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: 30-JAN-2007

Subject: **Pyrasulfotole**. Section 3 Registration for Use on Cereal Grains. Request for Petition Method Validation (PMV).

DP#:	335558	Decision#:	366490
PC Code:	000692	Registration #:	6F7509
40 CFR 180.	Xxx		

From: Jennifer R. Tyler, Chemist Jennifer R. Tyler
Registration Action Branch (RAB1)
Health Effects Division (HED) (7509P)

Through: George F. Kramer, Ph.D. Senior Chemist
RAB1/HED (7509P)

To: Frederic Siegelman, Ph.D., Chief
Analytical Chemistry Laboratory (ACL)
Biological & Economic Analysis Division (BEAD) (7503P)

Bayer CropScience has submitted a petition for the use of pyrasulfotole ((5-hydroxy-1,3-dimethyl-1*H*-pyrazol-4-yl)[2-(methylsulfonyl)-4-(trifluoromethyl)phenyl]methanone) on wheat (spring, durum, and winter), oat, triticale and timothy (grown for seed production only).

In conjunction with this request, Bayer CropScience proposed the establishment of permanent tolerances for the residues of pyrasulfotole and its metabolite pyrasulfotole-desmethyl ((5-hydroxy-1,3-dimethylpyrazol-4-yl) (2-mesyl-4-trifluoromethylphenyl) methanone) in/on the raw agricultural commodities (RACs) listed in Attachment 1. In addition, Bayer has requested permanent tolerances for pyrasulfotole *per se* in or on several livestock commodities, as listed in Attachment 1.

To enforce the proposed tolerances on cereal grains, the petitioner proposed a high-performance liquid chromatography (HPLC) with tandem mass spectrometry (MS/MS) method (Method AI-001-P04-01). In addition, to enforce the proposed tolerances on ruminant commodities, including milk, the petitioner proposed a HPLC/MS/MS method (Method AI-004-A05-01). These methods have been adequately validated by the petitioner and had undergone successful independent laboratory validations (ILVs). Adequate radiovalidation has also been received.

The petitioner has submitted copies of Method AI-001-P04-01 for determination of pyrasulfotole, in crop matrices (Appendix 1 of MRID 46801806, pages 36-58); Method AI-004-

A05-01 for determination of pyrasulfotole *per se* in ruminant commodities, including milk (Appendix 5 of MRID 46801809, pages 79-100); and ILVs for both methods in the following volumes which are appended to this memorandum as Attachment 5 (CD):

> MRID No. 46801806 Gould, T. Timberlake, B. and Brungardt, J. 2006. Validation of Bayer CropScience Method AI-001-P04-01 An Analytical Method for the Determination of Residues of AE 0317309, AE 1073910, and AE B197555 in Wheat, Corn, and Soybean Matrices Using LC/MS/MS. Unpublished Bayer CropScience Report No.: RAAIX005. 206 pages.
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> MRID No. 46801807 Billian, B. 2005. Independent Laboratory Validation of the Analytical Method AI-001-P04-01 for the Determination of Residues of AE 0317309, AE 1073910 and AE B197555 in Plant Material. Unpublished Bayer CropScience, Monheim, Germany Study No.: P612050574. Bayer CropScience Report No.: MR-097/05. 72 pages.
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> MRID No. 46801809 Lam, C.K., and Qadri, S.S. 9 January 2006. Validation of Bayer CropScience Method AI-004-A05-01. Analytical Method for the Determination of Residues of AE 0317309 in Animal Tissues and Milk Using LC/MS/MS. Bayer CropScience Study Number: RAAIX006. 100 pages.
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> MRID No. 46801810 Billian, P. and Wirkner, H. 4 November 2005. Independent Method Validation of the Analytical Method AI-004-A05-01 for the Determination of Residues of AE 0317309 in Animal Tissues and Milk Using LC/MS/MS. Bayer CropScience Report Number: MR-122/05. 56 pages.

RAB1 requests that ACL/BEAD conduct a PMV of the proposed plant and livestock enforcement methods as outlined in Attachments 2 and 3, respectively. All samples (including the controls) should be run in duplicate. Please complete and return this attachment 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 for the reference standards. 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 method, 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 pyrasulfotole is Tracy White. He should be contacted directly (703-308-0042) if you require guidance concerning the priority for initiation/completion of this PMV.

Please address and send your report to Dana Vogel, Acting Branch Chief, RAB1/HED, 7509P. If you need any further information, please call me at 703-305-5564.

Attachment 1: Proposed tolerances (from Section F of PP# 6F7509)
Attachment 2: Method report form - Plants
Attachment 3: Method report form - Livestock
Attachment 4: Bean sheet for PMV request (DP #: 335559; not available electronically)
Attachment 5: CD containing the following studies: 46801806, 46801807, 46801809, 46801810.

RDI: RAB1 Chemists (24-JAN-2007); G. Kramer (30-JAN-2007)
J. Tyler:S10943:PY1:(703)305-5564:7509P:RAB1

Attachment 1: Proposed Tolerances (from Section F of PP# 6F7509)

Bayer has requested the establishment of the permanent tolerances for pyrasulfotole and its metabolite (5-hydroxy-1,3-dimethylpyrazol-4-yl) (2-mesyl-4-trifluoromethylphenyl) methanone in or on the following RACs:

Wheat, grain	0.07 ppm	Oat, hay	0.8 ppm
Wheat, straw	0.25 ppm	Barley, grain	0.07 ppm
Wheat, forage	0.25 ppm	Barley, straw	0.25 ppm
Wheat, hay	0.8 ppm	Barley, hay	0.8 ppm
Wheat, aspirated grain fractions	1.4 ppm	Triticale, grain	0.07 ppm
Oat, grain	0.07 ppm	Rye, grain	0.07 ppm
Oat, straw	0.25 ppm	Rye, straw	0.25 ppm
Oat, forage	0.25 ppm	Rye, forage	0.25 ppm

In addition, Bayer has requested permanent tolerances for pyrasulfotole *per se* in or on the following livestock commodities:

Milk	0.005 ppm	Hog, fat	0.01 ppm
Cattle, meat	0.01 ppm	Hog, meat byproducts	0.3 ppm
Cattle, fat	0.01 ppm	Sheep, meat	0.01 ppm
Cattle, meat byproducts	0.3 ppm	Sheep, fat	0.01 ppm
Goat, meat	0.01 ppm	Sheep, meat byproducts	0.3 ppm
Goat, fat	0.01 ppm	Horse, meat	0.01 ppm
Goat, meat byproducts	0.3 ppm	Horse, fat	0.01 ppm
Hog, meat	0.01 ppm	Horse, meat byproducts	0.3 ppm

Attachment 2: Method Report Form - Plants

Method AI-001-P04-01 can be found as Appendix 1 (pages 36-58) of the following study:

MRID No. 46801806 Gould, T. Timberlake, B. and Brungardt, J. 2006. Validation of Bayer CropScience Method AI-001-P04-01 An Analytical Method for the Determination of Residues of AE 0317309, AE 1073910, and AE B197555 in Wheat, Corn, and Soybean Matrices Using LC/MS/MS. Unpublished Bayer CropScience Report No.: RAAIX005. 206 pages.

Please do not use control values for recovery corrections. Please do not report control values as 0.0 ppm; accurately state your limit of detection and note any commodity coextratives that could change the recovery values reported

Matrix	analyte	Fortification (ppm)	ppm Found	% recovery
Wheat, grain	Pyrasulfotole	0.0		
		0.01		
		0.035		
		0.07		
Wheat, forage		0.0		
		0.01		
		0.125		
		0.25		
Wheat, grain	Pyrasulfotole-desmethyl	0.0		
		0.01		
		0.035		
		0.07		
Wheat, forage		0.0		
		0.01		
		0.125		
		0.25		

Attachment 3: Method Report Form - Livestock

Method AI-004-A05-01 can be found as Appendix 5 (pages 79-100) of the following study:

MRID No. 46801809 Lam, C.K., and Qadri, S.S. 9 January 2006. Validation of Bayer CropScience Method AI-004-A05-01. Analytical Method for the Determination of Residues of AE 0317309 in Animal Tissues and Milk Using LC/MS/MS. Bayer CropScience Study Number: RAAIX006. 100 pages.

Please do not use control values for recovery corrections. Please do not report control values as 0.0 ppm; accurately state your limit of detection and note any commodity coextratives that could change the recovery values reported

matrix	Analyte	Fortification (ppm)	ppm Found	% recovery
milk	Pyrasulfotole	0.00		
		0.005		
		0.01		
beef liver		0.00		
		0.01		
		0.15		
		0.3		
milk	Pyrasulfotole-desmethyl	0.00		
		0.005		
		0.01		
beef liver		0.00		
		0.01		
		0.15		
		0.3		

Attachment 4: Bean Sheet for PMV Request (DP #: 335559; not available electronically)

Decision #: 366490

DATA PACKAGE BEAN SHEET

DP #: (335559)

Date: 12-Jan-2007

* * * Registration Information * * *

Registration: 264-RNEE - PYRASULFOTOLE TECHNICAL

Company: 264 - BAYER CROPSCIENCE LP

Risk Manager: RM 23 - Joanne Miller - (703) 305-6224 Room# PY1 S-7328

Risk Manager Reviewer: Jennifer-R Tyler JTYLER

Sent Date: _____ Calculated Due Date: 10-Apr-2008 Edited Due Date: _____

Type of Registration: Product Registration - Section 3

Action Desc: (R01) NEW AI;FOOD USE;

Ingredients: 000692, Pyrasulfotole Technical(98.6%)

* * * Data Package Information * * *

Expedite: ( ) Yes (●) No Date Sent: 12-Jan-2007 Due Back: _____

DP Ingredient: 000692, Pyrasulfotole Technical

DP Title: PMV Request

CSF Included: ( ) Yes (●) No Label Included: ( ) Yes (●) No Parent DP #: 328640

	Assigned To	Date In	Date Out	
Organization:	BEAD / ACL			Last Possible Science Due Date: 13-Oct-2007
Team Name:				Science Due Date:
Reviewer Name:				Sub Data Package Due Date:
Contractor Name:				

* * * Studies Sent for Review * * *

No Studies

* * * Additional Data Package for this Decision * * *

Printed on Page 2

* * * Data Package Instructions * * *

Attn. BEAD/ACL: Please provide petition method validation for proposed enforcement methods for new ai pyrasulfotole.

DP#: (335559) *** * * Additional Data Package for this Decision * * *** Decision#: (366490)

DP #	Division/Branch	Date Sent	Date Due	Instructions?	OSF	Label
328513	RD / TRB	18-Apr-2006	13-Jul-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328513	RD / HB	18-Apr-2006	13-Jul-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328521	RD / TRB	18-Apr-2006	13-Jul-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328521	RD / HB	18-Apr-2006	13-Jul-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328639	RD / HB	18-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328639	EFED / ERB4	18-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328640	HED / RAB1	18-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328640	RD / HB	18-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328651	RD / HB	19-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
328651	EFED / ERB4	19-Apr-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
330817	RD / HB	12-Jul-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
330817	EFED / ERB4	12-Jul-2006	13-Oct-2007	○ Yes ○ No	● Yes ○ No	● Yes ○ No
333412	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
333412	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
333434	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
333434	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
333435	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
333435	HED / RAB1	25-Oct-2006	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
335272	RD / HB	09-Jan-2007	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
335272	EFED / ERB4	09-Jan-2007	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
335558	HED / RAB1	12-Jan-2007	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No
335558	HED / RAB1	12-Jan-2007	13-Oct-2007	○ Yes ○ No	○ Yes ● No	○ Yes ● No

Attachment 5: CD containing the following studies 46801806, 46801807, 46801809, 46801810.

13544

R139837

Chemical: Pyrasulfotole Technical

PC Code:
000692
HED File Code: 11500 Petition Files Chemistry
Memo Date: 1/30/2007
File ID: DPD335558
Accession #: 000-00-0117

HED Records Reference Center
2/7/2007