Monsanto

FROM (NAME & LOCATION): G.J. Levinskas - A2SC

FEB 6 [illegible]

DATE: February 5, 1975

CC:

SUBJECT: AROCLORS 1260 and 1254

REFERENCE:

TO:

W. B. Papageorge - B2SK
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E. P. Wheeler - A2SA
G. Roush, M.D. - A2SA

Dea - open file in PCB files

Aroclor - Rat feeding studies 1975.

Advise CP of labelling of Chm file.

MONS 029371

AROCLOR 1260: Meeting at NCI, January 31, 1975

Present

Renate Kimbrough - EPA	Donovan Gordon - Industrial BIO-TEST
Robert Squire - NCI	Ward Richter - Industrial BIO-TEST
Morton Levitt - NCI	George Levinskas - Monsanto

A summary report of the meeting held at NCI is attached.

A copy of Dr. Kimbrough's remarks also is attached. This is essentially the same material presented by her at Monsanto on November 22, 1974. This information led to the meeting.

Dr. Kimbrough conducted a 2-year feeding study using 200 female rats to follow up on an earlier study in which she had detected a bladder tumor in rats fed AROCLOR 1260. At a meeting held in Quail Roost Conference Center, North Carolina in December, 1971, she presumably was dissuaded from her belief that the single bladder tumor she had observed in a female rat was due to AROCLOR 1260. However, she must have been unconvinced since she started the present study on January 14, 1972. She used a Sherman strain of rat which had been derived from an Osborn-Mendel strain by cesarean section and thus could be labeled as specific pathogen free (SPF). The Sherman strain has been maintained as a random bred closed colony. Since the bladder tumor had occurred in a female, she put 100 females on a diet containing 100 ppm of AROCLOR 1260 and she kept 100 females as controls. Animals had been born between December 18 and 22, 1971. Thus, they were about 3½ weeks of age when the study started. After 20½ months, on October 2, 1973, feeding of AROCLOR 1260 was stopped. Approximately one month later (November 4), animals were sacrificed.

It may be noted that Dr. Kimbrough did not detect bladder tumors, the original aim of this study. A control female did develop a bladder papilloma.

Control animals in this study had very "clean" livers. The incidence of spontaneous changes was quite low. Insofar as could be determined, Dr. Kimbrough has no data from other 2-year studies which could be used to assess the spontaneous tumor incidence of this strain of rat. Despite the absence of historical control data, her results would be hard to refute.

Animals were fed PURINA Laboratory Chow. It was analyzed periodically for several contaminants. Mycotoxins, naturally occurring products of mold growth which can cause liver tumors, were reported to be less than one part per billion.

There was no specific resolution of this issue. As an observer, I wanted to get the reaction of BIO-TEST's pathologists before

deciding what to do. There was no opportunity to caucus while at NCI. After we left, and they conceded the occurrence of hepatic carcinomas, there was little else to do. Although the subject wasn't raised, I got the distinct impression that Dr. Kimbrough plans early publication of her findings.

About the only palliative course of action would be to publish our 2-year study on AROCLOR 1260 before Dr. Kimbrough gets into print. This would at least blunt the impact of her publication. Another course of action would be to repeat the study and to include additional animals which would be fed AROCLOR 1260 for 18 months only. This would permit a determination of whether or not the liver lesions would regress after feeding of the product was interrupted. Obviously, it would be 2-3 years before the results of such an experiment would be available.

George J. Levinskas

/bkp
2/4/75