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Monsanto

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PCB's Debate Reopned by EPA; Monsanto Pleas

Environmental protection Agency has reopened the debate as to whether polychlorinated biphenyls, outlawed and vilified as one of the most hazardous industrial chemicals, actually do pose a major health risk, particularly a carcinogenic one, to humans.

Monsanto Company, the sole US manufacturer of PCB's before voluntarily ceasing production in 1977 two years before the flame-resistant dielectric fluids were banned here, insists that it has no intention to reenter the PCB business if the chemicals are cleared, but would welcome that development because of the help it would be in litigation over health problems blamed on exposure to the chemicals. Chemical Manufacturers Association, the sponsor of a study which helped influence EPA to take a new look at PCB's and their effects, is concerned because the substances can and do show up as contaminants in a variety of chemical products, and the imposition of a stricter limit on how much may be present could affect almost any sector of the industry which deals with chlorinated hydrocarbons.

In general, industry people praised EPA last week for reopening the issue while environmentalists and some scientists said that the agency's PCB's symposium, which was held in Bethesda, Md., last Wednesday and Thursday, was deliberately slated to air for the most part the views of industry technical people and industry-hired consultants.

"There is certainly sufficient information now that PCB's are not the unique health hazard they were once thought to be," CMA's Geraldine Cox, vice-president and technical director said in a statement on Thursday. Dr. Cox added that there is "no justification for lowering the current regulatory cut-off level of fifty ppm."

But Jacqueline Warren of Natural Resources Defense Council, who was with Environmental Defense Fund when that organization won a court

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battle focing EPA to reexamine its rules on PCB's and to promulgate new ones, said last week, "It troubles me that EPA would go to the industry to ask, 'Is this product a hazard?' "

She maintains that there is no new evidence exonerating PCB's, but rather numerous reevaluations of the results of health studies which were performed in the past. "All they (industry) have is industry reinterpretations," she said, adding, "Their reinterpretation of the data is that everybody's wrong."

The environmentalist wrote to EPA Administrator Anne Gorsuch to protest the nature of the Bethesda symposium. Mrs. Warren expressed "serious concern about the strong pro-industry bias of the majority of speakers" and said that the meeting's panels are composed either of persons directly employed by the former manufacturers of PCB's or consultants to those industries which stand to be affected by regulations currently under development.

As a result of the lawsuit which EDP won earlier this year, EPA has six months after the receipt of information which was supplied by the Edison Electric Institute through the Utility Solid Waste Activity Group to promulgate a new final rule. The agency received the EEI/USWAG study on February 19, and thus faces a deadline of August 19.

PRELIMINARY RULE

The rule mandated by the court order, however, will affect only electrical equipment and will specify from which types, if any, PCB's must be removed. The preliminary rule was published in the *Federal Register* on April 22 (CMR, 4/26/82 pg 5). The agency also intends by October to make final a rule which will set out exemptions to the current fifty ppm limit for so-called incidental PCB's, exemptions which will likely depend on whether the particular plants involved can demonstrate that the PCB's only exist in closed manufacturing processes. The proposal for that rule is reportedly being examined now by Office of Management & Budget, and could be published any time.

Thus it is in the interest of the chemical industry to persuade EPA that business is correct in its belief that the fear of PCB's and their popularly-accepted carcinogencity, which has led to their being banned not by regulation, but by statute, and specially regulated under other environmental laws (delegations of Resource Conservation and Recovery Act authorities to the states do not include the right to authorize the incineration of PCB's for instance), is a scientifically unfounded fear.

Industry has submitted two major overview studies to the agency for its consideration, and it is believed that these studies prompted the hasty convocation of last week's PCB's symposium. One study was undertaken by the consultants Drill, Friess, Hays, Loomis, & Shaffer, Inc., and was sponsored by the utility industry.

The second, performed by Ecology & Environment, Inc., was sponsored by CMA. After reviewing "all significant published or readily available studies of the effects of the PCB's as well as the pertinent current theories of carcinogenisis," the CMA consultants concluded that "the carcinogenic potential of this compound has not been convincingly demonstrated in an animal model relevant to man."

Monsanto also said that an often-cited animal test done at the Centers for Disease Control does not, as the original researchers found, demonstrate convincingly that the liver tumors which appeared in rats resulted from their being fed PCB's.

But Renate Kimbrough, the CDC researcher responsible for that 1975 paper, still maintains that PCB's pose a health hazard, "based on the animal data." She attended the Bethesda gathering as a discussion leader, and said that there are "still too many questions" for her to believe that the chemicals pose no human hazard.

Dr. Kimbrough said that the lack of hard epidemiological data is not surprising, because of the difficulties inherent in doing worker studies; the small numbers of workers involved is an example, as is the near impossibility of sorting out the effects of the many substances in and out of the workplace to which the subjects have been exposed through their working lifetimes.

The CDC researcher seconded Mrs. Warren of NRDC in her criticism of the way the Bethesda scientific gathering was arranged. Dr. Kimbrough said that she was not notified that the meeting was to take piace until April, and that such short notice is very unusual in the scientific world.

Ian Nisbet, vice-president of Clement Associates, Inc., another consulting firm, said last week that he had not even been invited to attend the symposium. When Dr. Nisbet worked for EPA in 1977, he was one of the principal authors of the agency's water effluent standards for PCB's, and in 1979, when the ban was promulgated, he worked on the health support documents under contract to the regulatory body.

He said last week that "it's known they (PCB's) pose a health hazard at sufficiently high exposure levels." He also commented on the list of participants in the EPA symposium: "This is not from the mainstream of PCB research," he said.

The industry has its work cut out for it at the informal hearing on PCB's which EPA is slated to hold in Washington on June 7. A preliminary evaluation by the agency of the E & E study submitted by CMA said that the overview "tends to misguide the reader as to what the actual articles present. The overall tone of the summary," the EPA document continues, "is a refutation of the technical presentation or an exaggeration of the 'negative' arguments presented in the six review articles."

EPA also found in its preliminary review that the consultants, while quick to point out the deficiencies in the data on adverse health effects, "do not mention the inadequacies of the negative studies." The EPA evaluators were also critical of the utility industry report, referring to one part of it as "exculpatory propaganda."