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

JUN 28 1985

EXPEDITE

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

Subject: Special Review Action Code 870 for Mancozeb
EBDC Data Call In. Requests for time extensions for residue chemistry
data. No Accession No. [RCB No. 1166]

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Rohm and Haas has requested time extensions for all of the residue chemistry data requirements as listed in our (M. Bradley) memo of March 25, 1985 as follows:

	Required by EPA	Extension requested	Submitted
Product chemistry	2/85	5/85	April 29, 1985
Plant metabolism	2/85	10/85	-
Animal metabolism	2/85	7/86	-
Crop residues	2/86	8/86	-
Processed products	5/86	11/86	-
Feeding studies	2/86	no formal reply	

I learned by personal communication with Mike McDavit of RD, June 26, 1985, that all of the above studies will be conducted and that all have been started except the livestock feeding studies for which planning is under way. The company also stated by telecon that the animal metabolism, crop residues and processed products data could be submitted by June of 1986.

Justification for time extensions

Product chemistry - In their letter of January 25, 1985, Rohm and Haas stated that the product chemistry data for Dithane M-45 was essentially complete. However, the manufacturing site was being changed to newer facilities and

time was needed to verify that the product chemistry data was applicable to the material produced at the new site. The company also wanted to include the product chemistry data for their other formulations of mancozeb.

The change in facilities used to manufacture mancozeb is a valid reason for the three month time extension for submission of product chemistry data.

Plant and Animal Metabolism - The data were not currently available, however studies have been started. A soybean study was started in June of 1984 and a goat study was started in November, 1984 before the data call in was received. A poultry study was started in March, 1985 probably as a result of our (M. Bradley) memo of March 25, 1985 clarifying that data for poultry as well as a large ruminant are required.

We agree that the agency deadline of three months given for completion of plant and animal metabolism studies was unrealistic. Normally, companies take two years or more to develop these kinds of data. A minimum of 6 months to a year actual experimental time is needed for this work.

Rohm and Haas should be informed that at least two additional crop metabolism studies are needed to support all the crops for which there are currently tolerances (see Residue Chemistry Guidelines).

Crop residues, processed products - Residue studies were started in April, 1985 and protocols were developed in concert with National Food Processors association. A summary of existing residue data was submitted including data for ETU that was collected as a result of the RPAR. Rohm and Haas stated in their letter of January 25, 1985, that the number of residue determinations to be conducted would exceed their in-house capabilities and that because of the increased work load due to an increase in Call In Notices, independent laboratories capable of the work may be overloaded and additional time would probably be needed.

A full growing season is needed to treat the various crops by the recommended use patterns and the sampling of the crops at maturity. Some of the crops can not be harvested until the fall. The company intends to support all of the crops for which there are currently tolerances, about 40, and this will result in an enormous amount of samples to be analyzed. In addition to the raw agricultural commodities, several of the crops will require processing studies for tolerance purposes as well as the special processing studies for the actual residue level determinations to be used with the Tolerance Assessment System (TAS).

We are uncertain whether Rohm and Haas will complete enough plant metabolism work to determine whether metabolite data, other than ETU, are needed by the time they start their residue analyses. If, after all the data are reviewed and it is determined that data are needed for additional metabolites, the residue and livestock feeding studies will either have to be repeated or reserve samples re-analyzed for the additional metabolite(s). The latter would require storage stability data for all compounds involved for the period of storage.

Cattle and poultry feeding studies - The company has not formally replied to the latest data call in for feeding studies to determine the residue levels in meat, milk, poultry and eggs. However, the agency deadline of February, 1986 is unrealistic. To conduct proper feeding studies, the results of plant and animal metabolism studies as well as the magnitude of the residues on livestock feed items are needed to determine the necessary feeding levels and which compounds to feed. Analytical methodology must be developed if any metabolites, other than ETU, are deemed necessary for tolerance purposes. In fact, the recommended method for ETU, AOAC 14th ED, may not have been validated for animal tissues, and eggs and may require further development.

Conclusions and Recommendations:

It is our experience that when residue chemistry studies are too hurriedly conducted, they are frequently inadequate and have to be repeated in light of information not available when the studies were started, such as processing studies on racs that have no detectable residues and the need for residue data and analytical methodology development for crops and animal tissues for additional metabolites determined from the results of plant and animal metabolism studies. Residue Chemistry Guidelines clearly delineate the order in which studies should be conducted. Although studies can be conducted out of order by guessing what will be needed, we strongly suspect that many of the ongoing studies will be inadequate and will have to be repeated.

The company has adequate scientifically valid reasons for the requested time extensions, until June, 1986, to complete the animal metabolism, crop residue and processing studies. We also believe that the requested time extension, until October of 1985, for the soybean metabolism study is reasonable. When the company learns that at least two additional plant metabolism studies are needed, they may request additional time for this work as well as for the animal feeding studies. A June, 1986 completion date for these studies would also be reasonable.

cc: Reviewer, EBDC SF, R F, circu, TOX, PM 21, Special Review F., Reg. Std. F.
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