



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

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: 19-MAY-2005

SUBJECT: **Residues of Concern in Transgenic Glyphosate-Tolerant Crops.** PC Code 103601. DP# 311356. Decision# 351808.

FROM: George F. Kramer, Ph.D., Chemist
Registration Action Branch 1 (RAB 1)
Health Effects Division (HED) (7509C)

THRU: P.V. Shah, Ph.D. Branch Senior Scientist
RAB1/HED (7509C)

TO: James Tompkins
Risk Management Team 25
Registration Division (RhD) (7505C)

A. Material Reviewed

The herbicide glyphosate (N-(phosphonomethyl) glycine) is effectively detoxified through N-acetylation by enzymes exhibiting glyphosate N-acetyltransferase (GAT) activity. Pioneer is developing glyphosate-tolerant crops which contain a microbial GAT gene. HED was asked whether N-acetylglyphosate, the resulting metabolite of GAT activity, would be of concern.

A group of HED metabolism experts reviewed and discussed the preliminary results of residue chemistry studies conducted with transgenic corn expressing the GAT gene and toxicological studies conducted with N-acetylglyphosate.

B. Conclusions

HED concluded that the toxicity of *N*-acetylglyphosate is comparable to the parent compound and needs to be included in the glyphosate tolerance expression. The petitioner is requested to perform bridging magnitude of the residue (MOR) trials in order to demonstrate that the combined residues of *N*-acetylglyphosate plus glyphosate in transgenic crops does not exceed the currently-established glyphosate tolerances. This residue program should consist of four side-by-side MOR trials per crop conducted in different growing regions. If the currently-established glyphosate tolerances are shown to be adequate to cover the combined residues of *N*-acetylglyphosate plus glyphosate in transgenic corn, cotton and soybeans; then it is not likely that HED would request additional MOR data for additional crops. Also, provided that residues of *N*-acetylglyphosate per se are well below the currently-established glyphosate tolerances, it is not likely that HED would request livestock MOR data for the metabolite.

C. Individuals in Attendance

Alberto Protzel, Christine Olinger, Richard Loranger, Thomas Bloem, P.V. Shah, James Tompkins

cc: G. Kramer (RAB1)
RDI: P.V. Shah (5/18/05), RAB1 Chemistry Team (5/18/05)
G.F. Kramer:806T:CM#2:(703)305-5079:7509C:RAB1



13544

R110592

Chemical: Glyphosate-isopropylammonium

PC Code: 103601

HED File Code 11000 Chemistry Reviews

Memo Date: 05/19/2005

File ID: DPD311356

Accession Number: 412-05-0098

HED Records Reference Center
07/11/2005