



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

PMSD / ISB
1207

NOV 13 1986

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: PP #6F3431 DPX-M6316 (Harmony®) on wheat and
barley. Preliminary Evaluation of Methodology
submitted for Method Trial

FROM: Cynthia Deyrup, Ph.D., Chemist *Cynthia Deyrup*
Tolerance Petition Section 2
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

THRU: Charles L. Trichilo, Ph.D., Chief
Residue Chemistry Branch
Hazard Evaluation Division (TS-769)

TO: Robert Taylor, Product Manager #15
Registration Division (TS-767)

and

Toxicology Branch
Hazard Evaluation Division (TS-769)

EPA's analytical Chemistry Section (ACS, COB, BUD) has reported to RCB on difficulties encountered in attempting to carry out a method trial of E.I. du Pont de Nemours & Co.'s Method No. AMR-235-84, revised 1/30/85 (memo of W.R. Bontoyan, 10/31/86).

The problems associated with this method were:

1. The method was unclear as written;
2. Probably the method would require a chemist of considerable experience in order to obtain reproducible results; and
3. After examining the submitted chromatograms, the Analytical Chemistry Section believes that the method is marginal and perhaps unacceptable for regulatory or monitoring analyses of wheat straw.

ACS submitted to RCB a copy of the original method which contained additions, changes, and clarifications which were the result of

a telecon (10/9/86) between Dr. E. Zahnow of du Pont and Ron Thomas (ACS; Attachment 1--analytical methodology revised by ACS as recommended by du Pont). ACS pointed out that substantial and significant information did not appear in the method as submitted.

ACS wanted to know whether it should proceed with the MTO. The ACS report of 10/31/86 on the proposed methodology is attached to this review (Attachment 2).

RCB's Comments/Conclusions

RCB concludes that the method should be returned to the petitioner for further revisions, evaluation, etc., after which the petitioner should return the corrected analytical procedure so that ACS (COB, BUD) may proceed with the MTO.

Recommendations

RCB recommends against the establishment of the proposed tolerance of 0.05 ppm for residues of DPX-M6316 on wheat and barley until problems associated with the nature of the residue and analytical methodology are resolved.

Attachments: Attachment 1, Method No. AMR-235-84, revised 1/30/85, with additional ACS revisions; Attachment 2, ACS Report on Methodology

cc (with attachment): PMSD/ISB, M. Bradley-RCB, H. Jacoby-SIS

cc (without attachment): RF, Reviewer-C.Deyrup, TOX, PM #15, Boodee, PP #6F3431, Circu, FDA

RDI: JHOnley:11/10/86:RDSchmitt:11/12/86

TS-769:RCB:CM#2:RM810:X7484:C.Deyrup:cd:11/12/86

Harmony Reviews

Page _____ is not included in this copy.

Pages 3 through 41 are not included in this copy.

The material not included contains the following type of information:

- Identity of product inert ingredients
 - Identity of product impurities
 - Description of the product manufacturing process
 - Description of product quality control procedures
 - Identity of the source of product ingredients
 - Sales or other commercial/financial information
 - A draft product label
 - The product confidential statement of formula
 - Information about a pending registration action
 - FIFRA registration data
 - The document is a duplicate of page(s) _____
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Attachment #2

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

Analytical Chemistry Section
Building 402, ARC-East
Beltsville, Maryland 20705

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

October 31, 1986

MEMORANDUM

SUBJECT: Petition Method Trial for Harmony
(PP#6F3431 - DPX M6316)

FROM: Warren R. Bontoyan, Head *was*
Analytical Chemistry Section

TO: Cynthia Deyrup, Chemist
Residue Chemistry Branch
Hazard Evaluation Division

We reviewed the method (AMR-235-84) submitted by E.I. duPont Nemours and feel that it is unclear in several aspects. In addition a chemist without considerable experience in using the method would probably have difficulty in obtaining repeatable results. After examining the submitted chromatograms, we believe the method is marginal and perhaps unacceptable for regulatory or monitoring analyses of wheat straw.

Attached are two copies of the method which is to be used for wheat grain and straw. One copy is as received from duPont. The other contains highlighted additions, changes, and clarifications which are the result of a phone conversation on October 9, 1986 between Dr. E. Zahnow of duPont and Ron Thomas. As you can see, some substantial and significant information does not appear in the method as submitted.

Should we proceed with the method tryout or should RCB request duPont to submit a revision containing the changes, additions, and clarifications? In order to properly adjust our laboratory schedules please let us know of RCB's decision as soon as possible.

Attachments

cc: Donald A. Marlow

RCB-11-1-86