July 30, 1971

MEMORANDUM FOR THE RECORD

SUBJECT: Updated review of toxicity studies in progress with polychlorinated biphenyls (Aroclor 1242, 1245 and 1260).

TO: Dr. Leo Friedman
Director,
Division of Toxicology (BF-150)

This memo is meant to update our review of extensive toxicological studies being carried out at Industrial BioTest Laboratories under the sponsorship of the Monsanto Company.

Prior to formation of the EPA progress reports related to these studies were being transmitted directly to Dr. O. G. Fitzhugh. When Dr. Fitzhugh transferred to EPA he left behind what data he had on hand, however, we had no way of knowing if any of the reports had been updated and at the same time lost in transit. For this reason I called Drs. Kelley and Wheeler of Monsanto Company to request that they provide us with an up-to-date set of progress reports. They agreed to both provide me with the requested reports and in addition to authorize the Industrial BioTest Laboratories to answer any direct questions I might have.

The following is a summary of the submitted reports. In essence they do not differ significantly from that incorporated into the toxicity section of Supplement 1 of the PCB Status Report.

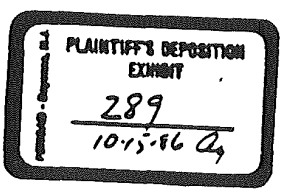
Dog fed Aroclor at levels of 0, 1, 10, 100 ppm.

The study has progressed for 18 months. Parameters studied are: body weight, food consumption, behavioral reactions, hematology, blood (bio-) chemistry studies and urine analysis.

Aroclor 1242 - No compound related effects noted.

Aroclor 1254 - There has been decreased weight gains for males and females at 100 ppm and for females at 10 ppm.

Aroclor 1260 - There has been decreased weight gains for males and females at 100 ppm and for females at 10 and 1 ppm. At 12 and 18 months male and female at 100 ppm have shown moderate increases in serum alkaline phosphatase.



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Rats fed Aroclor at levels of 0, 1, 10 and 100 ppm.

The study has progressed for 15 months. Parameters studied are those described for the dog with the addition of a 1 year sacrifice which includes gross and microscopic examinations along with organ and organ to body weight data.

Aroclor 1242 - No compound related effects noted.

Aroclor 1254 - At the 1-year sacrifice, males at 100 ppm had elevated liver weights, however, histopathology was negative.

Aroclor 1260 - At the 1-year sacrifice, males at 100 ppm had elevated liver and kidney weights, however, histopathology was negative.

Rats fed Aroclor at levels of 0, 1, 10 and 100 ppm through three successive a and b generations. The study has progress through the $F_{1a,b}$. In addition the F_0 parents have been examined.

Aroclor 1242 - There appeared to be a drop in lactation index (number of viable weaned pups/number of pups at day 5) for both F_{1a} and F_{1b} litters at the 100 ppm level.

Aroclor 1254 - There was a sharp drop in the number of pups delivered of parents in the 100 ppm group for the F_{1b} litters. A further F_{1c} litter confirmed this finding.

For the parents, the females at 100 ppm gained less weight then controls. For both male and female at 100 ppm liver to body wt. ratios were increased although absolute liver weights were not. Also for males and females at 100 ppm there were elevated thyroid weights. Histologic examination revealed thyroditis in 3 of 5 males.

Aroclor 1260 - There was an increase in stillborn pups in the F_{1b} group at 100 ppm. There appears to be a trend toward decreased litter size for both F_1 litters at 100 ppm.

The parents males at 100 ppm had increased liver weights and liver to body weight ratios.

Chickens fed Aroclor at levels of 0, 1, 10, and 100 ppm and observations made of egg production and hatchability.

Aroclor 1242 - For parents, body weights of males at 10 and 100 ppm were decreased. Food consumption at 100 ppm was decreased.

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Egg production at 100 ppm was decreased, and hatchability at 10 ppm was decreased. None hatched at 100 ppm. Unhatched eggs contained embryos 1-3 cm in size. Shell thickness was reduced in 100 and 10 ppm groups.

Aroclor 1254 - For parents body weight of males and females fed 100 ppm were slightly reduced. Food consumption at 100 ppm was reduced. There were some scattered pathological changes the significance of which is difficult to access at this time.

Egg production in the 100 ppm group was reduced. None of the eggs at 100 ppm hatched. Shell thickness was decreased at 100 ppm.

Aroclor 1260 - There were no untoward effects noted in either parents or eggs derived from them.

Chickens were fed at levels of 2, 4 and 8 ppm aroclor 1242 in an effort to establish where between the levels of 1 and 10 ppm a no effect level lies. Parameters studied were as for this previous chicken study. In addition a 30 day recovery period on normal diets was included.

Aroclor 1242 - The only effect noted was a decrease in the percent hatch for the 4 and 8 ppm diets.

CONCLUSION:

The summary of data to date indicates several areas of concern. Primary is the apparent effects on reproductive processes of the PCBs. Although the chicken is known to be sensitive to this class of compounds, reacting in a manner similar to its reaction to the chick edema factor, none the less a real effect has been recorded. While results vary for the three aroclors studied, for the 1242 effects on hatchability were noted at levels as low as 4 ppm in the diets of parents.

For the rat decreases of litter size or increases in stillborns are seen at levels of 100 ppm in parents fed 1254 and 1260. Since for 1254 these effects were magnified from the $F_{1a,b}$ to $_{c}$, it is possible that successive generations may show an increased severity in effect.

For the dogs it is conjectural what histology is reflected by the increased serum alkaline phosphatase.

Our conclusions at this time are that pending completion of studies in progress we are in a poor position to recommend guideline levels for contamination. This lack of complete toxicologic data when coupled with

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our essential lack of information about background levels of contamination in foodstuffs in general, makes it all the more imperative that we resist setting guidelines on anything more then a case by case basis at this time.

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cc:
BF-152
BF-2 (Dr. Kolbye)

HBlumenthal:mmt 7/30/71

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