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

MAY 24 1988

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Monocrotophos Registration Standard - Response to Data Call-In Notice on Poultry Metabolism - EPA Registration No. 352-459. (No MRID Number) [RCB No. 3687]

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and

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THRU: Robert S. Quick, Section Head, TPS-1
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Background

E.I. du Pont de Nemours and Company, Inc., registrant of products containing monocrotophos, trade named Azodrin®, has submitted by letter dated April 5, 1988, a request with rationale for a waiver of the poultry metabolism study. DuPont's request for a poultry metabolism waiver is in response to RD's notification via telephone that the poultry metabolism data requirement remained unsatisfied for the products under the Registration Standard.

The Residue Chemistry Chapter of the Monocrotophos Registration Standard was completed in December 1984, while the actual Standard was issued in September 1985. The Monocrotophos Registration Standard conclusion on poultry metabolism was as follows (see page 14 of the Residue Chemistry Chapter):

> o Metabolism studies utilizing poultry. Animals must be dosed for 3 days with either [^{32}P] or [^{14}C] monocrotophos at a concentration in the total diet which will result in sufficient residues in the eggs, liver, kidney, fat, and muscle for characterization. Eggs must be sampled twice daily throughout the treatment period. Animals must be sacrificed within 24 hours of the final dose. If poultry metabolism is found to differ significantly from that of ruminants, then nonruminant (swine) data will be required (i.e., in the absence of rat metabolism data). If poultry and ruminant metabolism differ from that in the rat then additional swine data are required. (Note: The type of labeling should be the same for both animal and plant metabolism studies.)

Our conclusions and recommendations follow:

Summary of Residue Chemistry Deficiencies Remaining to Be Resolved

Nature of the Residue - Livestock

- Provide a poultry metabolism study.

Conclusion

Nature the Residue-Livestock

- RCB reiterates the conclusions above of the Registration Standard. Dropping the proposed use on corn is not sufficient grounds for a waiver as long as these poultry feed items associated with RACs have established tolerances in 40 CFR 180.296. A poultry ^{32}P and/or ^{14}C monocrotophos metabolism study is required.

RCB Recommendation

RCB recommends the petitioner submit a protocol for a poultry monocrotophos metabolism study prior to the actual running of such a study.

RCB recommends this review be forwarded to the registrant for his comments.

Petitioner's Response

In a letter dated April 5, 1988, the registrant presents his rationale in requesting a waiver of the monocrotophos poultry metabolism data requirement.

RCB Comments

The petitioner contends that once the proposed use of Azodrin® on corn was dropped and other processing studies for monocrotophos in peanuts, cottonseed, and sugarcane showed essentially no residues of monocrotophos, then a poultry metabolism study would not be necessary.

Since RCB has not reviewed the processing studies of monocrotophos in cotton, sugarcane, and peanuts, we cannot say what residues are present in the processed livestock feed items. RCB agrees with the percent molasses in poultry feed.

The registrant should also review the established monocrotophos tolerances in 40 CFR 180.296 and determine what other potential poultry feed items are possible. All poultry feed items with the potential monocrotophos residues should be summed. Thus, with a monocrotophos tolerance on tomatoes at 0.5 ppm, tomato pomace is 2 to 3 percent of a poultry diet. Cottonseed has a 0.1 ppm tolerance. Poultry feed items are cottonseed meal at 10 to 3 percent and soapstock at 5 percent; Potatoes have a 0.1 ppm monocrotophos tolerance. According to Table II of the Residue Chemistry Guidelines and the Harris Guide, cull potatoes are a poultry feed item constituting between 7 to 20 percent of a diet. Thus, this poultry feed item could contribute 0.02 ppm to the diet. Peanuts have a 0.05 ppm monocrotophos tolerance and the peanut feed items of peanut meal and soapstock could comprise 10 percent and 5 percent resprctively of the poultry diet.

While a poultry diet containing all of the above feed items is artificial and not realistic, it nonetheless maximizes potential poultry exposure to monocrotophos.

The registrant uses the maximum percent of administered dose recovered in caprine muscle to get the expected maximum administered dose recovery in poultry muscle. RCB prefers not to accept a caprine study and translate its metabolism data to a poultry study. We will only translate poultry study data to turkeys, ducks, etc., and only translate a caprine study to bovine, equine, ovine, and porcine species. So for this given, RCB will require a monocrotophos poultry metabolism study. Once we have the maximum percent administered ^{32}P and ^{14}C dose in poultry, this can help determine the maximum administered dose that should be in poultry and the need for secondary

monocrotophos tolerances in eggs and poultry fat, meat, and meat byproducts.

The registrant also applies the same logic to beef cattle. Since the registrant's request is for a waiver of a poultry metabolism study, these arguments are not germane to this request and will not be reviewed further in regard to poultry metabolism. We suggest the registrant follow RCB's example of calculating an artificial but conservative approach to maximizing potential exposure to ruminants from all potential livestock feed items not concentrating on only one or two items from a processing study.

Accordingly, RCB considers that the registrant's request for a waiver of a poultry monocrotophos metabolism study is not justified. After thoughtful reconsideration, RCB reiterates the Registration Standard's request for a monocrotophos poultry metabolism study.

TS-769C:RCB:Reviewer(FDG):CM#2:Rm 814B:557-0826:JOB:10281:I:C.Disk:KENCO:5/17/88:rw:EK:CB:VO:PS:edited:fdg:5/24/88.

cc: Monocrotophos Registration Standard File (Boode), Monocrotophos Subject File, Reviewer(FDG), RF, Circu, ISB/PMSD (Eldredge)

RDI:Section Head:R.S.Quick:5/24/88:R.D.Schmidt:5/24/88