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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

DATE: 7/12/00

SUBJECT: **Comments on TI435 Pre-Consultation Meeting (3/14/00) Minutes.** -- New
Insecticide seeking Use on Corn, Canola, Apple, and Pear.

DP Barcode:	D266094	PRAT Case#:	293121
Submission #:	S579880	Caswell#:	None
Chemical#:	044309	Class:	Insecticide
Trade Name:	XXX	EPA Reg#:	Not Registered
40 CFR:	180.XXX	MRID:	None

TO: Dennis Mcneilly
Registration Division (7505C)

FROM: Yan Donovan, Chemist
RAB2/Health Effects Division (7509C)

Yan Donovan

THRU: Richard Loranger, Branch Senior Scientist
RAB2/Health Effects Division (7509C)

R. Loranger

We have been requested to comment on the minutes provided by Bayer for the March 14, 2000 pre-registration meeting on the insecticide TI-435 (being developed by Bayer and Takeda).

All conclusions are subject to change contingent on the review of future submission of toxicological data and the complete residue chemistry data.

Request for Waiver of Poultry Feeding Study

Based on the information presented at the pre-registration meeting with Bayer Corp./Takeda Chemical on March 14, 2000, the total radioactive residues (TRR) in poultry tissues and eggs would be < 0.0005 ppm at 1X the projected theoretical dietary burden for poultry. Therefore, HED considers it is reasonable to waive the poultry feeding study.

Animal Residue Method-Cattle

Based on the goat metabolism study presented at the March 14, 2000 meeting, residues which accounted >10% of the TRR are: parent compound in milk, PTMG and TZG in kidney, and TZU in muscle. HED concludes that it is agreeable to develop an analytical method for animal matrices which measures the parent compound, PTMG, TZG and TZU. It will be determined later whether correction factor for additional metabolites need to be included for purposes of risk assessment. Although HED questioned at the meeting whether a method with LC/MS/MS would be acceptable if no other procedures were provided, recent information on availability of this instrumentation has lessened OPP's concerns in this area.

Dose Selection for Cattle Feeding Study

HED agrees that the cattle feeding study should be conducted using parent compound only.

EPA Memorandum- Meeting of Metabolism Assessment Review Committee

Based on limited plant metabolism and toxicological studies, HED Metabolism Assessment Review Committee (MARC) concluded that for direct application to crops (foliar spray and seed treatment), parent compound is the residue of concern for all crops except for root crops, where metabolite TMG also needs to be included in the residue analysis and risk assessment. For rotational crops, in addition to the parent compound, metabolites TZNG and MNG will need to be analyzed and included in the tolerance expression and used for dietary risk assessment purposes for all crops. However, depending on the submission of the complete toxicological data, especially chronic toxicity study of the parent compound, the above conclusions may be changed. At this time, the Agency does not have enough information to make a decision as to whether Bayer's present analytical method for plants which measures parent only will be acceptable, especially for rotational crops. HED suggests to wait till more toxicological studies are available, and HED will then present those data to MARC again and a more conclusive decision on the analytical method will be made.

HED notes that we do not agree with the following statement in the minutes: "It had previously been verbally agreed that since the predominant residue in all target crops was the parent compound, a parent only residue method would be acceptable." At the May 1999 meeting we questioned whether "parent only" was appropriate based on the degree of metabolism noted in certain crop parts and stated that the issue of the residue of concern would be presented to the MARC after submission of the information (metabolism and toxicology data summaries) in writing.

cc: Y. Donovan (RAB2), Dennis Mcneilly/Tina Levine (RD-7505C, P.M.04), RAB2 reading file.