PCB Feeding Studies

Monsanto

DEPT. OF MEDICINE AND ENVIRONMENTAL HEALTH

TRIP REPORT No.

BY: Peter E. Berteau SECTION: Toxicology

TRIP DATE: July 28, 1978 SHEET 1 OF 2

LOCATION VISITED

Litton Bionetics
Kensington, Maryland

IN ATTENDANCE

Peter E. Berteau, Monsanto
The following were among the persons contacted:
Mr. M. Abbaticchio, Litton
Dr. J. Cicmanec, Litton
Dr. J. Dean, Litton

PURPOSE

To investigate the progress of the study on the effect of PCB's and on the reproductive performance of the rhesus monkey.

REPORT SUMMARY & CONCLUSIONS

Because of certain accidental deviations in protocol and further mortality among monkeys fed PCB's, I visited Litton Bionetics to review the progress of the study. Feeding of PCB's to adults had been discontinued on June 1, 1978, according to protocol and this procedure had been adhered to. One male monkey which had been fed the high dose (100 µg/kg) was sacrificed in extremis about 1½ months after discontinuing feeding; hematological values were significant reduced prior to death. Morbidity was attributed to possible bone marrow suppression such as had occurred in 3 high dose females earlier in the study.

Protocol also demanded that infants be left nursing the mother for 2 months after birth and then transferred to the nursery. This protocol had not been adhered to in many cases.

At the time of my arrival, one baby monkey from a mother fed the medium dose (25 µg/kg) died suddenly the previous night, apparently of respiratory infection. Due to clotting, hematological values were not obtained and it will be necessary to await the bone marrow histology to determine if there was an effect upon blood formation which lowered the resistance to infectio The monkey had been nursed from its mother for 2 months and 1 week before being removed to the nursery. Due to biomagnification, it is probable that the infant received a greater level

(continued -2-

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Peter E Berteau
PREPARED BY

August 9, 1978
DATE

of PCB's from the milk than the 25 µg/kg fed to its mother.

During the morning I conducted a brief audit of the data; except for one missing daily check sheet everything seemed to be in order. The need for explaining the reason for any deviation from protocol on the check sheets was stressed. I informed Dr. Cicmanec that I will recommend that Monsanto conduct a complete audit of all values in all animals prior to terminal sacrifice scheduled for December 1, 1978. Since then Dr. Martin of Litton has informed me that Litton will conduct its own audit by its Quality Assurance Group in August. This audit does not preclude my recommendation of an audit by Monsanto.

In viewing the animals, edema and eye-lid puffiness was very evident in the adults in the high dose group. One female animal in that group displayed what appeared to be chloracne. In the opinion of Dr. Cicmanec, visible signs of toxicity are not evident in the medium dose group. Alopecia is evident in the lower dose groups (1 monkey at 25 µg/kg was almost hairless but the relationship of this manifestation to administration of PCB's is questionable). In the nursery, the one infant (the only one) born to a female in the high dose group was still alive, but very small and sickly looking. This animal eventually died about 10 days later. It was continued on the mother 2 weeks longer than the required 2 months.

Dr. J. Dean, Immunologist, showed interest in conducting studies on the monkeys to determine if the effect of PCB's may be one of immunosuppression. If this were the case it might explain the effect upon bone marrow and blood formation. Due to the increased cost involved and the doubtful usefulness of the information which may be obtained, I am not recommending that such studies be conducted.

I made a point of questioning the Senior Technician (M. Abbaticchio) who has the first line responsibility for the technical aspect of the study. It appears that the deviation from protocol was the result of not double checking. Litton personnel pointed out that because of the open endedness of the study and the frequent changes requested by us, this situation may have contributed to the problem. Although unhappy that it occurred, I did not have the impression that there was a lack of middle management and supervision at Litton such as have occurred at some other contracting laboratories.

PEB