, although use of aerial equipment is not recommended. Ground applications should be made in a minimum volume of 30 gal/A, and can include the use of a non-ionic surfactant. The minimum preharvest interval (PHI) is 7 days for peppers. In conjunction with this use, IR-4 is proposing the following permanent tolerance for the combined residues of fenbuconazole and its lactone metabolites, RH-9129 and RH-9130, expressed as fenbuconazole:

Pepper0.4 ppm

The qualitative nature of fenbuconazole residues in plants is adequately understood based upon the adequate peach, peanut, sugar beet, and wheat metabolism studies. The residues of concern in/on peppers, bushberries, and cranberries, for purposes of both tolerance expression and risk assessment, are fenbuconazole and its lactone metabolites, RH-9129 and RH-9130.

The crop uses being proposed in this petition do not include any regulated livestock feedstuffs. As a result, issues pertaining to livestock metabolism, analytical methods, storage stability in animal commodities, and residues in livestock commodities are not relevant to the current petitions.

A GC/NPD method, 34-90-47R, is currently available for enforcing tolerances of fenbuconazole and its two lactone metabolites (RH-9129 and RH-9130) in/on stone fruits, and a slightly modified version of this method was demonstrated to be adequate for determining residues in peppers. For this method, the validated limit of quantitation (LOQ) for residues in/on peppers is 0.01 ppm for each analyte, for a combined LOQ of 0.03 ppm. The statistically calculated limit of detection (LOD) was 0.003-0.004 ppm for each analyte. The method was adequately validated in conjunction with the pepper field trials.

Method 34-90-47R was demonstrated to be adequate for determining residues in bushberries and cranberries. The validated LOQ is 0.01 ppm for each analyte in/on berries, for a combined LOQ of 0.03 ppm. The LOD was not reported. As currently written, the method expresses residues of RH-9129 and RH-9130 in terms of the individual analytes. To calculate combined residues (expressed as parent), the metabolites must be multiplied by the molecular weight conversion factor of 0.95x. The above method was adequately validated in conjunction with the blueberry and cranberry field trials. The average method recoveries were 89-106% for the three analytes.

Adequate storage stability data were submitted with the pepper field trials, indicating that fenbuconazole and its lactone metabolites are stable in peppers at $<-10^{\circ}\text{C}$ for up to 16.6 months of storage. These data adequately support the maximum duration of frozen storage (16.4 months) from the pepper field trials.

The available storage stability data indicate that residues of fenbuconazole, RH-9129, and RH-9130 are stable in frozen storage for at least 8 months in blueberries and 5.5 months in cranberries. In the current field trials, the maximum frozen storage durations were approximately 8 months for blueberries and approximately 5 months for cranberries.

Adequate field trial data are available supporting the proposed use on peppers. Following the last of four or five broadcast foliar applications of fenbuconazole (WP) at rates totaling 0.66-0.84 lb ai/A/season (0.9-1.1x rates), the combined residues of fenbuconazole, RH-9129, and RH-9130 were 0.05-0.23 ppm in/on 18 samples of bell and non-bell peppers harvested 6-7 days after the last treatment (DAT). Average combined residues were 0.14 ppm in/on peppers at ~7 DAT, and residues were shown to decline at longer post-treatment intervals. No processing studies are required for this petition, as there are no regulated processed commodities associated with peppers.

The available cranberry data are adequate and support the use of up to five foliar applications of fenbuconazole (WP or FIC) at up to 0.188 lb ai/A/application, for a maximum seasonal rate of 0.94 lb ai/A. The data support the label PHI of 30 days, a minimum RTI of 10 days, and the use of a non-ionic surfactant in the spray mix. In the five cranberry field trials, the combined residues of fenbuconazole and its lactone metabolites were 0.09-0.49 ppm in/on 10 samples harvested 25-28 DAT, and average combined residues were 0.199 ppm.

Nine of the ten submitted blueberry field trials are adequate. Eight acceptable field trials are needed for blueberries. Data from the blueberry field trials support the use of up to five foliar applications of fenbuconazole (WP or FIC) to bushberries at up to 0.094 lb ai/A/application, for a maximum seasonal rate of 0.47 lb ai/A. The data support the label PHI of 30 days, a minimum RTI of 10 days, and the use of a non-ionic surfactant in the spray mix. The combined residues of fenbuconazole, RH-9129, and RH-9130 (expressed as parent) were <0.03-0.24 ppm in/on 18 samples harvested 25-35 DAT and average combined residues were 0.083 ppm.

Adequate confined rotational crop studies are available and indicate that the metabolite profile in rotational crops is similar to the metabolite profile in primary crops. The rotational crop restrictions on the current label for the 75% WP are adequate. No limited rotational crop field trials or rotational crop tolerances are required.

Regulatory Recommendations and Residue Chemistry Deficiencies

In its February 7, 2006 risk assessment for 1,2,4-triazole and its metabolites, triazole alanine and triazole acetic acid (M. Doherty et al, DP# 322215), HED recommended that resolution of various issues be made a condition of registration for new uses of triazole-derivative fungicides and for new active ingredients which contain the 1,2,4-triazole ring. The requirement for a chronic toxicity/oncogenicity study in male rats and female mice in the 2/7/2006 memo was later modified by HED to a 1-year chronic study in male and female rats (D321328, Kit Farwell, 5/10/2006). The other conditions of registration that were listed in the 2/7/2006 risk assessment have not been satisfied and are conditions for the use of fenbuconazole on peppers.

No major deficiencies were noted in the subject petition that would preclude establishing a permanent tolerance for fenbuconazole on peppers. However, an error was noted in the proposed use directions and no data were provided on residues of 1,2,4-triazole, triazole alanine, or triazole acetic acid. These deficiencies (see below) need to be resolved as a condition of registration. HED recommends establishing a permanent tolerance with a conditional registration for the combined residues of fenbuconazole and Metabolites RH-9129 and RH-9130, expressed as parent, in/on pepper at 0.40 ppm.

- The use directions contain an error in the single use rate. The single application rate is specified as 2-4 oz. of product (75% WP)/A/application, which is equivalent to 0.094-0.188 lb ai/A/application. However, in terms of lb ai/A, the directions indicate that the rate is 0.10-0.167 lb ai/A. This error should be corrected. The data will support a maximum single use rate of up to 0.188 lb ai/A.
- Although adequate residue data were provided on fenbuconazole and its regulated metabolites RH-9129 and RH-9130, none of the samples were analyzed for residues of triazole, triazole alanine, or triazole acetic acid, as required by current Agency guidance (Memo, D327788, M. Doherty, 4/25/2006).

For Crop Subgroup 13-B, the Bushberry Subgroup, HED is in agreement with the registrant that adequate field trials have been submitted. In order for the conditional registration to be

converted to unconditional, the data for the triazole metabolites, discussed above, should be submitted and be considered to be adequate by the Agency.

Deficiencies Cited in Previous Actions

In its risk assessment of 8/3/2006, HED noted several data deficiencies (Memo, D316607, M. Collantes, et al, 8/3/2006). Dow AgroSciences addressed some of these deficiencies in two letters that were submitted to the Agency (3/30/2007 and 7/12/2007). HED has evaluated Dow's responses to the data deficiencies.

HED requested that Dow submit updated analytical reference standards for fenbuconazole, RH-9129, and RH-9130. These standards have been submitted.

HED requested that Dow submit an apple processing study. This study has been submitted; however, it has not been reviewed by HED.

HED requested that Dow submit the results of two additional blueberry field trial studies. As discussed in this summary document, two acceptable studies were submitted.

HED requested that Dow submit the results of 20 field trials performed on wheat forage and 12 field trials performed on wheat hay. Dow has not submitted the requested data. Dow's representative responded by stating that Dow is of the opinion that the 8 field trials that were performed for each commodity should be sufficient. The OPPTS Series 860 Guidelines recommend that 20 field trials be performed for each of these commodities. As stated above, Dow performed 8 trials for each. The forage trials were performed at a 2x application rate. Dow's representative gave 3 reasons as to why Dow felt that the original 8 trials should be satisfactory: (1) the maximum application rates used in the 8 trials were the same or lower than the currently labeled ones, (2) the cattle dietary intake of fenbuconazole residues through ingestion of wheat forage and hay is insignificant because very little wheat is treated with fenbuconazole (compared to other commodities), and because wheat forage and hay make up a small fraction of cattles' diets, and (3) based on the results of the ruminant metabolism study, the secondary residues in cattle would be very low. Most forage and hay used for cattle feed is grown in the Southern United States. The field trials were performed in Ohio, Michigan, Minnesota, North Dakota, South Dakota, Nebraska, Montana, and Wyoming. Most of these states are more northern. HED continues to request that twenty field trials be performed for forage and 12 trials be performed for hay. HED bases this request on the following three factors: 1) considerably fewer trials were performed than are generally needed, 2) all of the forage trials were performed at a 2x rate, and 3) the trials were not performed in major feedstuff producing geographical regions.

HED requested that Dow submit another citrus processing study. In the original study, samples were not analyzed within the time interval for which residues have been demonstrated to be stable. Fenbuconazole residues have been shown to be stable in fruit for 8 months and in oil and dried pulp for 12 months. In the citrus processing study, the maximum storage durations were 24 months for fruit and 39 months for oil and dried pulp. Rather than performing another citrus processing study, Dow requested that the Agency translate peach and apple storage stability data

to the processed citrus fractions. In peaches and apples, very little decay occurred in residues of fenbuconazole and the metabolites RH-9129 and RH-9130 over a period of 54 months (4.5 years) and 36 months, respectively. In peaches, percent recovery after 54 months for the 3 analytes is as follows: fenbuconazole (94%), RH-9129 (91%), and RH-9130 (87%). In apples, percent recovery after 36 months for the 3 analytes is as follows: fenbuconazole (103%), RH-9129 (97%), and RH-9130 (93%). The available storage stability data for peaches, apples, and processed citrus fractions demonstrate to the satisfaction of HED that residues of fenbuconazole, RH-9129, and RH-9130, would be stable in citrus fruit for 24 months and oil and dried pulp for 39 months.

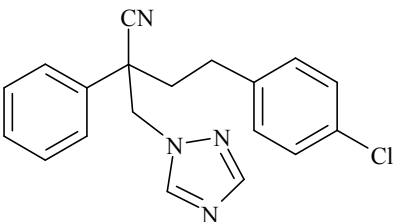
Finally, HED informed Dow that the analytical method proposed for enforcement of tolerances on animal commodities (GC/NPD Method TR 34-94-142), must undergo a tolerance method validation. BEAD/ACB has not performed the validation.

Background

Fenbuconazole is a broad spectrum, triazole-type fungicide used to control various fungal diseases. It acts by inhibiting sterol biosynthesis in fungi (MOA Group 3). Fenbuconazole is formulated as a 2 lb/gal FIC or 75% WP and is registered to Dow AgroSciences, LLC, for use on almonds, apples, bananas, bushberries, citrus fruits, cranberries, pecans, peanuts, stone fruits, sugar beets, and wheat.

IR-4 submitted a petition proposing the use of fenbuconazole, formulated as a 75% WP (Indar[®] 75WSP; EPA Reg. No. 62719-421), on peppers for the control of *Cercospora* leaf spot and powdery mildew. The nomenclature of fenbuconazole and its regulated metabolites is presented in Table 1, and the physicochemical properties of fenbuconazole are presented in Table 2.

On behalf of the Blueberry Research Council and the Cranberry Institute, IR-4 submitted tolerance petitions PP#9E5041 and PP#1E6252 supporting the use of fenbuconazole, formulated as a 75% WP, on various bushberries and cranberries for control of mummyberry disease, *Septoria* leaf spot, anthracnose leaf spot, cottonball disease, and fruit rot diseases. In conjunction with these uses, the petitioner proposed the establishment of permanent tolerances for the combined residues of fenbuconazole and its metabolites RH-9129 and RH-9130, expressed as fenbuconazole, in/on cranberries and Crop Subgroup 13-B, the Bushberry Subgroup. The tolerances are established at 0.3 ppm for bushberries and 0.5 ppm for cranberries.

Table 1. Fenbuconazole Nomenclature.	
Compound	
Common name	Fenbuconazole

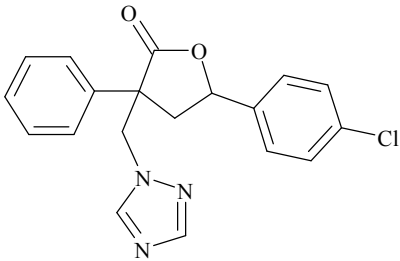
Company experimental name	RH-7592
IUPAC name	(<i>RS</i>)-4-(4-chlorophenyl)-2-phenyl-2-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)butyronitrile
CAS name	α -[2-(4-chlorophenyl)ethyl]- α -phenyl-1 <i>H</i> -1,2,4-triazole-1-propanenitrile
CAS #	114369-43-6
End-use product/EP	75% WP (Indar [®] 75 WSP Fungicide, EPA Reg. No. 62719-421)
Metabolites	 <p style="text-align: right;"><i>cis</i> and <i>trans</i> isomers</p>
Common name	<i>cis</i> and <i>trans</i> lactone metabolites; Lactones A and B
Company experimental names	RH-9129 and RH-9130
IUPAC names	(3 <i>R</i> ,5 <i>R</i>) or (3 <i>S</i> ,5 <i>R</i>)-5-(4-chlorophenyl)-3-phenyl-3-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)dihydrofuran-2(3 <i>H</i>)-one
CAS names	<i>trans</i> - or <i>cis</i> -5-(4-chlorophenyl)dihydro-3-phenyl-3-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)-2(3 <i>H</i>)-furanone
CAS #	<i>cis</i> isomer, 146887-38-9; <i>trans</i> isomer, 146887-37-8

Table 2. Physicochemical Properties of the Technical Grade Fenbuconazole.

Parameter	Value		Reference
Melting point/range	127°C		DP# D310959, S. Oonnithan, 7/25/2006
pH	not available		
Density (20°C)	0.50 g/mL		
Water solubility (mg/L at 22°C)	3.8 mg/L		
Solvent solubility (g/L at 25°C)	Acetonitrile: 231 Cyclohexanone: 445 ethyl alcohol: 39 1-octanol: 13	aromatic 200: 77 ethyl acetate: 159 heptane: 1.0	
Vapor pressure at 25°C	0.37 × 10 ⁻⁷ mm Hg (4.9 × 10 ⁻⁶ Pa)		
Dissociation constant (pK _a)	Not expected to dissociate in water		
Octanol/water partition coefficient Log(K _{ow})	3.02 ± 0.08		
UV/visible absorption spectrum	λ max (nm)	ϵ (L·mol ⁻¹ ·cm ⁻¹)	
	196	53,000	
	262	750	
	268	740	
	275	480	

860.1200 Directions for Use

There are currently three fenbuconazole end-use products (EPs) registered to Dow AgroSciences for use in the U.S. on food/feed crops. These EPs are marketed under the trade names Enable[™] and Indar[™] and include a 2 lb/gal FIC and two 75% WPs. IR-4 is proposing the use of a 75% WP (Indar[™] 75 WSP; EPA Reg. No. 62719-421) on peppers. An example label was provided for the 75% WP, and the proposed use directions are summarized below in Table 3.

A 75% WP formulation is registered for use on bushberries and cranberries. The use directions are summarized in Table 3.

Table 3. Summary of Directions for Use of Fenbuconazole.						
Applic. Timing, Type, and Equip. ¹	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
Peppers (Including but not limited to: bell, chili, cooking, non-bell, pimento and sweet)						
Broadcast foliar applications to peppers when disease first appears Ground or aerial equipment	75% WP [62719-421]	0.188 ³	NS	0.75	7	Apply in a minimum of 30 gal/A, using ground equipment. The minimum RTI is 10-14 days. Use of NIS is recommended.
Bushberry Subgroup (including blueberry, currant, elderberry, gooseberry, and huckleberry)						
Broadcast foliar applications beginning at bud break (green tip) through fruit development. Ground or aerial equipment	75% WP [62719-421]	0.094	5	0.47	30	A minimum retreatment interval of 10 days specified. Do apply through any type of irrigation system. For ground and aerial applications, apply in a minimum volume of 10 and 20 gal/A, respectively. A non-ionic surfactant should be used in the spray mix.
Cranberries						
Broadcast foliar applications beginning when 50% of shoots show ¼ inch of new growth, through fruit development. Ground or aerial equipment	75% WP [62719-421]	0.188	5	0.94	30	A minimum retreatment interval of 7 days is specified. Do apply through any type of irrigation system. For aerial applications, apply in a minimum volume of 10 gal/A. A non-ionic surfactant should be used in the spray mix.

¹ Do not apply through any type of irrigation system. Although application using aerial equipment is permitted, ground application is recommended.

² Rotational crop restrictions: the minimum plant-back interval is 35 days when the last application of the product is <0.188 lb ai/A, and 210 days when the last application of the product is 0.2-1 lb ai/A.

³ The maximum use rate is based on the use of 4 oz product/acre/application.

NS = not specified.

Conclusions. The use directions are adequate to allow for evaluation of the residue data relative to the proposed use. The available field trial data on peppers are adequate and support the proposed use; however, the maximum use rate on the label needs to be corrected. The label specifies a maximum application rate of 4 oz product/A or 0.167 lb ai/A; however, 4 oz product/A is actually equivalent to 0.188 lb ai/A. Although the single application rates used in the field trials were ~0.167 lb ai/A (0.9x rate), the residue data from these tests support the 0.188 lb ai/A/application rate.

The available blueberry and cranberry field trial data support the label use directions. Although only the WP formulation is registered for use on bushberries and cranberries, the field trial data using the 75% WP also support the use of FIC and dry flowable (DF) formulations.

860.1300 Nature of the Residue - Plants

MARC Decision memo (N. Dodd and W. Wassell, 3/9/94)

Memo, D200171, N. Dodd, 4/5/94

Memo, D241864, G. Otakie, 3/30/06

Adequate studies are available depicting the metabolism of [¹⁴C]fenbuconazole in peaches, peanuts, and wheat. Results from these studies were previously summarized for review by the HED Metabolism Committee (Memo, N. Dodd and W. Wassell, 12/10/93).

In the peach metabolism study, peach trees received five foliar applications of either [phenyl-¹⁴C] or [triazolyl-¹⁴C] fenbuconazole (6.8% emulsifiable concentrate (EC)) at rates totaling approximately 1 lb ai/A, and whole fruit were sampled at 22 days after the last application. For both ¹⁴C-labels, the major residues identified in fruit were fenbuconazole (16-45% TRR) and the lactone metabolite RH-9129 (4-14% TRR). Triazole alanine (RH-3968, 48% TRR) and triazole acetic acid (RH-4098, 7% TRR) were also identified in the [triazolyl-¹⁴C]-labeled fruit, and additional analysis by the petitioner detected only minor amounts of glucose conjugates of RH-4911 (4.4% TRR).

In the peanut metabolism study, vine and nutmeat samples were collected 28 days after the last of four foliar applications of either [phenyl-¹⁴C] or [triazolyl-¹⁴C] fenbuconazole (6.8% EC) at one-month intervals, at rates totaling ~2 lb ai/A. For both ¹⁴C-labels, the major residues in vines were parent (45-54% TRR), RH-9129 (4-5% TRR), RH-6467 (8-10% TRR), and the glucose conjugates of 4911 (18-19% TRR). Triazole alanine (7% TRR) was also identified in the [triazolyl-¹⁴C]-labeled vines. The major residues in nutmeats were triazole alanine (88% TRR) from the [triazolyl-¹⁴C]-label and the glucose conjugate of 4911 (29% TRR) from the [phenyl-¹⁴C] label.

In the wheat metabolism study, plants received two foliar applications, 8 days apart, of either [Phenyl-¹⁴C] or [Triazolyl-¹⁴C] fenbuconazole (7% EC) at rates totaling ~0.72 lb ai/A. Samples of straw, chaff, and grain were collected at 39 days after the second application. For both ¹⁴C-labels, the major residues in straw were parent (65% TRR), RH-9129 (8% TRR), and RH-6467 (3-5% TRR). The glucose conjugates of 4911 (3% TRR) were only a minor component of wheat straw. The major residue identified in [phenyl-¹⁴C]-labeled grain was parent (12.5% TRR), and the major residues identified in [triazolyl-¹⁴C]-labeled grain were triazole alanine (48% TRR) and triazole acetic acid (20% TRR).

Based on the above metabolism studies, the HED Metabolism Committee concluded that the residues of concern for uses on stone fruit, wheat, pecans, bananas, apples, and almonds are fenbuconazole and its lactone metabolites RH-9129 and RH-9130 (N. Dodd and W. Wassell, 3/9/94). Based on differences in metabolism between the three crops, the Committee also concluded that a metabolism study would be required for any crop not botanically similar to the crops for which metabolism studies are available.

The conclusion regarding the residues of concern was contingent upon the petitioner providing data showing that RH-4911 is only a minor residue in these crops. The petitioner subsequently

fulfilled this requirement by providing data from the wheat and peach metabolism studies showing that conjugates of RH-4911 accounted for <5% of the TRR in peaches and wheat straw (D200171, N. Dodd, 4/5/94).

In addition, the Metabolism Committee noted that the iminolactone metabolite (RH-6468) would also be included *de facto* in the residues of concern, as the petitioner has indicated that this compound is converted to the lactones by the analytical methodology.

In addition to the above metabolism studies, an adequate sugar beet metabolism study was reviewed (D241864, 44343303.der) in conjunction with a petition for use on sugar beets. In this study, [phenyl-¹⁴C] fenbuconazole (EC) was applied to sugar beets as three foliar applications at 39, 103, and 183 days after planting, at rates totaling 3 lb ai/A, and samples of tops and roots were collected 7 days after the final application. The major residue identified in both tops and roots was parent (83-91% TRR), along with minor amounts of the lactone metabolites (<3% TRR).

Conclusions. Adequate studies are available depicting the metabolism of [¹⁴C]fenbuconazole in peaches, peanuts, sugar beets, and wheat. The qualitative nature of fenbuconazole residues in plants is adequately understood for the purposes of the current tolerance petitions. The residues of concern in/on peppers, bushberries, and cranberries are fenbuconazole, its lactone metabolites, RH-9129 and RH-9130, and the triazole metabolites, 1,2,4-triazole, triazole alanine, and triazole acetic acid.

860.1300 Nature of the Residue - Livestock

There are no livestock feedstuffs associated with the established or proposed uses on peppers, bushberries, or cranberries; therefore, data requirements for livestock metabolism are not relevant to this tolerance petition

860.1340 Residue Analytical Methods

A GC/NPD tolerance enforcement method, 34-90-47R, is available for determining residues of fenbuconazole, RH-9129, and RH-9130 in/on stone fruits. For this method, residues are extracted with methanol, filtered through Celite, diluted with aqueous 9.1% NaCl, and partitioned into methylene chloride. Residues are then concentrated, redissolved in toluene:acetone (100:10, v:v), and cleaned up using a silica gel column eluted with toluene:acetone (100:30, v:v). Residues in the resulting eluate are concentrated to dryness, redissolved in toluene:acetone (100:5, v/v), and eluted through a Florisil column with toluene:acetone (100:30, v:v). Residues are again concentrated to dryness, redissolved in toluene:methanol (100:3, v:v), and analyzed by GC/NPD using external standards. The reported LOQ is 0.01 ppm each for fenbuconazole, RH-9129, and RH-9130.

Residues in/on peppers were determined using a slightly modified version of the above method. The modifications were made to improve the performance of the method. The GC/NPD method was adequately validated prior to, and in conjunction with, the analysis of field trial samples

using control samples fortified with each analyte at 0.01-1.0 ppm. The validated LOQ for each analyte is 0.01 ppm in/on peppers, for a combined LOQ of 0.03 ppm.

The above method was validated for analysis on blueberries and cranberries in conjunction with the field trials. For cranberry samples fortified with each analyte separately at 0.01-2.0 ppm, average method recoveries were 101% with a standard deviation (s.d.) of 10% for parent, 100% (s.d. 14%) for RH-9129, and 97% (s.d. 13%) for RH-9130. For blueberry samples fortified with each analyte separately at 0.01-1 ppm, average method recoveries were 102% (s.d. 9%) for parent, 95% (s.d. 6%) for RH-9129, and 96% (s.d. 4%) for RH-9130.

Conclusions. The available GC/NPD method, TR 34-90-47R, is adequate for enforcing tolerances and collecting data on fenbuconazole residues in/on peppers, bushberries, and cranberries.

860.1360 Multiresidue Methods

Adequate multiresidue method testing data are available for fenbuconazole and its lactone metabolites. The FDA PESTDATA database, dated 11/01 (PAM Vol. I, Appendix I), indicates that fenbuconazole is completely recovered using Multiresidue Methods Section 302 (Protocol D), but is not recovered by Methods 303 and 304 (Protocols E and F). The recovery of the lactone metabolites (RH-9129 and RH-9130) through Method 302 was variable or partial (68-92% for RH-9129 and 48-71% for RH-9130), and the recovery of RH-6467 was small (<50%). None of these metabolites were recovered through Methods 303 or 304.

860.1380 Storage Stability

Memo, D249012, W. Wassell, 11/19/98
Memo, D223761, W. Wassell, 4/23/96
Memo, D239002, G. Otakie, 3/30/06

Adequate storage stability data are available indicating that fenbuconazole and its lactone metabolites (RH-9129 and RH-9130) are stable in frozen storage for up to 54 months in pecans and stone fruits, and 36 months in apples, wheat grain, and wheat straw.

In addition, a freezer storage stability study was conducted in conjunction with the pepper field trials. A separate control sample of homogenized peppers was fortified with fenbuconazole, RH-9129, and RH-9130, each at 1.0 ppm, and stored under the same conditions ($\leq -10^{\circ}\text{C}$) as the field trial samples. No 0-day analysis was conducted prior to placing the samples in frozen storage; therefore, the original fortification levels could not be verified. After 16.6 months of frozen storage, the stored samples were analyzed in triplicate along with a control sample and control samples freshly fortified with each analyte at 1.0 ppm. The average recovery (corrected for concurrent recovery) was 89% for fenbuconazole and RH-9130 and 91% for RH-9129. These data indicate that fenbuconazole, RH-9129, and RH-9130 are stable in frozen peppers for up to 16.6 months. Samples from the pepper field trials were stored at $< -10^{\circ}\text{C}$ for up to 16.4 months prior to analysis.

Studies examining the stability of fenbuconazole, RH-9129, and RH-9130 during frozen storage were conducted in conjunction with the blueberry (44690601.der) and cranberry (45296001.der) field trials. Triplicate control samples of blueberry fruit were fortified separately with the three analytes at ~1 ppm and placed in frozen storage (<-14°C) for 240 days, and triplicate control samples of cranberry fruit were fortified separately with the three analytes at 2.02 ppm and placed in frozen storage (<-10°C) for up to 168 days. The stored samples were analyzed along with freshly fortified control samples. For blueberry, average corrected recoveries of parent, RH-9129, and RH-9130 were 99%, 98%, and 100%, respectively, following 7.9 months of frozen storage. For cranberry, average corrected recoveries of parent, RH-9129, and RH-9130 were 91%, 81%, and 91%, respectively, following 5.5 months of frozen storage. In the field trials, the maximum frozen storage durations were 7.9 months for blueberries and 5.3 months for cranberries.

Conclusions. In the pepper storage stability study, no 0-day analysis was conducted on the fortified samples prior to storage. However, for the purposes of the pepper tolerance petition, HED accepts the available data to support the pepper field trials.

The available storage stability data are adequate and support the sample storage durations and conditions used in the blueberry and cranberry field trials.

860.1400 Water, Fish, and Irrigated Crops

There are no proposed uses that are relevant to this guideline topic.

860.1460 Food Handling

There are no proposed uses that are relevant to this guideline topic.

860.1480 Meat, Milk, Poultry, and Eggs

As there are no livestock feedstuffs associated with the proposed/established uses on peppers, blueberries, and cranberries, data requirements pertaining to meat, milk, poultry, and eggs are not relevant to these tolerance petitions.

860.1500 Crop Field Trials

47215801.der (peppers)

IR-4 submitted field trial data on bell and non-bell peppers to support the proposed use of fenbuconazole (WP) on peppers. The results from these tests are discussed below, and the residue data are summarized in Table 4.

Table 4. Summary of Residue Data from Pepper Field Trials with Fenbuconazole (WP).									
Crop matrix	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels (ppm) ¹						
			n	Min.	Max.	HAFT ²	Median	Mean	Std. Dev.
Peppers (proposed use = 0.75 lb ai/A total application rate, 7-day PHI)									
Bell and Non-bell Peppers	0.656-0.844	6-7	18	0.05	0.22	0.21	0.15	0.14	0.06

¹ The calculated LOQs were 0.008 ppm for fenbuconazole, 0.010 ppm for RH-9129 and 0.011 ppm for RH-9130. The calculated LODs were 0.003 ppm for fenbuconazole and RH-9129, and 0.004 ppm for RH-9130. The LLMV in/on peppers for each analyte is 0.01 ppm, for a combined LLMV of 0.03 ppm.

² HAFT = Highest average field trial result.

Nine field trials were conducted on bell peppers (6 tests) and non-bell peppers (3 tests) during 2000 in EPA Growing Zones 2, 3, 5, 6, and 10. At each test site, fenbuconazole (75% WP) was applied to peppers during fruit development and maturation as four or five broadcast foliar applications at rates of 0.163-0.173 lb ai/A (0.9x single rate), at RTIs of 10-14 days, for totals of 0.66-0.68 or 0.84 lb ai/A (0.9-1.1x total rate). Three of the nine trials used a fifth application because peppers in these tests were too immature for harvest following the fourth application. All applications were made using ground equipment in volumes of 29-53 gal/A, and included the use of non-ionic surfactants at 0.12-0.13% v/v. Single control and duplicate treated samples of peppers were harvested from each test site at 6-7 DAT. Additional samples from three field trials were collected at 0 and 14 DAT to measure residue decline. Samples were stored frozen for up to 493 days, a duration supported by available storage stability data.

The GC/NPD method used to determine residues of fenbuconazole and Metabolites RH-9129 and RH-9130 in/on peppers was adequately validated prior to, and in conjunction with, the analysis of field trial samples. This method is a slightly modified version of the current tolerance enforcement method for stone fruits. The statistically calculated LOQs were 0.008 ppm for fenbuconazole, 0.010 ppm for RH-9129 and 0.011 ppm for RH-9130. The calculated LODs were 0.003 ppm for fenbuconazole and RH-9129, and 0.004 ppm for RH-9130. The lower limit of method validation (LLMV) in/on peppers for each analyte is 0.01 ppm, for a combined LLMV of 0.03 ppm.

Following four or five foliar applications of fenbuconazole (WP) to peppers at rates totaling 0.66-0.68 or 0.84 lb ai/A (0.9x or 1.1x maximum seasonal rate), residues of fenbuconazole were 0.03-0.21 ppm in/on all 18 samples of bell and non-bell peppers harvested at 6-7 DAT. The extra fifth application had no apparent effect on residue levels. Residues of metabolites RH-9129 and RH-9130 were ≤0.01 ppm in/on all pepper samples harvested at 6-7 DAT. The average combined fenbuconazole residue in/on peppers was 0.14 ppm and the highest average field trial (HAFT) combined residues were 0.21 ppm. In the three residue decline tests, average combined fenbuconazole residues in/on peppers declined from 0.25-0.43 ppm at 0 DAT to 0.10-0.19 ppm by 14 DAT.

44690601.der (blueberry)
 45268401.der (blueberry)
 45296001.der (cranberry)

To support the use of fenbuconazole (75% WP) on cranberries and bushberries, IR-4 submitted field trial data for cranberries and high bush blueberries, respectively. Blueberries are the representative crop for Crop Subgroup 13-B. The results from these field trials are discussed below and summarized in Table 5.

Table 5. Summary of Residue Data for Crop Field Trials using Fenbuconazole (WP).										
Commodity (MRIDs)	Formulation	Total Rate (lb ai/A)	PHI (days)	Combined Residues (ppm) ¹						
				n	Min.	Max.	HAFT ³	Median (STMdR ⁴)	Mean (STMR ⁴)	Std. Dev.
Bushberries (proposed use = 0.47 lb ai/A total application rate, 30-day PHI)										
Blueberry ⁵ (44690601 & 45268401)	75% WP	0.47	25-35	18	0.03	0.24	0.19	0.080	0.083	0.048
Cranberry (proposed use = 0.94 lb ai/A total application rate, 30-day PHI)										
Cranberry (45296001)	75% WP	0.918-0.944	25-28	10	0.09	0.49	0.45	0.160	0.20	0.13

¹ The combined residues include parent and the lactone metabolites RH-9129 and RH-9130, expressed in parent equivalents. The LOQ is 0.01 ppm for each analyte in/on berries, for a combined LOQ of 0.03 ppm. For calculation of the median, mean, and standard deviation, ½LOQ was used for samples with residues <LOQ.

³ HAFT = Highest Average Field Trial.

⁴ STMdR = Supervised Trial Median Residue; STMR = Supervised Trial Mean Residue.

⁵ Includes data from the 9 acceptable blueberry field trials only.

Blueberry

Eight blueberry field trials were conducted during 1996 and 1997 (44690601.der) in EPA Growing Zones 1 (NH, 1 trial), 3 (NJ, NC, GA, 1 trial each), 5 (MI, 3 trials) and 12 (OR, 1 trial). Except in the NJ field trial, fenbuconazole (75% WP) was applied to high bush blueberries as five broadcast foliar applications beginning at green tip and continuing through fruit development at target rates of 0.094 lb ai/A/application, for a total of 0.47 lb ai/A/season. Actual application rates were reported for the NJ test only, in which fenbuconazole was applied below the target rate, for a total of 0.28 lb ai/A (0.6x rate). RTIs varied considerably, but were generally 7 to 21 days between the first 4 applications, and 28-39 days between the fourth and fifth applications. In each trial, applications were made using ground equipment at 16-91 gal/A and included the use of a non-ionic surfactant at an unspecified rate. Duplicate control and treated samples of berries were collected from each test at 25-35 DAT. Samples were stored frozen from collection to analysis for up to 7.9 months, a duration supported by the available stability data.

Residues of fenbuconazole, RH-9129, and RH-9130 were determined using the current GC/NPD tolerance enforcement method (Report No. 34-90-47R), with minor modifications. The method was adequately validated in conjunction with the field trial analyses and has an LOQ of 0.01 ppm for each analyte, for a combined LOQ of 0.03 ppm. The LOD was not reported.

There is a question as to the adequacy of the three Michigan field trials that were performed in 1996 and 1997. The trials were conducted with a hand-pumped sprayer. It took about 50 seconds to spray the plot. The sprayer was pumped to 60 psi and then re-pumped to 60 psi after every 15 seconds of spray time. IR-4 personnel stated that they were not certain that that procedure would maintain the appropriate spray pressure, and the low pressures reached were not recorded. Because of the question concerning the adequacy of the Michigan field trials, IR-4 performed two additional trials in 1998. HED considered these trials to be adequate (Memo, D316607, M. Collantes, *et al.*, 8/3/2006). However, HED felt that only six of the ten blueberry field trials that were submitted were adequate. Three were considered to be inadequate because of the pump pressure issue, and the New Jersey trial was considered to be inadequate because it was performed at a 0.6x application rate. In 2006, HED recommended in favor of a conditional registration on bushberries and requested that IR-4 perform two additional field trials. HED requested that these two trials be performed because eight were needed for the Bushberry Subgroup and, as stated above, HED felt that only six acceptable trials had been submitted.

IR-4 personnel responded by stating that they felt that the three original Michigan field trials should be considered to be acceptable. They were of that opinion because the person who made the applications in the field trials was an experienced applicator. They stated that the applicator probably observed the pressure drop during previous applications and compensated for it by re-pumping every 15 seconds of spray time. He calibrated his apparatus in this manner. They also stated that the results of the Michigan field trials were consistent with the results of the other four acceptable field trials. The data from 2 of the 3 trials fall within the ranges of the data from the other trials. Excluding the Michigan trials, the combined residues of parent and metabolites range from 0.05 ppm to 0.24 ppm. In 2 of the Michigan trials the residues range from 0.05 to 0.09 ppm. In the 3rd trial, the combined residues are 0.03 ppm for both samples. In that case, the parent and isomers were all detected at the LOQ of 0.01 ppm.

In the eight field trials, residues of fenbuconazole ranged from <0.01 ppm to 0.20 ppm. Residues of RH-9129 ranged from <0.01 ppm to 0.03 ppm, and residues of RH-9130 were either at, or below, the LOQ of 0.01 ppm. Combined residues, expressed as parent equivalents, ranged from 0.03 ppm to 0.24 ppm.

In the 2 additional blueberry field trials conducted during 1998 in Michigan (45268401.der), fenbuconazole (75% WP) was applied to high bush blueberries as five broadcast foliar applications beginning at green tip and continuing through fruit development at 0.094-0.096 lb ai/A/application, for a total of 0.47 lb ai/A/season. RTIs were 7-17 days between the first 4 applications, and 54-64 days between the fourth and fifth applications. Applications were made using ground equipment at ~50 gal/A and included the use of a non-ionic surfactant at ~0.1% of the spray mix. Duplicate control and treated samples of berries were collected from each test at 30 DAT. Samples were stored frozen from collection to analysis for up to 5.2 months, a duration supported by the available stability data.

Residues of fenbuconazole, RH-9129, and RH-9130 were determined using the current GC/NPD tolerance enforcement method (Report No. 34-90-47R), with minor modifications. The method was adequately validated in conjunction with the field trial analyses and has an LOQ of 0.01 ppm for each analyte, for a combined LOQ of 0.03 ppm. The LOD was not reported.

Residues of fenbuconazole were 0.06-0.07 ppm in/on the 4 blueberry samples from the two additional trials, and residues of both RH-9129 and RH-9130 were at or below the LOQ of 0.01 ppm in all samples. Combined residues (expressed in parent equivalents) were 0.08 to 0.09 ppm.

Considering both sets of blueberry field trials together, nine field trials are available reflecting the 1x application. The combined residues of fenbuconazole, RH-9129, and RH-9130 (expressed as parent) were 0.03-0.24 ppm in/on 18 samples harvested 25-35 DAT. Average combined residues are 0.083 ppm (with a standard deviation of 0.048 ppm) and combined HAFT residues are 0.19 ppm. Apparent residues of each analyte are <LOQ in/on all 18 control samples.

The geographical representation of field trials is not completely in accordance with that which is recommended in the OPPTS Series 860 Guidelines. Three trials in Zone 2 are recommended, but only two acceptable trials were submitted. The New Jersey trial was performed in Zone 2, but it is not acceptable. However, 5 acceptable trials were performed in Zone 5 whereas only 3 are recommended.

Cranberry

In five field trials conducted during 1998, fenbuconazole (75% WP) was applied to cranberries as five broadcast foliar applications at 0.178-0.194 lb ai/A/application, for a total of 0.918-0.944 lb ai/A/season. Applications began at flowering and continued through fruit development at RTIs of 10-14 days. Applications were made using ground equipment at 30-300 gal/A and included the use of a non-ionic surfactant at ~0.1% of the spray volume. Duplicate control and treated samples of cranberries were harvested from each test at 25-28 DAT. Samples were stored frozen from collection to analysis for up to 5.3 months, a duration supported by the available storage stability data.

Residues of fenbuconazole, RH-9129, and RH-9130 were determined using the GC/NPD tolerance enforcement method (Report No. 34-90-47R), with minor modifications. The method was adequately validated in conjunction with the field trial analyses and has an LOQ of 0.01 ppm for each analyte, for a combined LOQ of 0.03 ppm. The LOD was not reported.

At 25-28 days after the final application, residues of fenbuconazole were 0.07-0.45 ppm in/on 10 treated cranberry samples. Residues of RH-9129 were 0.01-0.04 ppm and residues of RH-9130 were <0.01-0.01 ppm, for total combined residues of 0.09-0.49 ppm (expressed in parent equivalents). Average combined residues were 0.20 ppm and combined HAFT residues were 0.45 ppm. Apparent residues of each analyte were <LOQ in/on all 10 control samples.

Conclusions. Although the single application rates for peppers were slightly below (0.9x) the maximum proposed use rate, the submitted field trial data are adequate and support the use of fenbuconazole (WP) on peppers. Adequate numbers of tests were conducted in the appropriate geographical regions, and samples were analyzed for residues of concern using an adequate data collection method.

HED concludes that nine of the ten submitted blueberry field trials are adequate. The trial performed in New Jersey is not adequate because the application rate is only 0.6x the label rate.

HED feels that the three original Michigan field trials are acceptable. Although there is a question as to the application technique, the results of the trials in question are consistent with the results of the other trials. In one of these trials, residues were below the range of residue values in the other trials; however, they were not significantly below. When the recommended tolerance is determined using HED's statistical tolerance generator, the same tolerance is generated regardless of whether or not this sample is included. The recommended tolerance is 0.25 ppm. In addition, the field report states that application instrumentation was calibrated at each application.

In the nine acceptable field trials, fruit samples were collected at the appropriate intervals, and were analyzed using an adequate method. The sample storage durations are also supported by the available storage stability data. Data from these nine blueberry field trials support the use of up to five foliar applications of fenbuconazole (WP or FIC) to bushberries at up to 0.094 lb ai/A/application, for a maximum seasonal rate of 0.47 lb ai/A. The data support the established PHI of 30 days, a minimum RTI of 10 days, and the use of a non-ionic surfactant in the spray mix.

For cranberries, adequate numbers of tests were conducted in representative geographic regions, and the fruit samples were collected at intervals slightly shorter than the proposed PHI. Samples were analyzed using an adequate method, and the sample storage durations are supported by the available storage stability data. The available cranberry data are adequate and support the use of up to five foliar applications of fenbuconazole (WP or FIC) at up to 0.188 lb ai/A/application, for a maximum seasonal rate of 0.94 lb ai/A. The data support the proposed PHI of 30 days, a minimum RTI of 10 days, and the use of a non-ionic surfactant in the spray mix. As maximum combined residues were 0.49 ppm at 25-28 DAT, a tolerance of 0.5 ppm will be sufficient to cover the 30-day PHI. In the pepper, blueberry, and cranberry field trials, no residue data were provided on 1,2,4-triazole, TA, or TAA as required under the current guidance for field trials using triazole compounds (Memo, D327788, M. Doherty, 4/25/2006).

860.1520 Processed Food and Feed

HED does not require residue data for any processed commodities associated with peppers, blueberries, or cranberries. Therefore, data requirements for processed food and feed are not relevant to these tolerance petitions.

860.1650 Submittal of Analytical Reference Standards

Analytical reference standards for fenbuconazole and its metabolites, RH-9129 and RH-9130, are available at the EPA National Standards Repository (Electronic communication, D. Wright, 4/21/2008). Their expiration dates are as follows: fenbuconazole (3/21/2009), RH-9129 (1/4/2009), and RH-9130 (8/17/2009).

860.1850/1900 Confined and Field Accumulation in Rotational Crops

D259204, S. Oonnithan, 7/25/06

An adequate confined rotational crop study is available indicating that the metabolite profile for fenbuconazole in rotational crops is similar to the metabolism in primary crops. Limited rotational crop field trials and rotational crop tolerances are not required provided that the labels specify a minimum PBI of 35 days following applications to peppers totaling ≤ 0.188 lb ai/A and a minimum PBI of 210 days following applications totaling 1.0 lb ai/A.

As bushberries and cranberries are perennial crops, requirements pertaining to rotational crops are not relevant to these petitions.

860.1550 Proposed Tolerances

For purposes of establishing tolerances, HED has concluded that the residues of concern in plants include fenbuconazole and its lactone metabolites, RH-9129 and RH-9130. A permanent tolerance is established for the combined residues of fenbuconazole and Metabolites RH-9129 and RH-9130, expressed as parent equivalents on cranberries at 0.5 ppm. A tolerance is established for the Bushberry Subgroup, Crop Subgroup 13-B, at 0.3 ppm.

Using the Agency's *Guidelines for Setting Pesticide Tolerances Based on Field Trial Data*, the appropriate tolerance for pepper was calculated using the 6-7 DAT residue data from the adequate U.S. field trials conducted at a 0.9x rate. The calculated tolerance for peppers was 0.40 ppm (Appendix II). The tolerances that are generated for cranberries and blueberries are 0.70 ppm and 0.25 ppm, respectively.

Maximum residue limits (MRLs) for residues of fenbuconazole have been established by Codex, Canada, and Mexico. The residue definition for both Codex and Mexico is fenbuconazole, *per se*, and the Canadian residue definition is the combined residues of fenbuconazole and its metabolites, RH-9129 and RH-9130, each expressed as parent (*i.e.*, the same as the U.S. tolerance definition). As there are no established or proposed Canadian, Mexican, or Codex MRLs for fenbuconazole on peppers, there are no international harmonization issues for the pepper tolerance petition.

The U.S. has already established tolerances for cranberries at 0.5 ppm and bushberries at 0.3 ppm. Mexico established tolerances for these commodities based on the established U.S. tolerances. Therefore, HED recommends that the current tolerances remain in effect, even though they are different than the tolerances that are recommended by HED's statistical tolerance generator. As a result, HED recommends that the 0.30 ppm tolerance for bushberries remain in effect, even though the tolerance generator recommends a tolerance of 0.25 ppm, and the 0.50 ppm tolerance for cranberries remain in effect, even though the tolerance generator recommends a tolerance of 0.70 ppm.

Table 6. Tolerance Summary for Fenbuconazole.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; Correct Commodity Definition
Pepper	0.4	0.40	Adequate field trial data are available on peppers. Commodity definition: Pepper

References

Fenbuconazole on Stone Fruit, Pecans, Almonds, Bananas, Apples, and Wheat. New Chemical Registration. Issues to be Presented at the 12/15/93 Meeting of the HED Metabolism Committee., N. Dodd and W. Wassell, 12/10/93

Fenbuconazole Metabolism in Stone Fruit, Pecans, Almonds, Bananas, Apples, and Wheat. The HED Metabolism Committee Meeting Held on 3/1/94., N. Dodd and W. Wassell, 3/9/94.

D200171, PP#1F3995. Fenbuconazole on Pecans. Amendment dated 2/25/94, N. Dodd, 4/5/1994.

D197760, PP# 1F3989 - Fenbuconazole on Stone Fruit. Revised Enforcement Method, N. Dodd, 4/8/94, MRID: 43044401.

D223758, PP#2F4127. Fenbuconazole, Govern 2F and Govern 75WSP Agricultural Fungicide in or on Wheat. Amendment of 2/1/96, W. Wassell, 4/23/96.

D249012, Fenbuconazole (RH-7592 Technical, Enable 2F and Indar 75WSP, respectively) in/on the Crop Group Stone Fruit (except plums and prunes) and the Crops Bananas and Pecans. Evaluation of Crop Field Trial Data and Storage Stability Data, W. Wassell, 11/19/98.

D241864, Fenbuconazole. Request for Tolerances on Sugar Beets. Summary of Analytical Chemistry and Residue Data. Petition Number: 7F4887, G. Otakie, 3/30/06.

D239002, Fenbuconazole. Request for Tolerances on Apples. Summary of Analytical Chemistry and Residue Data. Petition Number 2F4135, G. Otakie, 3/30/06.

327788, Triazole-Based Metabolites: Guidance On Residue Chemistry Data Submissions, M. Doherty, 4/25/2006.

D259204, Fenbuconazole. Request for Tolerances on Peanuts. Summary of Analytical Chemistry and Residue Data, S. Oonnithan, 7/25/06.

Multiresidue Test Information for Updating PAM I, N. Dodd, 1/27/93, MRID: 41875044.

Attachments:

Appendix I – International Residue Limit Status sheet

Appendix II - Tolerance Assessment Calculations and Field Trial Results

Appendix I. International Tolerances

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: α -[2-(4-chlorophenyl)ethyl]- α -phenyl-1 <i>H</i> -1,2,4-triazole-1-propanenitrile	Common Name: Fenbuconazole	X Proposed tolerance <input type="checkbox"/> Reevaluated tolerance <input type="checkbox"/> Other	Date: 1/22/2008
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
<input type="checkbox"/> No Codex proposal step 6 or above X No Codex proposal step 6 or above for the crops requested		Petition Numbers: 7F7256 DP Number: 345256 Other Identifier:	
Residue definition (step 8/CXL): Fenbuconazole		Reviewer/Branch: C. Swartz/RAB2 Residue definition: Combined residues of fenbuconazole and its lactone metabolites, RH-9129 and RH-9130, each expressed as fenbuconazole.	
Crop (s)	MRL (mg/kg)	Crop(s)	Tolerance (ppm)
		Peppers	0.40
		Bushberry Subgroup	0.3
		Cranberry	0.5
Limits for Canada		Limits for Mexico	
<input type="checkbox"/> No Limits X No Limits for the crops requested		<input type="checkbox"/> No Limits <input type="checkbox"/> No Limits for the crops requested	
Residue definition: Combined residues of fenbuconazole and its lactone metabolites, RH-9129 and RH-9130, each expressed as fenbuconazole.		Residue definition: Fenbuconazole	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (mg/kg)
		Blueberries	0.3 ppm (US tolerance)
		Cranberries	0.5 ppm (US tolerance)
Notes/Special Instructions:			

Appendix II - Tolerance Assessment Calculations and Field Trial Results.

The dataset used to establish a tolerance for fenbuconazole on peppers consisted of field trial data representing application rates of 0.66-0.84 lb ai/A (4 or 5 applications at 0.163-0.173 lb ai/A/application, 0.9x single rate) with a 6 or 7-day PHI. As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data SOP*, the field trial application rates and PHIs are within 25% of the maximum label application rate and minimum label PHI, respectively. The residue values used to calculate the tolerance are provided in Table II-1. The combined residues of fenbuconazole and its metabolites were above the LOQ (0.03 ppm) in all field trial samples.

The dataset was entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plot (Figure II-1) provided in the spreadsheet indicates that the dataset is reasonably lognormal. The result from the approximate Shapiro-Francia test statistic (Figure II-2) confirmed that the assumption of lognormality should not be rejected. Because the field trial data for the combined residues represent a large dataset (>15 samples) and are reasonably lognormal, the 99th percentile was selected as the appropriate percentile for the pepper tolerance level (0.40 ppm).

Table II-1. Residue data used to calculate tolerance for fenbuconazole on peppers.	
Regulator:	EPA
Chemical:	Fenbuconazole
Crop:	Bell and Non-Bell Peppers
PHI:	6-7 days
App. Rate:	0.66-0.84 lb ai/A/season
Submitter:	IR-4
MRID Citation:	MRID 47215801
Combined Residues	
	0.05
	0.16
	0.06
	0.16
	0.07
	0.17
	0.07
	0.17
	0.07
	0.18
	0.07
	0.19
	0.10
	0.22
	0.12
	0.22
	0.14
	0.22

Figure II-1. Lognormal probability plot of fenbuconazole field trial data for peppers

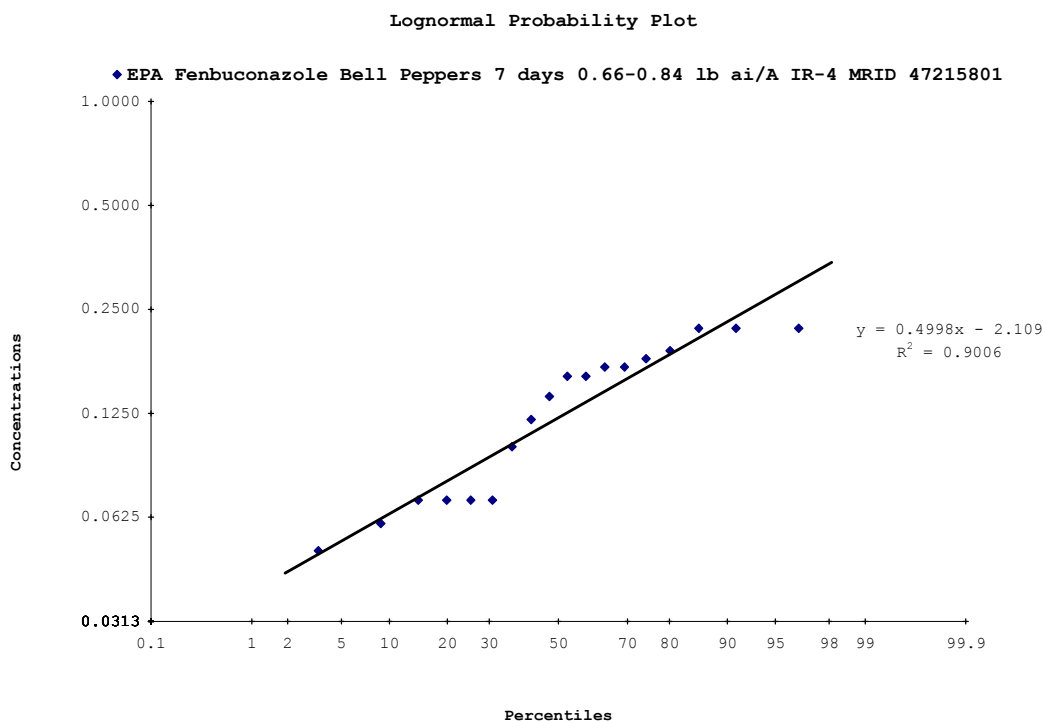


Figure II-2. Tolerance spreadsheet summary of fenbuconazole field trial data for peppers.

Regulator: EPA Chemical: Fenbuconazole Crop: Bell Peppers PHI: 7 days App. Rate: 0.66-0.84 lb ai/A Submitter: IR-4 MRID Citation: MRID 47215801			
n: 18 min: 0.05 max: 0.22 median: 0.15 average: 0.14			
	95th Percentile	99th Percentile	99.9th Percentile
EU Method I	0.25	0.30	0.35
Normal	(0.30)	(0.35)	(--)
EU Method I	0.30	0.40	0.60
Log Normal	(0.45)	(0.70)	(--)
EU Method II	0.40		
Distribution-Free	0.40		
California Method	0.35		
$\mu + 3\sigma$	0.35		
UPLMedian95th	1.0		
Approximate	0.9006		
Shapiro-Francia	p-value > 0.05 : Do not reject lognormality assumption		
Normality Test	p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==>

Y

Table II-2. Blueberry Field Trial Data		
Chemical:	Fenbuconazole	
Crop:	Blueberries	
PHI:	25-35 days	
App. Rate:	0.47 lb ai/A/season	
Submitter:	IR-4	
MRID Citation:	MRIDs 44690601 and 45268401	
	Combined Residues (ppm)	
	0.03	0.08
	0.03	0.08
	0.05	0.08
	0.05	0.09
	0.05	0.09
	0.05	0.10
	0.07	0.12
	0.08	0.13
	0.08	0.24

Table II-3. Cranberry Field Trial Data		
Chemical:	Fenbuconazole	
Crop:	Cranberries	
PHI:	25-28 days	
App. Rate:	0.92-0.94 lb ai/A/season	
Submitter:	IR-4	
MRID Citation:	MRID 45296001	
	Combined Residues (ppm)	
	0.09	0.17
	0.10	0.17
	0.11	0.20
	0.12	0.41
	0.16	0.47