

K. W. Easley - 1920

DATE

December 13, 1977

CC

R. C. Isham - B1NB
E. T. Mollica - B2SB
A. M. Navarro - A3NB
R. A. Stohr - B2SC
D. Wood - B2SD
G. Roush, Jr. - A2SA

SUBJECT

PCBs

REFERENCES

TO

G. J. Levinskis - A2SG

In your memo of November 9, you asked that I chase down the Massachusetts Audubon Society letters which question the IBT data on PCBs and to seek confirmation of EPA's view that IBT's raw data is not being questioned. To get my hands on the letter, I had to go to the FDA Hearing Clerk's Office in Rockville. Attached is a rough transcription of my tape recording of the letter. The attachments referred to in the letter are not included, but should come along in a week or two and will include copies of the letters themselves. I requested them under the Freedom of Information Act, incidentally. The Audubon Society letter which was sent to EPA is identical to that which was sent to FDA. I do not plan to get a separate set from EPA. The EPA acknowledgment, like FDA's, doesn't really say anything, I'm told.

I had a long talk with John Wessel of FDA's Office of Compliance. As you know, he has been involved in this issue for some time. Incidentally, he is going to transfer to some other part of FDA and this work will be picked up by Betty Campbell in the Office of Compliance. Wessel does not know how FDA is going to react to the letter. He says that the Bio Research Monitoring group is examining it. The '73 PCB tolerances were established, according to John, primarily on the basis of Yusho data which, as he put it, is confirmed by the observations at IBT. If the IBT data turns out to be unreliable, they will still have the Yusho data to fall back on. He pointed out that it was after the 1973 tolerances were set that the cancer question arose. This got them into a box because no amount of PCBs in food could be considered safe, and they had to work toward getting the levels as low as possible considering analytical uncertainties, unavoidability of some contamination, and scientific judgments as to the levels people would consume over time. They could not fall back on a formula relating intake and toxicity. It follows then that even if the IBT data is discredited after their reassessment, there would still be no change in the final standard. Also, he noted, if FDA were to lower the standards, there would not be much of a reduction in PCB intake from foods. For

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example, if they were to cut certain species of fish in the Great Lakes and the Hudson from 5 to 2, a change that looks significant on paper, it would, in practice, make no big difference. Asked when there might be something coming out of FDA, he said that they would probably be slow and that nothing will appear until 1980. The matter has a fairly low priority.

The person at EPA who is most responsible for this issue is Dr. Eugene Wallen. I have not talked to him about PCBs in connection with your memo, although I can do so if indicated. I have talked with George Wirth, Dave Downer, and Tom Kopp, all in the Office of Toxic Substances and all concerned with PCB. Kopp was the source of the report that EPA has no argument with the basic data that IBT developed, but probably does have some disagreement with IBT's conclusions. Kopp was giving us the opinion of others. He is not willing, of course, to put such an opinion in writing and it wouldn't mean anything if he did. I have no hesitancy about getting into a detailed conversation with Wallen on this, but before I do so, I would like for you to react to the material attached and the additional material you will be getting.



K. Warren Easley

KWE/pah
Attachment

MONS 011185