Monsanto

FROM (NAME & LOCATION) Dept. of Medicine & Environmental Health - G.J. Levinskas, A2SG

DATE: November 9, 1977 CC:

SUBJECT: PCBs

REFERENCE:

TO:

R.C. Isham - B1NB
W.T. Mollica - B2SB
A.M. Navarro - A3NB
R.A. Stohr - B2SC
D. Wood - B2SD
W. Easley - 1920
G. Roush, Jr. - A2SA

As a follow-up to our meeting on November 2, 1977, I am attaching copies of 4 items dealing with PCBs.

1) Food Chemical News, October 17, 1977, p. 8
We should get copies of the letters sent to FDA and EPA by the Audubon Society. If they are attacking our long-term studies on PCBs, we should know the specifics of their attack.

2) Fed. Register, vol. 38, July 6, 1973 pp.18096-18104 and vol. 42, April 1, 1977, pp. 17487-17494.
This discusses PCB toxicity and sets out the basis for the proposed tolerances. Nisbet's statement, or at least the portion cited above, is misleading because it fails to note FDA's consideration of human data in setting PCB tolerances. (See pp. 18097 and 17488).

3) Chem. Reg. Reporter, August 12, 1977, p. 752
A proviso in the Clean Air Act Amendments requires EPA to publish a list of environmental contaminants and to explain what is known about how they get into the environment. This is bound to reveal new sources of PCB contamination.

4) Chem. Reg. Reporter, July 22, 1977, p. 666
The attitude expressed by the EDF, that no type of exposure to PCBs can be termed insignificant, will be the basis for continuing controversy.

Subsequent to our meeting, Dave Wood told me that Warren Easley had been told by someone in EPA that they were satisfied with the data Monsanto had on PCBs, i.e., they were not challenging IBT's conduct of the studies. They did indicate that they disagreed with us on the interpretation of the data.

Recommendations:

On the basis of the preceding diverse items, I recommend:

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1) Warren Easley obtain copies of the Audubon Society letters to FDA and EPA.

2) Warren Easley attempt to get a written confirmation of the comments made to him by EPA regarding their views of our PCB studies. If he cannot get written confirmation, he should at least commit his recollection of that conversation to writing and send a copy of it to the person at EPA who made the remarks.

3) A rebuttal to the Audubon Society letter be sent to FDA and EPA after we have had an opportunity to review the remarks which have been made.

George J. Levinskas

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The Commissioner added: "Until we can generate a basic research establishment that provides useful shortcuts to what is now a hopelessly unimaginative and time-consuming process, until we can rebuild and improve the private-sector testing establishment, and until we can develop similar capabilities in the public sector to monitor and extend it, we will continue in the uncomfortable position of constantly having to pick up the pieces rather than preventing breakage."

The Commissioner said much of the current regulatory reform talk "amounts to a mindless request to 'Make 'em go away,'" commenting: "But to go away would be to pretend that in the food supply there simply aren't any public costs of private activity, and that's not true. What we need is an FDA so well equipped, so well able to offer advice, that unpleasant surprises don't happen."

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RECONSIDERATION OF PCB TOLERANCES URGED BECAUSE OF IBT QUESTIONS

The Massachusetts Audubon Society has asked that the Food and Drug Administration "reconsider" its proposed revised temporary tolerances for polychlorinated biphenyls because of questions raised about studies conducted by Industrial Bio-Test Laboratories (See FOOD CHEMICAL NEWS, March 28, Page 2).

The Society, in letters to FDA and to the Environmental Protection Agency, urged that the temporary tolerance proposal be reconsidered and, "if judged necessary," that FDA "propose new tolerances or ... re-open the matter for public comment." The group said:

> "Although the discrepancies in the reports can be resolved only by a thorough re-examination of the pathological material, the data are already sufficient to show that the assumption of no-effect levels at 10 p.p.m., on which FDA's proposed temporary tolerances were based in 1973 and 1977, is no longer tenable."

The Society said "the IBT reports on toxicological studies with PCBs in rats and dogs contain discrepancies and inconsistencies which appear similar to those reported to have been identified by FDA and EPA in IBT reports on tests with other chemicals," adding that "the data in the IBT reports give prima facie evidence of toxic effects of PCBs in both rats and dogs at dietary levels as low as 1 p.p.m."

Audubon's Ian C. T. Nisbet said the 1973 temporary tolerances for PCBs were based "primarily on data from tests carried out at IBT," noting that the same data were cited in FDA's 1977 proposal to reduce the tolerances, "and appear to be the primary toxicological basis for the proposed tolerances."

Nisbet said he has "reviewed the IBT experiments with PCBs, on behalf of EPA, and found discrepancies similar to those reported to have been found in other IBT reports." Saying that his "findings have been reviewed and accepted by the Administrator of EPA," he wrote that, "The raw data in the IBT reports show serious toxicological effects at dose levels at and below those reported as 'no-effect' levels and utilized as such by FDA in establishing temporary tolerances."

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