APPENDIX "A"

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May 2, 1972

BY HAND

Mr. Russell M. Roberts
Director of Public Services
Department Information Center Officer
Office of Public Affairs
Department of Health, Education
and Welfare, Room 1528
Washington, D. C. 20201

Dear Mr. Roberts:

On March 18, 1972 there was published in the Federal Register (37 Fed. Reg. 5705) a Notice of Proposed Rule Making by the Food & Drug Administration re polychlorinated biphenyls. The Notice referred to studies, investigations, surveys, calculations, and information as the basis for the proposal.

Pursuant to 5 U.S.C. §552 and 45 C.F.R. §§5.13(c), 5.51 and 5.52, the American Paper Institute through its counsel hereby requests the Department promptly to produce a copy of each item of material, whatever its form or nature, which has contributed to or constitutes in whole or in part the following items referred to or reflected in the Notice:

1. All "investigations" which "have * * * revealed PCB migration to food resulting from the use of PCB containing food packaging material" (Notice, 5th Par.).

2. All "studies" of the foregoing "problem" by "FDA and the paper and food industries" (Notice, 5th Par.).

MONS 089621

3. The "national survey conducted by FDA" which "revealed" PCB levels in food packaging and in the foods contained therein (Notice, 6th Par.).1/

4. All "other information which became available subsequent to the FDA survey" which "shows a continuing and substantial reduction in the PCB concentration of paper-packaging materials" (Notice, 7th Par.).

5. All "FDA total diet studies" on which was "based" the statement in the Notice that "the dietary intake of PCB's appears to be of a low order" (Notice, 9th Par.).

6. All analyses of "the total diet market basket samples for the past 2-1/2 years" which showed PCB residues or absence of residues (Notice, 9th Par.).

7. All calculations of "average PCB levels found in the market basket" "on the basis of dietary intake" (Notice, 9th Par.).

8. All "available information" which "indicates that PCB's are classified as being of moderate acute toxicity" (Notice, 10th Par.).

9. All comparisons of the toxicity of PCB's with that of DDT (Notice, 10th Par.).

10. All protocols and available preliminary reports from studies of "the chronic toxicity of PCB's being conducted by "the Government, industry, and the scientific community" (Notice, 10th Par.).

1/ On April 6, 1972 the President of the American Paper Institute (Mr. Edwin A. Locke, Jr.) was supplied by Associate Commissioner Fine with a report entitled "FDA Survey of Polychlorinated Biphenyl in Food Packaged in Paper Products", prepared by FDA's Bureau of Foods. If this "Survey" is the one referred to above, then this request is directed to the data and worksheets from each of the seventeen districts whose reports constituted the survey.

11. All "preliminary reports and observations" which "indicate that it would be prudent to reduce and, wherever possible, eliminate long-term, low-level human exposure to PCB's" (Notice, 10th Par.).

12. All "other available information" "on the basis of" which the Notice stated that "the current dietary level of PCB's is not considered an immediate hazard to the public health" (Notice, 11th Par.).

13. The "report of the Interdepartmental PCB Task Force" (Notice, 11th Par.).2/

The sufficiency of identification of the foregoing items, for purposes of 5 U.S.C. §552, is established by Bristol-Myers Co. v. FTC, 424 F.2d 935 (D.C. Cir. 1970). The applicability of 5 U.S.C. §552 to requests for information and records relied upon by the Commissioner of Food & Drugs in a Notice of Proposed Rule Making is established by Ackerly v. Ley, 420 F.2d 1336 (D.C. Cir. 1969).

We will be pleased to tender the necessary copying fees pursuant to 45 C.F.R. §5.52 upon notice of the amount due.

Yours truly,

Selma M. Levine

Joel E. Hoffman

Attorneys for American Paper Institute

SML:JEH:asl
cc: Dr. Charles C. Edwards
Peter B. Hutt, Esq.

MONS 089623

2/ On April 6, 1972 Associate Commissioner Fine wrote the President of the American Paper Institute (Mr. Edwin A. Locke, Jr.) that the report "will be available * * * in about two weeks * * * from the National Technical Information Service * * **. As of this writing the report is not yet available therefrom, and Associate Commissioner Fine's office advises us that it will not be available generally for another two weeks.