FDA DEFENDS ON PCB-DELAY CHARGES, ASKS EPA FOR DATA

While defending itself against charges of "endless studies" on polychlorinated biphenyls (PCBs), the Food and Drug Administration is investigating another report of PCB contamination of food in Bloomington, Ind., and has asked the Environmental Protection Agency to look into the possibility of other cases.

The Environmental Defense Fund wrote to the agency that an "in-depth evaluation" of EDF's proposal for lower PCB action levels is "superfluous in light of what is already known about PCB toxicity" (See FOOD CHEMICAL NEWS, April 19, Page 30).

A recent letter from FDA Associate Commissioner for Compliance Sam Fine to EDF, however, insisted:

> "It is not, as you have implied, our intention to conduct or initiate additional studies on PCBs. However, we believe that mere possession of raw data is not enough to initiate changes in the PCB tolerances. Rather, a comprehensive evaluation of that data is necessary so that FDA can clearly and objectively state the scientific basis for any proposed adjustments of the existing tolerances and so that FDA's action will withstand scientific scrutiny."

Fine also told EDF that lower tolerances, which might have a significant effect on the food supply, would not necessarily deal with "the more urgent public health issue of the consumption of PCB-contaminated freshwater fish" by sports fishermen and their families. In this respect, action by State officials "is an important first step."

Saying FDA does not believe it is taking an unreasonable amount of time in the consideration of EDF's petition, Fine assured EDF the petition "is under active consideration." He said FDA expects to "have a proposal addressing the issues... ready for publication in the next several months."

PCBs in Milk Found Near Bloomington, Ind.

In the Bloomington, Ind., case brought to FDA's attention in late April, State officials reportedly found PCBs up to 5 p.p.m. (on a fat basis) in the milk of one cow which grazed on land treated with sewage sludge.

Investigation of the case prompted FDA to ask EPA for a current report on PCB effluents for each of 50 electrical equipment manufacturing plants in the country. FDA is considering an independent study if EPA is unwilling or unable to provide the information.

A Westinghouse facility near Bloomington reportedly fills transformers by immersing them in Aroclor 1016, after which the transformers are washed with water and the washings released to a local stream.

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PCBs were found in sewage sludge at a level of 300 p.p.m. on a dryweight basis.

Contamination of PCBs Pointed Out

Meanwhile, Klaus L. E. Kaiser of the Canada Center for Inland Waters wrote to the May 14 issue of Science magazine to note that polychlorinated dibenzofurans (PCDFs) are contained as impurities in some PCBs and exceed the toxicity of PCBs by four to six orders of magnitude. He recommended that all present and past studies of PCBs be looked at in terms of PCDF content.

POSSIBLE IMPACT OF CHLOROFORM BAN ON FLUOROCARBON USE POINTED OUT

The impact of the Food and Drug Administration's proposal to ban chloroform (See FOOD CHEMICAL NEWS, April 12, Page 13) on use of fluorocarbons has been pointed out to the agency in comments from du Pont and Allied Chemical.

Du Pont noted that fluorocarbons are used as propellants in drug, cosmetic and food aerosol products, as blowing agents in plastic foam food containers and as direct immersion freezants for quick frozen foods. As did Allied, du Pont noted that fluorocarbon 22 uses chloroform as a "main raw ingredient."

Asking for a meeting sometime after the results of further tests are in, by mid-June, du Pont said, "...Our main purpose would be to seek the FDA's concurrence that we do not have an adulterated drug or cosmetic or food additive problem with respect to the present uses of our fluorocarbon formulations, or, if necessary, to seek appropriate modifications to the FDA's proposed regulations regarding chloroform."

"None of the fluorocarbon formulations...contain chloroform as an added, active ingredient," du Pont said, "but minute amounts of chloroform may be formed in some of the formulations during the manufacturing process."

The company asked FDA to postpone final regulations "for at least 30 days or until such time as we have an opportunity to discuss this matter in the light of our test results."

Allied asked for clarification "that the intent of the proposed regulations is not to ban fluorocarbons as an ingredient of a drug or cosmetic product or as a food additive." The company said, "Recent tests conducted to determine presence of chloroform in fluorocarbons 11, 12 and 22...detected no chloroform at a level less than one part per million."