JUN 3 1980

cc to John Craddock
Keep copy

Monsanto

DEPARTMENT OF MEDICINE & ENVIRONMENTAL HEALTH

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June 2, 1980

David P. Martin, DVM
Litton Bionetics, Inc.
5516 Nicholson Lane
Kensington, Maryland 20795

Dear David:

Enclosed is a suggested re-writing of page 31 of the main section of the report entitled "Effect of PCB on the Reproductive Performance of the Rhesus Monkey". Copies of the legend page and Tables 1, 2A, 2B, 2C, and 2D from Appendix G with the handwritten changes are also enclosed. The rest of Appendix G can remain unchanged since no scoring system was used.

Again, I would like to stress that we have no objection to Dr. Seibold's interpretation of the pathological findings nor with his grading system which assesses their severity. We are also willing to accept the incidence of a "trace morphologic effect" in one low dose infant, and that this lesion may be related to the administration of PCB to the mother. What we object to is the scoring system which assigns equal values to all lesions irrespective of their severity. We have tried to utilize the grading system in developing a true "score", which is reflected in the revised Table B. Table C is omitted. We have arbitrarily assigned a value of 0.5 to ungraded lesions although we would be willing to consider having another value assigned.

The other alternative would be to drop the scoring system entirely and merely report the numerical grade as is done in most pathology reports that I have read.

Sincerely,

Peter

Peter E. Berteau, PhD
Senior Toxicology Specialist

PEB:sfe
cc: R.D. Harbison, PhD
W.E. Ribelin, EHL
bcc: G.F. Callis, B2SA
F.A. Provorny, B3NA
J.C. Weber, B2SK

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Table 2D: Summary of Direct Morphologic Effects of Compound - Infants - Males and Females.

At the end of each table, a numerical score of the number of pathologic alterations listed for each animal was entered. Each pathologic alteration was given a value based upon the grading system of 1 through 5. Ungraded alterations were assigned a value of 0.5.

A final table was prepared (Table I) entitled "Survey of Direct Morphologic Effects of Compound." This table identifies each animal in relation to the test and furnished individual and average group numerical scores of pathologic alterations for use in final interpretation of the pathologic examination. Incidence of direct morphologic effects of the compound was dose related, being highest in Group IV animals and substantially lower in Group III animals. There was a trace morphologic effect in one Group II infant and absence of effects in Group I animals (controls). Only 1 of the 18 Group II animals showed a direct morphologic effect of the compound; it was an infant with minimal pathologic alteration in the mandible. In Groups IV and III, where comparisons could be made, the incidence of direct morphologic effects of the compound was greatest in the infants and least in the adult males.

Average scores of direct morphologic effects of the compound are summarized in text Table B.

TABLE B

Average Score of Pathologic Alterations
Representing Direct Morphologic Effects of the Compound

	Group IV	Group III	Group II	Group I
Adult males	3.75	0.38	0	0
Adult females	6.88	0.44	0	0
Infants	35.0	2.29	0.17	0