

Memorandum for the Record
of a Telephone Conversation
late Tuesday Afternoon, August 19, 1975

between: Mr. Jeffrey Tannenbaum
Wall Street Journal
22 Cortlandt Street
New York, NY 10007
212/285-5108

File FDA

and

Dr. Raymond E. Shapiro
Epidemiology Unit, HFF-108 FDA, Washington D.C.

Mr. Tannenbaum had been referred to this office by Mr. John Wessel (ACC). He had talked with Mr. Wessel about PCBs in foods, the subject having arisen from two articles in the New York Times, August 8, 1975 and August 17, 1975.

The article in the New York Times, by implication, stated that there were 16 PCB's related deaths in Japan from the Yusho tragedy. Mr. Tannenbaum asked if I was aware of this information and whether we had further details. I told him that to the best of our knowledge we did not have any data and would appreciate receiving anything he might obtain on this matter.

He then asked whether PCBs would be banned from foods since it is a carcinogen. Mr. Tannenbaum was aware of the PCBs review in Vol. 7 of the IARC reports wherein it was pointed out that it produced hepatocarcinoma in the mouse. He was also aware of the unpublished paper by Kimbrough and Squire showing it produced hepatocarcinomas in rats. I pointed out to Mr. Tannenbaum that the "ban" or the Delaney Amendment applied only to food additives. Environmental unavoidable contaminants which might get into foods call for scientific judgement as to permissible levels; i.e., Delaney does not apply.

The next point raised, by Mr. Tannenbaum, was that wouldn't the recent findings of carcinogenicity with respect to PCBs lead to a tightening of the PCBs temporary tolerances, particularly with respect to PCBs in fish. Implicit, if not explicitly contained in this question is the following:

The PCBs temporary tolerances were set before anything was known as to their carcinogenicity. One does not question your value judgements made at that time. Now, with the introduction of a new toxicological parameter; namely, carcinogenicity - an irreversible effect, should there not be a lowering of these temporary tolerances taking into account this new data. The main interest was PCBs in fish.

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I replied to Mr. Tannenbaum that the FDA was studying all aspects of PCBs toxicity in great depth, particularly in terms of the upcoming paperboard hearings. He was aware of these hearings and the issues involved. With respect to this new data, I told him, our analysis must take into account a balancing of the following factors (1) maintaining proper and adequate protection of public health, (2) insuring the safety, and integrity of the nations food supply, and (3) not removing a major source of food from the market place unless public health considerations deemed it absolutely essential. I also pointed out to Mr. Tannenbaum that many of the sources of fish above guideline, mentioned in the EPA reports, did not enter into interstate commerce and were outside our legal mandate. However, we would supply backup materials to those needing it for local decision making.

I promised to send Mr. Tannenbaum copies of the Federal Register proposal and final order with respect to PCBs.

Raymond E. Shapiro, Ph.D.
Epidemiology Unit, HFF-108

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HFF-108 - 4
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Dr. H. Blumenthal, HFF-150
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