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

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OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Response to R. Stanley's (OPPE) Comments on Draft Propanil Registration Standard (see memo of 11/20/87 to Frank Sanders [RD])

FROM: Debra F. Edwards, Ph.D.
Residue Chemistry Branch
Hazard Evaluation Division (TS-769C)

Debra F. Edwards

THRU: William J. Boodee, Supervisory Chemist
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Hazard Evaluation Division (TS-769C)

WJB.

TO: Brinson Conerly
SIS (HED) Coordinator for Propanil Standard

I do not agree with Mr. Stanley's comments regarding the appropriateness of raising tolerances for residues of propanil in or on the straw of barley, oats and wheat, and in the bran of rice. If the required metabolism and method validation data reveal that the available data for these commodities are acceptable, the tolerances should be raised as suggested in the Guidance Document.

In general, the Registrant develops an application regimen (rates, timing, etc.) for a given pesticide/crop/pest combination based on efficacy considerations and submits residue data depicting the maximum expected residues when the maximum permissible rate and lowest permissible preharvest interval are used. The Agency then sets a tolerance that will be high enough to cover all expected residues of concern and low enough to detect illegal use, provided the tolerance level is acceptable from a toxicological point of view (dietary risk). If the tolerance level is not toxicologically acceptable, the Registrant may submit "actual" residue data (average residue values and/or cooking, canning, washing or other processing data) to permit a more realistic dietary exposure estimate or they may alter the use if they feel that sufficient efficacy can be maintained.

In this case (propanil), we are suggesting that tolerances for residues in or on certain feed items be raised because we have discovered that they were originally set too low, based on the registered use pattern and available residue data. Theoretically, increases in tolerances for feed items could result in increased residues in meat, milk and eggs. However, in this case, no change in use which could result in increased residues is proposed. We are merely suggesting an administrative measure to correct the fact that the tolerances were set too low in the first place.

By increasing the tolerances to an appropriate level we would be acting as a "public advocate", ensuring that growers will not have their products seized due to the presence of residue levels above established tolerances when the product is used legally (i.e., according to the label directions).

I have discussed this issue with W. Dykstra of the Toxicology Branch (HED). TOX has no objection to the raising of tolerances for propanil since the theoretical dietary exposure of propanil to the U.S. population average is equivalent to only 29% of the established PADI (safety factor = 1000). Furthermore, when an ADI is established (on receipt of required TOX data), the dietary exposure as a percent of the ADI may be considerably lower.

cc: Registration Standards File for Propanil
Joanne Miller, RD

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