Monsanto INDUSTRIAL CHEMICALS COMPANY

FROM (NAME & LOCATION): E. S. Tucker

DATE: November 10, 1971

SUBJECT: MEETING MINUTES OF 11/2/71: INDUSTRIAL BIO-TEST LABORATORIES - ENVIRONMENTAL ANALYTICAL PROGRAM - TOXICOLOGY SUPPORT STUDIES

REFERENCE:

cc: W. R. Richard - GO
W. B. Papageorge - GO
E. P. Wheeler - GO
C. W. Roos/T. M. Patrick - Res. 1

TO:

R. E. Keller
Research 1

Monsanto Industrial Chemicals Co.

J. D. Hinchen
W. M. Mees
E. S. Tucker

Industrial Bio-Test Laboratories

M. L. Keplinger
J. B. Plank
P. Wright

The following topics were discussed and the appropriate actions agreed upon.

I. Analytical Chemistry Special Study 71-7, "Determination of Polychlorinated Biphenyl Residues in Rats from a Two Year Chronic Oral Toxicity Study"

The results of the tissue analysis were reviewed by E. S. Tucker and discussed in terms of the validity to toxicologists of Monsanto's interpretation of the data. Copies of the study were left with Bio-Test so that they could review the report in detail and make recommendations concerning objectives for residue studies, reporting of results, and design of future toxicity/residue studies.

II. Statistics Special Study 71-14, "Statistical Analysis of Bio-Test Oral Toxicity Study - Albino Rats"

The techniques used by Monsanto to statistically treat the data were reviewed by J. D. Hinchen and our efforts to reduce the number of samples analyzed by proper choice (statistical) briefly discussed.

III. "Inventory of Industrial Bio-Test Laboratories Tissues", 10/25/71, Memo to R. E. Keller from W. M. Mees/E. S. Tucker.

The problems Monsanto has had with identification of the tissue samples shipped to St. Louis by Bio-Test were reviewed by W. M. Mees/E. S. Tucker as outlined in the above memo. IBT agreed to review in detail the inventory list and to identify the samples according to the matrix numbers provided them. They also agreed to locate the missing samples and ship them to Monsanto as soon as possible.

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IBT indicated that they were adding on site tissue storage facilities at their farm and that had reviewed the labeling and storage practices previously used so that future problems of this sort could be avoided.

No attempt will be made by IBT to identify the rat pups collected from the rat reproduction study since it was agreed that only a minimum of additional information would be gained by analysis of these samples. These samples will therefore not be analyzed.

IV. Development of written guidelines to cover the following areas for current and future Monsanto/Bio-Test cooperative toxicity/residue studies.

1. Study objectives to be achieved by analysis of the tissues.
2. Labeling, packaging, and shipping of tissues.
3. Control measures involving sample contamination and exposure levels.

It was jointly agreed that we needed a better mutual understanding on the above points and that one manner in which it could be obtained was to set down written guidelines covering these topics. As a first step toward achieving this goal Monsanto agreed to write tentative guidelines covering these points and submit them to Bio-Test for review. Monsanto will then issue the final, jointly approved version of the guidelines.

V. Toxicity Studies Currently Being Carried Out by IBT for Monsanto Industrial Chemicals Company Requiring Tissue Analysis Support

A countdown of the planned toxicity studies was reviewed as well as a more detailed discussion of the structure of the polyhalogenated Quaterphenyls screening study in rats. The following is a list of the studies and our schematic understanding of the Quaterphenyl screening studies.

<u>90 Day Subacute Oral Toxicity Studies</u>

in Beagle Dogs	MCS 1109 Aroclor 1221 Aroclor 1016 Aroclor 5432 Aroclor 5442
in Albino Rats	MCS 1109 Aroclor 1221 Aroclor 1016 Aroclor 5432 Aroclor 5442

<u>Liver Enlargement and Residue Screening Studies in Albino Rats</u>

Brominated Quaterphenyl
Chlorinated Quaterphenyl

<u>Toxicity, Reproduction, and Residue Studies in White Leghorn Chickens</u>

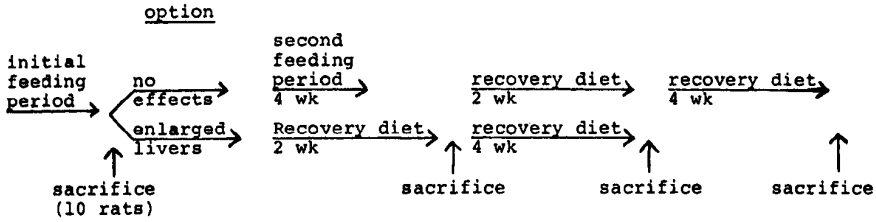
MCS 1109
Aroclor 1221
Aroclor 1016

MONS 030241

VI. Study Outline for Halogenated Polyphenyls

40 Rats/material/exposure level
40 Controls
80 Total

(EPW letter to MLK (IBT) on 10/26/71.)



J. D. Hinchen

W. M. Mees

E. S. Tucker