PCB DISCUSSIONS
GOVERNMENTAL AGENCIES
NOVEMBER 13 AND 14, 1975

Monsanto Representatives -- G. Roush
W. B. Papageorge
J. C. Weber
K. W. Easley
J. Calandra--Industrial Bio Test Labs

Purpose of Discussions

1. To show that positive action was taken by Monsanto in response to Dr. Kimbrough's report that Aroclor 1260 caused malignant tumors in the liver of the rat.

2. To report that the recent review by Industrial Bio Test and Eppley Institute Consultants confirmed that high levels of PCB's does cause liver damage in the rat, but the lesions are not hepatocellular carcinomas.

NIOSH

John Finklea - Director (Present for the introductions only)
K. Bridbord - Assistant to the Director
R. A. Rhoden - Criteria Documents
R. Moore - Editor "Alert" Bulletin
R. Stein - Criteria Documents
D. P. Brown - Epidemiologist, NIOSH Cincinnati Laboratory
E. J. "Bud" Fairchild - Director, Cincinnati Laboratory
T. Kopp - EPA, Office of Toxic Substances
R. Shapiro - FDA, Bureau of Foods, Office of Science
Renate Kimbrough - Center for Disease Control

Discussion centered on the fact that we and Dr. Kimbrough agree that PCB's cause lesions in the liver of the rats but disagree with her interpretation that some of these are hepatocellular carcinomas. Our interpretation is that these lesions are the expected damage you would see in the liver caused by chlorinated hydrocarbons. Dr. Kimbrough's work was done on female rats using only Aroclor 1260. The point was made that the production of Aroclor 1260 was stopped in 1971.

There is a real problem in that the people concerned with PCB's treat them as one chemical like "DDT" and do not recognize the difference between Aroclor 1260, 1242, etc.

Dr. Brown and Dr. Fairchild of the Cincinnati office plan to conduct a mortality study at Westinghouse's Bloomington, Ind. capacitor plant covering the past 30 years. This study will take about two years to complete. Dr. Roush discussed our review of causes of death of employees associated with the production of PCB's over the past 25 years. Dr. Fairchild offered to help us complete our study.

NIOSH is concerned that there is poor control in containment and plant practices once the PCB leaves our plant. NIOSH mentioned a "use permit" as a control. It appears NIOSH will not recommend the banning of PCB's but very restrictive practices on using them.

CEQ - (Council of Environmental Quality)

Warren Muir - Assistant Director
Peter Winkel - TNO - Netherlands
David Walsh - OSHA

Short discussion on our review with NIOSH covering the same ground. CEQ has no specific plans regarding PCB's. Dr. Muir did report the Administration is backing the McAllister bill in the House on toxic substances.

Dominick Daniels (N.J.) House Subcommittee
Manpower, Compensation, Health and Safety

Daniel Krivit - Counsel
Mrs. Susan Nelson - Staff Assistant

These people are interested in PCB's because they are concerned that NIOSH and OSHA are not carrying out their responsibilities as directed by Congress and can use PCB's as a political tool. Also PCB's are important to them because Representative Daniels will be proposing a bill called "Hazardous Substances Dispersion Act" and will use PCB's to show the need for such legislation. We expect that this Subcommittee will conduct hearings on the PCB problems. Krivit's and Nelson's knowledge about PCB's is very limited, but they are eager to establish a working relationship with the chemical industry and invite active discussion with Monsanto.

Krivit was involved in drafting the current Occupational Health and Safety Act.

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NCI

Dr. Jim Peters - Director, Division of Cancer, Cause and Effect
Dr. Garry Flamm - Assistant Director
Dr. Herman Kraybill - Toxicologist
R. A. Rhoden - NIOSH
R. Shapiro - FDA - Bureau of Foods

Short discussion of our interpretation of Dr. Kimbrough's data and Industrial Bio Test report. Dr. Peters readily recognized the problem that the pathologists need to resolve the differences. Dr. Peters recommended that HEW's Toxicology Coordinating Committee take it under advisement. This committee is chaired by Dr. David Rall.

NCI also reports that Aroclor 1254 is included in the Stanford Research Institute's multi chemical chronic feeding studies with rats.

FDA

Dr. Al Kolbye - Ass. Director for Sciences, Bureau of Foods
Ray Shapiro - Bureau of Foods
Charles Jalinek - Bureau of Foods
Jerry Burke - Bureau of Foods
Larry Garthoff - Bureau of Foods
Al Pohland - Bureau of Foods
A. R. Bennett - Office of the General Council
S. M. Pape - Office of the General Counsil

We reviewed the data we had presented to the other agencies. Kolbye's concern is body burden. The FDA is considering lowering the allowable level of PCB's in fish. If this happens, it will have a serious impact on sport fishing as many lakes and streams will be out of bounds. Kolbye reports that Canada will soon announce a guideline of 2 ppm PCB's maximum allowed in edible fish. Kolbye is also disturbed about the lasting effect of the Japanese PCB incident that happened in 1968.

EPA

John Buckley - Consultant
Leonard J. Guarraia
Arthur J. Pallotta - Toxicologist
Lawrence A. Plumbe - M.D.
A. M. Kuamack
David Garrett - Office of Toxic Substances
R. M. Hutlif - Office of the General Council
Blake Biles - Attorney, Enforcement Office
R. E. Shapiro - FDA Bureau of Foods

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EPA is continuing their concern about the high chlorinated homologs of PCB's in the environment. In general this group of EPA was not receptive to our concept that PCB's are not cancer causing agents. EPA most probably will treat PCB's as such which appears to be consistent with their desire to have a Toxic Substances Act.

In general, it appears that our visit to these agencies on an individual basis was beneficial to Monsanto and did cause them to recognize the bigger problem of defining a cancer causing agent. This definition is extremely important not only to the status of PCB's but any other chemical that may cause lesions in an animal.

J. Coleman Weber
11/17/75

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