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

JUL 13 1990

MEMORANDUM

OFFICE OF
PESTICIDES AND TOXIC SUBSTANCES

SUBJECT: Telone, Plant Metabolism. DowElanco's Summary of 4/18/90 Meeting with EPA.
DEB # 6698. RD Record No. 264686.

FROM: Michael T. Flood, Ph.D.
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THROUGH: Richard D. Schmitt, Chief
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TO: L.J. Schnaubelt/H.T. Toma, PM #74
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With a letter dated 4/30/90, DowElanco Company has submitted its summary of the April 18, 1990 meeting between DowElanco and EPA. The conference had been requested by DowElanco to discuss our review of previously submitted plant metabolism studies as well as future metabolism requirements. DEB has summarized the proceedings of this conference in its memorandum dated 5/4/90 (attachment). Rather than discuss in detail DowElanco's summary, which is mostly in agreement with our own, we will only indicate the discrepancies between the two summaries.

In the meeting, the company presented additional fractionation data using the soybean "trash" sample from the original study. HPLC analyses of similar aqueous/organic extracts from the soybean "trash" sample made in 1987 and 1989 showed virtually superimposable 14C profiles. DowElanco states that ..."the EPA personnel felt that these chromatograms were not sufficiently convincing since components in the mixture could have degraded to give products such that the overall profile of the product mixture would look identical to that of the starting mixture. Therefore, they were unable to accept the re-analysis data presented for the soybean 'trash' samples, in terms of specific information content".

The issue of stability of metabolites is rather complex. How does one demonstrate stability of numerous metabolites which have never been isolated? We agree that two solutions giving

superimposable HPLC chromatograms contain the same components at the same concentrations in solution. But how representative are these solutions of the entire samples? The extraction scheme shown in Figure 2 of the submission shows that more than one-half the residue was insoluble. How can we know that the components comprising this insoluble residue did not change with time -- e.g., by becoming more irreversibly bound. If the workup of this insoluble residue -- as shown in Figures 9 and 10 -- had produced similar (if unidentifiable) residues to that done two years earlier, a better argument could be made that no substantive change had occurred in the residue. But the complete fractionation procedure as outlined in Figure 9 was not done on the earlier sample, so comparison is not possible.

Because we could not be certain that the telone residue did not change over a two year period we required a new metabolism study on soybeans in addition to a metabolism study on tomatoes. DowElanco's summary only mentions a tomato metabolism study. Protocols for these two studies should be submitted.

In our 12/21/89 memo, DEB (Otakie) required metabolism studies on soybeans and tomatoes grown in both sandy loam and clay loam soils. In the 4/18/90 meeting this requirement was modified so that studies need only be done in the soil that would result in higher 14C residues. Thus two rather than four metabolism studies are required. However it is the registrant's responsibility to provide us with data to indicate which soil type will yield the higher 14C residues. (See attachment.)

Maintenance of samples under dry ice temperature (-78 C) is not a current DEB requirement but is recommended in cases where lengthy time periods between sampling and analysis are likely and -- such as the present example -- set criteria are lacking to assess storage stability.

Attachment: DEB 5/4/90 Memorandum of Conference.

cc: RF, SF, Circu., Flood, Otakie, Lisa Engstrom (H7508).
RDI: R.A. Loranger:7/10/90.