

MEMORANDUM

SUBJECT: PP# 3G04263. New Chemical - Fipronil in or on corn.
Request for Petition Method Validation. MRID# 429186-66.
Barcode D197451. Chemical No 129121. CBTS# 12927.

FROM: G.F. Kramer Ph.D., Chemist
Tolerance Petition Section III
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

THRU: D.F. Edwards Ph.D., Branch Chief
Chemistry Branch I, Tolerance Support
Health Effects Division (7509C)

TO: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and Economics Analysis Division (7503C)

Rhône-Poulenc has submitted an application for an EUP and temporary tolerances for fipronil (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(1R,S)-(trifluoromethyl)sulfinyl]-1H-pyrazole-3-carbonitrile) and its metabolites MB46136 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)sulfonyl]-1H-pyrazole-3-carbonitrile) and MB45950 (5-amino-1-[2,6-dichloro-4-(trifluoromethyl)phenyl]-4-[(trifluoromethyl)thio]-1H-pyrazole-3-carbonitrile) on corn. The petitioner has proposed the following tolerances for corn RACs (expressed as parent plus metabolites):

Corn, Field, Grain	-	0.02 ppm
Corn, Forage	-	0.05 ppm
Corn, Fodder	-	0.07 ppm

The registrant has submitted a copy of method R-P 1199 and an Independent Laboratory Validation (ILV) in the following volume which is appended to this memorandum as Attachment 2:

Fipronil Independent Laboratory Method Validation. 8/19/93. By P. Vorndam and W. Rhoads. Colorado Analytical Research & Development Corp., Colorado Springs, CO MRID#429186-66

Note that the actual analytical method is found as attachment 1 on page 82 of the ILV.

CBTS has conducted a preliminary review of the ILV. Acceptable recoveries were obtained by the laboratory for all analytes except MB45950 (average recovery of 56.7 at 0.04 ppm). Reproducible recoveries of MB45950 in the range of 50-70% may be acceptable as this metabolite does not appear to comprise a significant portion of the total fipronil residues in corn. A summary of the laboratory's findings may be found on page 10 of the ILV report.

CBTS requests that BEAD review the method for acceptability as a tolerance enforcement method. The ILV should also be reviewed to determine if the method has been adequately validated. If the method and the ILV are satisfactory, CBTS requests that BEAD conduct a Petition Method Validation (PMV) on the submitted analytical method.

The registrant has agreed to send analytical standards of fipronil and its metabolites MB45950 and MB46136 to the EPA Pesticide Repository (Record of Communication, G. Kramer 3/15/94).

Samples should be run in duplicate per the experimental design specified in Attachment 1. Please complete and return this attachment as part of your report. Also, please include with your report, copies of the standard curves, sample calculations, and representative chromatograms for controls and fortified samples. Any deficiencies in the methods, as written, should also be noted and reported. Please comment on the length of time necessary to complete a set of samples.

One of the purposes of conducting a PMV is to determine whether all necessary instructions are included in the submitted method. For this reason, we are requesting that laboratory staff scientists do not discuss this PMV with the registrant. Any problems encountered should be documented and included in your report.

Please address your written reports to: P.V. Errico, Section Head, Tolerance Petition Section III, Chemistry Branch I, Tolerance Support, Health Effects Division (7509C)

Attachment 1- Experimental Design for PMV

Attachment 2- Fipronil Independent Laboratory Method Validation.
MRID#429186-66

cc (with Attachment 1 and 2): M. Clower (FDA, HFS-335)

cc (with Attachment 1 only): PP#3G04263, S.F., Kramer, circ., R.F.,
H. Hundley (ACB/BEAD), C. Giles-Parker (PM22/RD)/D. Wilson, R.
Thompson (RTP-NC)

RDI: P.V. Errico (3/16/94), R.A. Loranger (3/16/94)

G.F. Kramer:804V:CM#2:(703)305-5079:7509C

USER\CB:fipronil.001

2

ATTACHMENT 1

METHOD: Fipronil Independent Laboratory Method Validation.
8/19/93. By P. Vorndam and W. Rhoads. Colorado
Analytical Research & Development Corp., Colorado
Springs, CO MRID#429186-66

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	Chemicals Added	ppm Added	ppm Fipronil Found	% Recovery	ppm MB45950 Found	% Recovery	ppm MB46136 Found	% Recovery
Corn, Grain	Fipronil MB45950 MB46136	0.00						
		0.01						
		0.02						
Corn, Stover	Fipronil MB45950 MB46136	0.00						
		0.02						
		0.04						
Corn, Forage	Fipronil MB45950 MB46136	0.00						
		0.02						
		0.04						

Modifications made to method (major or minor):

Special precautions to be taken:

Source of analytical reference standards:

If derivatized standards used, give source:

Instrumentation for confirmation:

If instrumentation parameters differ from the method as written,
list parameters actually used:

Commercial source for any special chemicals or apparatus:

Comments:

Chromatograms: