



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

OPP OFFICIAL RECORD HEALTH EFFECTS DIVISION SCIENTIFIC DATA REVIEWS EPA SERIES 361

MEMORANDUM

DATE: June 8, 2006

SUBJECT: Fluopicolide (AE C638206) in/on imported grapes, domestic use in/on food crops and ornamental turf. Request for Petition Method Validation.

Petition No. 5E6903 & 5F7016 Decision No: 353910
DP Barcodes: 329686 40 CFR: Not Established
Chemical No.: 027412 Class: Fungicide
Trade Name: Fluopicolide EPA Reg No.: 59639-RUE, 59639-RUR, 59639-RUN, 59639-RUE
MRID Nos. 46474027- 46474031, 46708522-46708525 and 46708516.

FROM: Amelia M. Acierto, Chemist Registration Action Branch 3 Health Effects Division (7509P)

Handwritten signature of Amelia M. Acierto

THROUGH: Leung Cheng, Ph.D., Senior Chemist Registration Action Branch 3 Health Effects Division (7509P)

Handwritten signature of Leung Cheng

TO: Frederic Siegelman, PhD., Chief Analytical Chemistry Branch/BEAD (7503P)

Bayer CropScience has submitted petitions for the establishment of tolerances for the combined residues of the fungicide fluopicolide, AE C638206 (2,6-dichloro-N-[[3-chloro-5-(trifluoromethyl)-2-pyridinyl]-methyl]benzamide and its primary metabolites AE C653711 (2,6-dichlorobenzamide) and AE C657188 (3-chloro-5-trifluoromethylpyridine-2-carboxylic acid). One petition is for an import tolerance (PP# 5E6903) on grapes and raisins and the second petition (5F7016) is for domestic use on various food crops. The petitions and data have now been transferred to Valent. The proposed tolerances are provided below:

Table with 2 columns: FOR IMPORT USE (PP# 5E6903) and tolerance values. Rows: Grapes (2.0 ppm), Raisin (9.0)

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<b>FOR DOMESTIC USE (PP# 5F7016)</b>	
Tuberous and corm vegetables subgroup 1C	0.02 ppm
Vegetable, leafy, except brassica, group 4	20.0
Vegetable, fruiting, group 8	0.8
Vegetable, cucurbit, group 9	0.4
Grape	2.0
Raisins	6.0
Wheat forage*	0.2
Wheat grain*	0.02
Wheat hay*	0.5
Wheat straw*	0.5

\*Inadvertent residues.

The proposed tolerance enforcement method (MRID# 46708524, Valent Method RM-43C-1) is an LC/MS/MS method based on Bayer CropScience Method 00782, Report No. C024784 and modifications M001, M002, and M003 for the combined residues of fluopicolide and its metabolites, all calculated as fluopicolide. Modification M001 is for grapes and potatoes, M002 is for wheat, and M003 is for cereals (wheat). Independent laboratory validation (ILV) of the plant methods have also been submitted (MRID# 46708522). These studies are being sent to you in a CD.

A livestock method for ruminants is also being submitted (MRID# 46708516). No ILV has been submitted. If needed, tolerances will be established at the LOQ of the method (i.e., 0.01 ppm for milk, 0.02 ppm for muscle and 0.05 ppm for fat, liver and kidney. This method is also included in the CD.

HED requests that ACB conduct a petition method validation (PMV) of proposed tolerance enforcement methods per the experimental design specified in **Attachment 1**. All samples should be run in duplicate. Please complete and return these attachments as part of your report. Also, please include in your report all relevant information and supporting documentation concerning the method validation, including modifications which were made, and indicate the suitability of the analytical method for enforcement purposes. Please include the Repository ordering code(s) for the reference standards if required.

We note that for both methods, the petitioner concluded that the specificity of the LC/MS/MS method precludes the need for confirmatory procedures. Please comment on the need for confirmatory procedures for the methods.

Should you find that the necessary analytical reference standards, internal standards, and/or MSDSs are not available to you, please contact Melvin Tolliver (Registration Product Manager, Regulatory Affairs, Bayer CropScience, Research Triangle Park, NC, 919-549-2631) to request that they be provided.

Since one of the purposes of conducting an in-house PMV is to determine whether all necessary

instructions are included in the submitted proposed enforcement methods, your laboratory staff scientists should have minimal contact with the petitioner during the conduct of this trial. Any problems encountered in the method as written should be documented and included in your report. The petitioner will be informed of any deficiencies in the method and asked to resolve them.

The RD Product Manager for fluopicolide is Tony Kish and he should be contacted directly (703-308-9443) if you require guidance concerning the priority for initiation/completion of the PMV.

Please address and send your report to me, A. M. Acierto, RAB3/HED 7509P. If you need any further information, please call me at (703) 308-8377. The DP barcode assigned by HED for conducting this PMV are D329578 and D329670.

Attachment 1: Method Report Form (Crops)

Attachment 2: Method Report Form (Ruminants)

Attachment 3: List of Methods sent in CD

## ATTACHMENT 1

METHOD: 46708524. Tolerance Enforcement Method for the Analysis of Residues of Fluopicolide in/on Crops Method RM-43C-1. Valent Accession No. 200500282.

Please: (i) indicate the limit of detection and quantitation; (ii) do not use control values for recovery calculations; and (iii) do not report control values as zero; if less than the limit of detection, report as such.

Commodity	Chemical Added	ppm Added	ppm Found	% Recovery
Potato	Fluopicolide (AE C638206)	0.01		
		0.02		
	BAM (AE C653711)	0.01		
		0.02		
	PCA AE C657188	0.01		
		0.02		
Grapes	Fluopicolide (AE C638206)	0.01		
		1.0		
		2.0		
	BAM (AE C653711)	0.01		
		1.0		
		2.0		
	PCA AE C657188	0.01		
		1.0		
		2.0		
Raisin	Fluopicolide (AE C638206)	0.01		
		4.0		
		9.0		
	BAM (AE C653711)	0.01		
		4.0		
		9.0		
	PCA AE C657188	0.01		
		4.0		
		9.0		
Wheat, grain	Fluopicolide	0.01		

Commodity	Chemical Added	ppm Added	ppm Found	% Recovery
	BAM (AE C653711)	0.20		
		0.50		
		0.01		
		0.20		
		0.50		
		0.01		
	BAM-OH (AE C657378)	0.20		
		0.50		
		0.01		
	PCA (AE C657188)	0.20		
		0.50		
		0.01		
Wheat, hay	Fluopicolide (AE C638206)	0.01		
		0.20		
		0.50		
	BAM (AE C653711)	0.01		
		0.20		
		0.50		
	BAM-OH (AE C657378)	0.01		
		0.20		
		0.50		
	PCA (AE C657188)	0.01		
		0.20		
		0.50		
Tomato	Fluopicolide (AE C638206)	0.01		
		0.4		
		0.8		
	BAM (AE C653711)	0.01		
		0.4		
		0.8		
	PCA (AE C657188)	0.01		
		0.4		
		0.8		
Cucumber	Fluopicolide (AE C638206)	0.01		
		0.2		

Commodity	Chemical Added	ppm Added	ppm Found	% Recovery
	BAM (AE C653711)	0.4		
		0.01		
		0.2		
		0.4		
		0.01		
		0.2		
	PCA (AE C657188)	0.4		
		0.01		
		0.2		
		0.4		
		0.01		
		0.2		
Leaf lettuce	Fluopicolide (AE C638206)	0.01		
		10.0		
		20.0		
	BAM (AE C653711)	0.01		
		10.0		
		20.0		
	PCA (AE C657188)	0.01		
		10.0		
		20.0		

## ATTACHMENT 2

Method: 46708516. Analytical Method AR 303-02 for the Determination of Residues in Foodstuffs of Animal Origin. (Bayer Project No. C035414, 200500924, 02/125).

Commodity	Chemical Added	ppm Added	ppm Found	% Recovery
Milk	Fluopicolide (AE C638206)	0.01		
		0.02		
	BAM (AE C653711)	0.01		
		0.02		
	PCA AE C657188	0.01		
		0.02		
Muscle	Fluopicolide (AE C638206)	0.02		
		0.04		
	BAM (AE C653711)	0.02		
		0.04		
	PCA AE C657188	0.02		
		0.04		
Fat	Fluopicolide (AE C638206)	0.05		
		0.10		
	BAM (AE C653711)	0.05		
		0.10		
	PCA AE C657188	0.05		
		0.10		
Liver	Fluopicolide (AE C638206)	0.05		
		0.10		
	BAM (AE C653711)	0.05		
		0.10		
	PCA (AE C657188)	0.05		
		0.10		
Kidney	Fluopicolide (AE C638206)	0.05		
		0.10		
	BAM (AE C653711)	0.05		
		0.10		

Commodity	Chemical Added	ppm Added	ppm Found	% Recovery
	PCA	0.05		
	(AE C657188)	0.10		

## ATTACHMENT 3

### List of Methods in CD

46474027. Study Profile. Residue Analytical Method

46474028. Determination of the Residues of AE C638206 and Metabolites in Wheat (Straw and Grain), Grapes and Cabbage using LC/MS/MS Method Validation. Bayer No. CO24784

46474029. Modification M001 of the Residue Analytical Method 00782 for the Determination of the Residues of AE C638206 and its Metabolites AE C657188 and AE C653711 in/on Grape and Potato by HPLC-MS/MS. Bayer No. CO31433.

46474030. Validation of the Modification M002 to the Analytical Method 00782 for the Determination of the Residues of AE C638206 and its Metabolites AE C657188, AE C653711 and AE C1344122 in/on Wheat by HPLC-MS/MS. Bayer No. CO38955.

46474031. Modification M003 of the Analytical Method 00782 for the Determination of the Residues of AE C657378 (3-OH-BAM) in/on Cereals (Wheat) by HPLC-MS/MS. Bayer No. CO38960.

46708522. Independent Laboratory Validation of "Validation of the Modification M002 to the Analytical Method 00782 for the Determination of Residues of AE C638206 and its Metabolites AE C657188, AE C653711 and AE C1344122 in/on Wheat by HPLC-MS/MS" for Tomatoes and Modification M003 to the Analytical Method 00782 for the Determination of Residues of AE C657188 (3-OH-BAM) in/on Cereals (Wheat) by HPLC-MS/MS" for Wheat Forage According to PR Notice 96-1, OPPTS 860.1340 Guidelines, and SANCO/825/00 Rev.7 (Valent Accession No. 200500277).

46708524. Tolerance Enforcement Method for the Analysis of Residues of Fluopicolide in/on Crops Method RM-43C-1 (Valent Accession No. 200500282).

46708525. PAM I Multiresidue Protocol Testing for AE C638206 (Fluopicolide) and its Metabolites AE C653711 (BAM) and AE C657378 (BAM-OH), AE C657188 (PCA), and AE C1344122 (PIX). Valent Accession No. 200500927.

46708516. Analytical Method AR 303-02 for the Determination of Residues in Foodstuffs of Animal Origin. (Bayer Project No. C035414, 200500924, 02/125).

cc (with Attachments 1-3 only): A. M. Acierto.

RDI: RAB3 Chem. Team: 06/06/2006



13544

**R128830**

**Chemical: Fluopicolide**

**PC Code:  
027412**

**HED File Code: 11500 Petition Files Chemistry**

**Memo Date: 6/8/2006**

**File ID: DPD329686**

**Accession #: 412-06-0192**

**HED Records Reference Center  
7/12/2006**

