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

3/19/98

OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES

sty 3/19/98

MEMORANDUM

SUBJECT: Terbufos. List A Reregistration Case No. 0109/Chemical I.D. No. 105001.

Anticipated Residue Assessment. No MRID No. DP Barcode D244268.

FROM: William J. Hazel, Ph.D., Chemist

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THRU: Whang Phang, Ph.D., Branch Senior Scientist

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TO: Christina Swartz/Felecia Fort

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and

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Special Review and Reregistration Division (7508W)

Background

Anticipated residues (ARs) have been calculated for incorporation into a chronic dietary risk assessment for terbufos. An earlier assessment, made prior to the conduct of a chronic dietary risk assessment (DRES), was incorporated into the Revised HED Chapter of the Terbufos RED dated 10/17/95. This earlier assessment made use of tolerance level residues in raw agricultural products corrected by percent crop treated data provided by BEAD.

Present Considerations

It is requested that the subject ARs be utilized in a DRES run to refine the chronic dietary risk to assist in the conduct of risk management decisions in association with SRRD's Organophosphate Implementation Plan. These ARs make use of field trial and plant metabolism data to refine dietary exposure. Percent crop treated (%CT) figures provided by A. Grube of BEAD 2/26/98

are being relayed **but have not been incorporated into the AR calculations**. Note that banana %CT data reflected usage on imported bananas in 1993-95 and %CT data on the four domestic crops represented usage from 1987-96 with more emphasis on recent years; as in the 10/17/95 HED Chapter, the maximum %CT out of a range of annual values has been chosen to be applied to the Ars in the DRES program.

Anticipated Residues for Chronic Dietary Risk Assessment

Banana and sweet corn monitoring data are available from USDA/AMS/PDP. Although sampling was extensive and representative, the data were deemed less preferable than field trial data for generating ARs for the following reasons: (i) of the six residues that are regulated and that comprise the total toxic residue (TTR), four are not sought by PDP due to analytical difficulties; (ii) the two most terminal TTR components (the sulfoxides of terbufos and terbufos O-analog) were not only shown to be predominant in plant metabolism studies but are not analyzed by PDP; (iii) the data collection method used in the field trials is more sensitive than the PDP method because the former determines all six TTR components (combined) and at a typical limit of detection (LOD) of 0.01 ppm; (iv) HED cannot assign a LOD to the four TTR components not sought by PDP; and (v) to attempt to sum the ½LOD values for all six components of the TTR would most likely result in grossly exaggerated exposure estimates. HED's Chemistry Science Advisory Council (ChemSAC), convened 3/4/98, agreed that the available monitoring data are of limited utility in this case and strongly advised the use of field trial data for the calculation of ARs for the reasons given above. Insufficient monitoring data are available to permit exposure refinements for any other commodities.

Refer to Table 1 for the ARs and %CT figures that should be incorporated into the DRES run. HED has confidence in the residue chemistry data used to determine the ARs for corn (field, popand fresh), sorghum, and sugar beet. In the case of bananas, we do not have the confidence in the field trial data necessary to permit refinement of the exposure estimate. ARs were calculated from the data sources presented below. Note that no attempt was made to locate and analyze the chromatograms supporting the original studies to estimate and draw distinction between the LOD and the Limit of Quantitation (LOQ). The reviewer's nomenclature was accepted as accurate and, except for the detectable banana residues, we feel that residues were below the level of detection. Therefore, 1/2LOD was used to represent "nondetects" resulting in more realistic estimates of dietary exposure.

Beet sugar. The AR is derived from an exaggerated rate field trial (MRID 00036129) and the sugar beet metabolism study (MRID 00036123) summarized in the 1/19/83 Residue Chemistry Chapter; this decision was upheld by the ChemSAC (3/4/98).

Sorghum. Field trial data described in the 12/6/91 Residue Chemistry Registration Standard Update and the 9/27/93 C. Swartz memorandum demonstrated combined residues in grain below the detection limit in all cases. The sorghum processing study was waived in the 5/5/94 C. Swartz review because sorghum flour is no longer considered to be a significant food.



Sweet corn. The sweet corn AR is based on nondetectable residues from field trials described in the 8/3/94 C. Swartz review.

Field corn/popcorn. The AR for field corn and popcorn is based on nondetectable combined residues in grain harvested in field trials described in the 12/6/91 Update. The 5/5/94 C. Swartz review stated that, based on exaggerated rate field trials, the corn processing study could be waived.

Bananas. Field trial data submitted under PP#6E3409 to support the banana tolerance were presented in the W.T. Chin review of 8/27/86. HED cannot further refine the banana exposure based on these data because: (i) all but one of the trials were conducted in Costa Rica; (ii) none of the samples were collected at the label PHI of 7 days (all but one were 14 days or more) and there were several cases in which decline was evident from day 14 forward; (iii) none of the trials reflected the proposed combination of application rate and number of treatments; and (iv) residues are translocated from the soil to the fruit resulting in TTR just below the tolerance level in some cases. Therefore, the tolerance value must be used for the chronic dietary risk assessment.

Table 1. Anticipated Residues and Percent Crop Treated for Chronic Risk Assessment.

Crop/Food	Anticipated Residue (ppm)	Percent Crop Treated (max.)
- Banana	0.025	26 %
Field corn and all processed products	0.005	11 %
Popcorn	0.005	11 %
Sorghum and any processed products	0.025	4 %
Sugar beet (sugar)	0.001	37 %
Sweet com	0.005	9%

References/EPA Correspondence:

0.06 | 0.1

- 1. Chemistry Science Advisory Council of HED. Meeting convened 3/4/98.
- 2. Chin, W.T. 8/27/86 review of banana field trial data submitted under PP# 6E3409.
- 3. Grube, A. of BEAD. 2/26/98 E-Mail summarizing terbufos usage on bananas, corn, sorghum, and sugar beets.

- 4. McCall, D. 10/17/95. Revised HED Chapter of the Reregistration Eligibility Decision Document (RED) for Terbufos.
- 5. HED/RCB. 1/19/83. Terbufos Residue Chemistry Chapter.
- 6. Zager, E. 12/6/91. Terbufos Product and Residue Chemistry Reregistration Standard Updates.
- 7. Swartz, C. 9/27/93. Magnitude of the residue in sorghum (D188916).
- 8. Swartz, C. 8/3/94. Upgrade of lactating goat metabolism study and proposed PHI's for sweet corn and sugar beets (D203823 and D203825).
- 9. Swartz. C. 5/5/94. Addendum to the Residue Chemistry Chapter of the Reregistration Eligibility Document [re. Corn and sorghum processing study requirements] (D202677).

cc: W.J. Hazel, List A Registration Standard File, RF

7509C:WJHazel:RRB-1:CM-2:Rm.703:3/16/98

RDI: RRB-1 ExpoTeam:3/18/98; ChemSAC:3/4/98 and 3/18/98