Monsanto

FROM (NAME & LOCATION) LAW DEPARTMENT

DATE August 24, 1971 CC:

SUBJECT Date of Monsanto's Notice of Potentially Harmful Effects from PCB

REFERENCE

TO Mr. C. B. Holleran

Monsanto is currently faced with a product liability suit for damages to a silo manufacturer and his dairy farmer customers resulting from the use of paint containing PCB used on the silo interiors. If plaintiff proceeds on a strict liability theory against Monsanto, one issue in the action will be whether the product manufactured by Monsanto was "defective." In this instance, the "defect" in the PCB-containing paint will most likely be predicated upon an allegation of inadequate labelling. Monsanto's response to such a charge might well be lack of knowledge of any harmful effects in the foreseeable uses of PCB. Before Monsanto can be assured that its warning label on PCB was adequate, it must be determined that Monsanto could not have discovered the harmful effects through reasonable human skills and foresight.

The purpose of this memo is to determine what risks could have been discovered, and when, by the application of reasonable skill and research efforts. The memo results from a reading of selected correspondence between Monsanto's product research and safety personnel and various governmental agencies, and from a limited number of newspaper clippings and other publications. Limitations of the memo arise from its reliance on hearsay instead of an original reading of scientific articles. It does not purport to determine from scientific data the date when Monsanto should have known of the risks involved in PCB's, but rather to find the earliest date when Monsanto personnel in charge of product safety expressed a concern over the compound's effects that might reasonably be said to constitute notice of possible harms.

The history of the use of PCB, or polychlorinated biphenyls, is relatively uneventful until 1966. The compound was first manufactured for industrial uses in the United States in the 1930's by the Swann Chemical Company, later taken over by Monsanto. While there is some mention of a small number of industrial mishaps in the early use of PCB, trademarked Aroclors, the mishaps were not publicized and drew little attention. It is possible that these early accidents resulted from failure to abide by instructions for safe handling and use. It was known at this time that repeated contact with skin and inhalation of fumes and dust from the compound might be harmful, and warnings to this effect were printed on the labels. Monsanto has continuously warned of these known hazards in the use of PCB products.

In 1966 the first published article on PCB's appeared, written by a Swedish biologist who found PCB residues in fish and wild birds. Following this publication, comments on the Swedish study appeared

in various scientific journals, but apparently there was no consensus in the scientific community throughout 1967 and 1968 as to the effects of PCB on the environment. Nature magazine, in December 1967, traced the PCB residues in seals and birds to water pollution, and concluded that any toxic hazard to humans from the compound was unlikely.

The United States Department of Agriculture conducted experiments on PCB's in early 1968, but the first audible alarm wasn't sounded in the United States until October 1968. On this date a California biologist, Risebrough, published his conclusions from investigations of PCB in falcons and other wildlife. Risebrough concluded that PCB's presented a danger to the environment by rendering the eggs of certain birds unhatchable and that, when vaporized, PCB fumes could be toxic to humans.

Risebrough's work was brought to Monsanto's attention prior to publication. The materials examined in the preparation of this memo do not reveal Monsanto's response to Risebrough's work, but later actions by Monsanto indicate that it must have investigated the validity of the charges made by Risebrough against the compound. At most, it may be said that Risebrough's study indicated that PCB residues might impair the reproductive capacity of certain wildlife species. Since Risebrough's investigations were limited to wildlife, the basis for his conclusions of toxicity to humans is not apparent. Monsanto knew of, and warned against, the possible harm of inhaling PCB dust and vapors, although its label did not specifically mention toxicity.

Monsanto made no changes in its warning label until May 18, 1970--a year and a half after publication of Risebrough's work. At this time, Aroclor's label was modified by the addition of a warning that PCB might be an environmental contaminant and that extreme care should be taken to prevent leakage, disposal or vaporization resulting in its entry into the environment. This label change followed a letter in April 1970 by Monsanto's Medical Director to the United States Department of Agriculture in which he announced Monsanto's commitment to a program restricting sales of aroclors to uses where escape to the environment could be avoided. Essentially this meant the elimination of Aroclor 1254 in insecticides. Monsanto's voluntary action preceded a notice by the USDA in October 1970 requiring the elimination of PCB's from economic poisons. USDA PR Notice 70-25.

It is apparent from Monsanto's action in eliminating PCB's from insecticides that it had notice of possible environmental harm at some date between October 1968, the date of Risebrough's publication, and April 1970, the date of the Medical Director's letter. A letter to the USDA in September 1969 indicates Monsanto's reluctance to recommend PCB's in insecticides. However, the precise date of notice of environmental hazards is not as significant to the silo manufacturer's action against Monsanto as is the date of notice of possible harm from human consumption of PCB's.

The earliest evidence of harm from human consumption of PCB-contaminated food appears to be a Japanese newspaper article, dated July 24, 1969 and brought to the attention of Monsanto's Medical Department on August 11, 1969. The article announced the death of a 14 year old Japanese boy from the consumption of rice bran oil contaminated with PCB. The contamination apparently arose from a leakage of heat transfer fluid containing Aroclor 1254. Monsanto's Product Manager of the Heat Transfer Fluid Department, in a memo to the Medical Department, called attention to the possibility of a similar leakage of the fluid used in food processing equipment in the United States. At that time, the PCB-containing fluids were used by several snack food outfits to heat cooking oil.

The Medical Department's response to this memo demonstrates a serious concern over the use of PCB's in food processing equipment. In early tests conducted by Monsanto, it was found that less than 1 ppm could be detected by taste or odor, hence the risk of consumption of harmful quantities was deemed to be minimal. Later, however, a customer reported that 25 ppm could not be detected in doughnuts. The Japanese incident reportedly involved oil containing more than 1000 ppm.

An August 15 memo from the Medical Department recommends that heat transfer fluid containing PCB be used in food processing equipment only if contamination of the food was impossible, except where fluid loss would be obvious from the large quantity of fluid leaking from the system. By recommending this restriction of PCB's to closed systems when used in food process equipment, it might reasonably be said that Monsanto had notice, by August 15, 1969, that PCB consumption by humans could be hazardous in large quantities.

No change was made in the labelling of PCB after the Medical Department's recommendation of restrictions on sales of the PCB-containing fluid. Since the fluid would no longer be sold for use where contamination of cooking oil through pinhole leaks would be possible, presumably there was no need to warn of dangers involved in human consumption of the compound.

In April 1970, a letter from Monsanto's Medical Director to the USDA states Monsanto's decision to limit the sale of PCB's to use as fire resistant fluids in closed systems. It is not clear from the materials read for the memo precisely when the recommendation of August 15, 1969 became official Company policy, but this occurred at some date prior to April 1970. Monsanto's decision to restrict the use of PCB's in food processing equipment preceded the F.D.A.'s setting of "action level" standards of PCB in milk, fish and poultry. The FDA standards were established in July 1970.

By the end of August 1970 Monsanto had decided to discontinue the use of PCB's in plasticizers and to cease selling PCB-containing fluid for use in food processing equipment, whether or not it was

a closed system. This action came after the filing of the first suit in Ohio by dairy farmers whose milk had been condemned by state agricultural departments.

In conclusion, it may be said that, based on materials read for this memo, Monsanto cannot fairly be said to have had notice of harmful effects from consumption of PCB prior to October 1968. At that date, the date of Risebrough's publication, Monsanto had notice that one biologist found the compound to have harmful effects on wildlife reproductive systems. Whether or not Risebrough's article should have alerted Monsanto to the possibility of harm to the reproductive systems of cattle eating silage from a PCB-lined silo is a question of foreseeability and reasonableness. By April 1970, when Monsanto's Medical Director recommended the discontinuance of PCB sales for all uses except as fire resistant fluids in closed systems, it may be said that Monsanto had knowledge of possible harm from the compound to the environment. If the dairy farmers attempt to hold Monsanto liable for the stillborn births of several calves, Monsanto may have to meet the contention that the October 1968 notice of harm to falcons' reproductive capacity should have indicated a similarly harmful effect on cattle. On Monsanto's behalf it may be noted that knowledge of possible harm to cattle's reproductive systems doesn't necessarily or logically follow from a report indicating that PCB resulted in thin-shelled, unhatchable falcon eggs. To date, there appears to be little evidence of a cause-and-effect relationship between the stillborn calves and the cattle's consumption of PCB. Nevertheless, if a date of notice of possible harm to animals is to be set, it should not be earlier than October 1968 nor later than April 1970.

Notice of potentially harmful effects on humans from the consumption of PCB in large quantities was probably given to Monsanto in August 1969 when its Medical Director recommended restricting the use of PCB fluid in food processing equipment to closed systems. As to food products containing minimal amounts of PCB, the earliest date of notice of possibly harmful effects is probably January-February 1970, unless the August 1969 memo is deemed to be sufficient notice. This is the date that Environment magazine published an article which stated that small amounts of Aroclor residues in milk could be harmful to humans. By July 1970, when the FDA set its "action level" standards for PCB contamination in poultry and milk, Monsanto had notice that minimal contamination of food products was impermissible.

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