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OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Animal Feeding Studies: Requirement Status Modification:
Reconsideration (No MRID #, No CBRS #, No Barcode).

FROM: R. B. Perfetti, Ph.D., Chemist *RB Perfetti*
Special Review Section 1
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Health Effects Division (H7509C)

THRU: E. Zager, Chief *E Zager*
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TO: Lois Rossi, Acting Deputy Director
Special Review & Reregistration Division-(H7508W)

and

A. Rathman, Acting Chief
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In our memo of 2/4/93 (R. B. Perfetti), CBRS changed the status of guideline requirement 171-4 j (Magnitude of the Residue in Animals) from reserved to required for a number of chemicals. SRRD has requested that CBRS reconsider this change. The Branch has reevaluated all of the affected chemicals and in cases where the 171-4 j studies are essential for CBRS to complete a chapter for a RED, we have provided an explanation of why the studies are required.

Malathion The ruminant and poultry metabolism studies for malathion indicate that there is no need for oral magnitude of the residue in animals studies. However if a dermal use is supported, then the dermal 171-4 j studies will be required.

Trichlorfon (FY '94 Candidate) There are no metabolism or magnitude of the residue studies whatsoever for the dermal application of trichlorfon to livestock. CBRS has not received any studies for review. Due to the type of protocol employed in dermal metabolism studies, a determination as to the level of residues to



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be expected in milk, eggs and tissues cannot be made using the metabolism study. Therefore CBRS reiterates that the 171-4 j study is required.

Allethrin/bioallethrin (Was a FY '93 Candidate, Possible FY '94 Candidate) CBRS has not received any data for this chemical. It is our understanding that metabolism studies are in progress. There are presently no tolerances established for residues of allethrin in animal commodities. Due to the nature of pyrethroid chemicals in general, CBRS believes that residues of allethrin would transfer to meat, milk poultry and eggs to a significant level and therefore an acceptable determination of an appropriate tolerance level cannot be made unless animal feeding studies are performed.

Hexazinone (Was a FY '93 Candidate) Earlier feeding studies on livestock indicated that there was little transfer of hexazinone residues to milk, eggs and tissues. This information was used to determine an appropriate tolerance level in animal commodities. The most recent metabolism studies have shown that there is a **very significant** transfer of hexazinone residues to meat, milk, poultry and eggs. Thus the results of the previous studies are in question and CBRS cannot make any reasonable determination as to appropriate tolerance levels in animal commodities without the magnitude of the residue in livestock studies. Therefore they are required.

Methomyl (FY '95 Candidate) There are, at present, no acceptable animal metabolism studies available for methomyl. CBRS has recently reviewed a protocol for a ruminant metabolism study. Also, there are no tolerances for residues of methomyl in animal commodities. In light of these facts CBRS cannot make any determination as to appropriate tolerance levels in animal commodities. Therefore we reiterate that the Registrant should be informed that feeding studies are required. The Registrant should also be informed that they should submit interim reports on the metabolism studies so that CBRS can attempt to determine the nature of the residue to be regulated in meat, milk, poultry and eggs as soon as possible. The feeding studies can be initiated at that time. This should significantly shorten the time frame for fulfilling residue chemistry data requirements.

2,4-D (and Esters) The HED Metabolism Committee has recently concluded that the residue to be regulated in animal commodities is 2,4-D (including conjugated 2,4-D). CBRS has reevaluated all of the available feeding studies and has determined that they are not adequate. An appropriate tolerance in animal commodities cannot be determined from the metabolism studies due to the low level of material in the diet vs the 1X dietary burden. Therefore the Registrant should be informed that feeding studies are required. In light of the fact that the residue to be regulated is known these studies should be initiated as soon as possible.

Phorate The Registrant has committed to do a cattle feeding study

for phorate in lieu of required cooking studies. No poultry study is needed. The tolerances can be assessed using the metabolism study.

Anilazine The Registrant has canceled all of their products and therefore unless another Registrant wishes to support this chemical, there are no 171-4 j requirements. If another party supports a food use involving a feed item however, appropriate feeding studies as well as all other residue chemistry data requirements must be fulfilled.

Diuron Animal feeding studies were called in on 9/28/90 in a DCI. Therefore the point is moot. The studies are required.

TPTH (Was a FY '93 Candidate, Possibly Dropped Because of Special Review Concerns) The available animal metabolism studies indicate that residues of TPTH transfer to milk, eggs and tissues. The available metabolism studies cannot be used to evaluate the present tolerances in liver and kidney nor to determine appropriate tolerance levels in other tissues, milk or eggs. Feeding studies submitted previously are not useful since they did not measure the total residue of concern for animal commodities. The Guidance Document for TPTH did however conclude that the liver and kidney tolerances were not supported.

Trifluralin The 171-4 j feeding studies for this chemical have been waived earlier.

Dichlorvos The Registrant has previously been asked to perform oral 171-4 j studies. In a recent review of a dermal goat metabolism study, CBRS concluded that there were no residues of concern in tissues or milk as a result of dermal treatment. Based on this, there is no need for dermal magnitude of the residue studies for DDVP.

Naled (FY '94 Candidate) Based on recent information for DDVP (See above), the Magnitude of the residue studies for naled stay reserved.

Pendimethalin The Registrant has not ,to date, submitted the required ruminant metabolism study. The poultry study is deficient but may be upgradable. Without the ruminant metabolism information it is impossible to determine whether residues of pendimethalin transfer to tissues and milk. There are no tolerances established on animal commodities for this chemical. In light of this situation, CBRS believes that the feeding studies should be required at this time.

Chlorothalonil (FY '94 Candidate) The 7/31/91 DCI for this chemical required the feeding studies (171-4 j) therefore this point is moot. The studies are required.

Thiram The 9/16/91 DCI called in the 171-4 j studies but the Registrant is apparently under the impression that they are reserved. The goat metabolism study which was submitted recently indicates significant transfer of residues to milk and tissues. We would expect the same situation for poultry and eggs. There are currently no tolerances for thiram in animal commodities. Based on this information, CBRS cannot make a determination as to appropriate tolerance levels in meat, milk, poultry and eggs without the required Magnitude of the Residue studies.

CBRS recommends that the required feeding studies for the chemicals above be called in as soon as possible.

While CBRS realizes that it is the prerogative of SRRD to enforce study deadlines, the Branch cannot emphasize strongly enough that Residue Chemistry Guideline requirements in general and metabolism studies in particular must be submitted within the imposed deadlines in order that CBRS can complete the RED chapters in a timely manner. With respect to the chemicals above, in order to shorten the timelines for reregistration, SRRD may wish to impose due dates for the 171-4 j studies in the way proposed for 2,4-D above.

cc: RBP, Reregistration Standard Files of the following chemicals; Chlorothalonil, TPTH, pendimethalin, Bioallethrin Allethrin, Dichlorvos, Naled, 2,4-D, Hexazinone, Anilazine, Methomyl, Phorate, Diuron, Malathion, Thiram, Trichlorfon and 2,4-D ester(s), Subject Files of the following chemicals; Chlorothalonil, TPTH, pendimethalin, Bioallethrin Allethrin, Dichlorvos, Naled, 2,4-D, Hexazinone, Anilazine, Methomyl, Phorate, Diuron, Malathion, Thiram, Trichlorfon and 2,4-D ester(s), RF and Circ..