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

SEP 6 1985

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

MEMORANDUM

Subject: Special Review for Maneb
EBDC Data Call In. Request of 8/23/85 for time extension for
residue chemistry data . No Accession No. [RCB No. 1419]

From: Martha J. Bradley, Chemist *MJB*
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Thru: Charles L. Trichilo, Chief
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To: H. Jacoby, PM 21
Registration Division (TS-767C)

Susan Lewis, Data Call In
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Frank Sanders
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The Maneb Task Force is requesting time extensions for the cattle and poultry feeding studies from February 1, 1986 to December 31, 1986 or April 30, 1987 if extensive method development work is required.

In our memo of June 28, 1985, we discussed this issue. There is no new information on this subject, therefore we repeat below our previous discussion and recommendation.

" Cattle and poultry feeding studies - The company has 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.

The requested time extensions for these studies is too long under the conditions of the Data Call In. The studies should be submitted no later than June, 1986.

Conclusions

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 rags that have no detectable residues and the need for residue data and analytical methodology development on 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 Maneb Task Force has adequate scientifically valid reasons for the requested time extensions, however, in view of the conditions of the data call in, the livestock feeding studies should be submitted no later than June, 1986.

cc: Reviewer, EBDC SF, R F, circu, TOX, PM 21, Special Review F., Reg. Std. F.
Frank Sanders, Amy Rispin, PMSD/ISB

RDI:Section Head:RSQuick:Date:9/05/85:RDS:9/06/85

TS-769:RCB:Reviewer:MJBradley:MJB:CM#2:RM:810:557-7377:9/05/85