MEMORANDUM

Subject: PP# 6F4604 - DICAMBA (BANVAL®) ON COTTON, ASPARAGUS, GRASS FORAGE AND HAY, AND WHEAT FORAGE AND HAY.
Tolerance Method Validation (TMV) Request.
Chemical Nos. 029802, 029806, and 128931.
PRAT CASE # 287073
(MRID #s 438140-02 and 428832-01)[DP Barcode D227359]

From: Francis D. Griffith, Jr., Chemist
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

To: Donald A. Marlow, Chief
Analytical Chemistry Branch
Biological and economic Analysis Division (7503W)

Thru: E. Zager, Acting Branch Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

INTRODUCTION

Sandoz Agro, Inc. proposes tolerances for its herbicide dicamba, trade named Banval® and Clarity® (salts or esters of 3,6-dichloro-*o*-anisic acid) and its metabolite 3,6-dichloro-5-hydroxy-*o*-anisic acid in/on the raw agricultural commodities asparagus and cottonseed at 3 ppm, cottonseed meal at 6 ppm, grass forage at 400 ppm, grass hay at 250 ppm, wheat forage at 80 ppm, and wheat hay at 20 ppm.

The petitioner submitted a copy of the updated method AM-0691B-0593-3 for dicamba and its hydroxy metabolite in various crops along with its validation data (method and concurrent recovery data with supporting chromatographic data). The results of an independent laboratory validation (ILV) performed by ChemAlysis Inc., for method AM-0691B-0593 recovering the same two compounds in corn forage and grain were presented. These are appended to this memorandum as Attachments 2 and 3.

CBTS requests ACB review the updated capillary column EC-GC method with MSD confirmation for acceptability as a tolerance enforcement method. The ILV data should be reviewed to determine if the method has been adequately validated. If the method and ILV are satisfactory, then CBTS requests that ACB conduct a TMV on method AM-0691B-0593.

CBTS has completed its review of this method. We did not detect deficiencies in the procedure. We note that method AM-0691B was initially reviewed in PP#4F3041 (see memorandum by F. Griffith dated 4 Nov 88). However, since that initial review there have been a number of evolutionary changes in the extraction step (no extraction with 80% ethanol in 1N HCl), changes in the GC columns, and the addition of the GC-MSD confirmation step. During reregistration it was determined a new TMV for the updated method AM-0691B-0593 was warranted.

The TMV is for 2 chemicals (parent and its hydroxy metabolite) at 0.01 (LOQ) and 1 ppm in corn forage, at 250 ppm in grass hay, and 0.2 ppm in cottonseed. The petitioner states that the limit of quantitation (LOQ) is 0.01 ppm. Once the TMV is completed we request your concurrence that the LOQ is 0.01 ppm. Also, once the TMV is completed we request your best **estimate** on an appropriate limit of detection (LD). The CBTS estimates the LD is approximately 0.005 ppm. The LD is essential for the reliability of our data when we prepare our dietary exposure estimate in risk assessment.

A major reason for conducting TMVs is to insure that all necessary instructions are included in the method write-up, and the method can be completed in a reasonable time to serve as an enforcement procedure. Thus, we request that your report includes an estimate on how long it takes to complete a set of samples for dicamba and its metabolite. We expect there will be contacts with Sandoz to clarify points in method AM-0691B-0593. CBTS suggests that ACB keep a log of all company contacts on the TMV, and include a copy of the log in your final report.

Please obtain all necessary analytical reference standards from the EPA Repository. If any of the analytical reference standards of dicamba and its metabolite are not available from the Repository, then please contact the Sandoz Product Registration Manager, Dr. J. Bryant in Des Plaines, Illinois (telephone (708)-390-3717) directly requesting several hundred milligrams of each standard not available along with the required MSDS be provided directly to ACL to start the TMV. In your final report please note that all standards are, or are not, available from the Repository as of ___(date)___. Also, please confirm the Repository ordering code for dicamba and its hydroxy metabolite.

The petition has a Priority 6 ranking. The Registration Division Product Manager for dicamba is Robert F. Taylor, PM-25. He should be contacted directly concerning the priority for completion of the TMV.

Please return all of the requested information on the attached Method Report Form, and all other pertinent information concerning the TMV that are generated according to the TMV's SOP including the source of the control samples, fortification of samples, standard curves, modification/deviations to the method, and examples of sample calculations. A copy of any revised or additional dicamba residue analytical method(s), and/or any comments for improvements to the requested TMV method supplied directly to you by Sandoz during the TMV should be returned to CBTS with your final report.

Please address your written report to:

E. Zager, Acting Branch Chief
Chemistry Branch I - Tolerance Support
Health Effects Division (7509C)

ATTACHMENTS (1 copy each):

1) *Method Report Form.*

2) Sandoz Agro Method AM-0691B-0593-3, "*Determination of Dicamba, 5-Hydroxy Dicamba Residues in Barley, Corn, Cotton, Cotton Processed Fractions, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC)*", 64 pages, **MRID # 438140-02.**

3) "*Confirmatory Method Trial of the Residue method, AM-0691B-0593-2 'Determination of Dicamba, 5-Hydroxy Dicamba Residues in Barley, Corn, Cotton, Cotton Processed Fractions, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC)'*", 110 pages, **MRID # 428832-01.**

cc(w/ attachment 2 and 3):M.Clower(FDA,HFS-335).
cc(w/ attachment 1):Reviewer/PAM-IIFile(FDG),PP#s4F4604,and4F3041,R.F.,Circu.,
R.Keigwin[PM-10,7505C],D.McCall[RCAB/RS,7509C].
7509C:CBTS:Reviewer(FDG):CM#2:Rm804Q:305-5826:FDG:6/20/96:edit:fdg:6/28/96.
RDI:TPT1:6/27/96:BrSrSci:RALoranger:6/27/96:ActBrCh:EZager:6/28/96.

SANDOZ Method AM-0691B-0593-3

Determination of Dicamba, 5-Hydroxy Dicamba Residues in Barley, Corn, Cotton, Cotton Processed Fractions, Pasture Grass, Peanut, Sorghum, Soybean, Sugar Cane, Tomato, Tomato Processed Fractions, Wheat and Wheat Processed Fractions (GC), N. Jimenez, 30 July 93, 64 pages, **MRID # 438140-02.**

Please do not use control values for recovery calculations and do not report control values as zero. If they are less than the LD, then please report them as such.

COMMODITY	CHEMICAL ADDED	PPM ADDED	PPM FOUND	% RECOVERY
CORN FORAGE	Dicamba	Control		
		0.01		
		1		
	5-Hydroxy-dicamba	Control		
		0.01		
		1		
GRASS HAY	Dicamba	Control		
		250		
	5-Hydroxy dicamba	Control		
		250		
COTTONSEED	Dicamba	Control		
		0.2		
	5-Hydroxy dicamba	Control		
		0.2		