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

JAN 4 1993

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: SAN-582H. Request for Animal Feeding Study Waiver. Sandoz Request for EPA Method Validation. Submission Dated 5/20/92.

DP Barcode D178985. CBTS # 9978.

FROM: Michael T. Flood, Ph.D., Chemist
Tolerance Petition Section II
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

THROUGH: Debra F. Edwards, Ph.D., Chief
Chemistry Branch I -- Tolerance Support
Health Effects Division (H7509C)

TO: Cynthia Giles-Parker/James Stone, PM 22
Fungicide-Herbicide Branch
Registration Division (H7505C)

and

Toxicology Branch II
Health Effects Division

By letter dated 5/20/92 Sandoz Agro Inc. formally requests waiver of animal feeding studies for SAN-582H Herbicide and that EPA validate the analytical method for SAN-582H in corn racs.

In our memo of 10/30/92 to the HED Metabolism Committee, we concluded that residues of SAN-582H and/or metabolites would not be detectable in animal products as a result of feeding corn treated with the herbicide. The Committee concluded that tolerances on animal products were not necessary. Therefore, a residue transfer study with ruminants would not likely produce any useful information and is not required. Future uses resulting in higher residue levels in crops could lead to reassessment.

Sandoz's analytical method for SAN-582H -- "A Method for the Determination of Residues of SAN-582H in Corn and Soil Samples" -- has undergone EPA Method Validation. Recovery data for corn grain samples were inconsistent, and recommendations were made.

"If the above comments are taken into consideration and incorporated, the method would meet 40 CFR 158 and EPA's requirements as published in the Pesticide Assessment Guidelines, Subdivision 'O' for Residue Chemistry, Part 171-4(b) as an enforcement method." (Memorandum of 12/21/92 from D.M. Swineford and E. Hayes, BEAD/ACB, to D. Edwards, CBTS, copy attached.)

Therefore, Sandoz should submit a revised version of the analytical method in which ACB's changes are incorporated. In the meantime, this deficiency remains unresolved.

Attachment: Petition Method Validation, BEAD/ACB.

cc (with Attachment): PP#0G3892, PP#0F3918, Mike Flood.

cc (without Attachment): RF, SF, Circu., E. Haeberer, Harvey Hundley (H7503).

H7509C:CBTS:Reviewer(MTF):CM#2:Rm804P:305-6362:typist(mtf):12/31/92.
RDI:SectionHead:ETHaeberer:12/31/92:BranchSeniorScientist:RALoranger: 12/31/92.