

Monsanto

Monsanto Company
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June 7, 1982

Mr. Ronald Clark
Editorial Page Editor
ST. PAUL PIONEER PRESS
55 E. 4th Street
St. Paul, MN 55101

Dear Mr. Clark:

Your May 17 editorial on PCB chemicals wrongly assails industry's motives in seeking a review of the latest health-effects information on PCBs.

Contrary to your assertion that "those pushing for the review are eager to resume manufacturing and using PCBs," Monsanto Company, formerly the sole U.S. producer of PCBs, has no intention or desire whatsoever to resume PCB production.

Once PCBs had been judged an environmental problem, Monsanto took prompt and responsible action toward them. In 1972, the company voluntarily began phasing out the sale of PCBs for certain uses, and by 1977 had halted all PCB manufacture. This occurred two years prior to the 1979 federal ban on new production of PCBs.

Your editorial also states that industry studies of PCB effects "ought to generate more skepticism than optimism." Setting aside the patent unfairness in implying that all industry health-related research is suspect, you and your readers should know that the studies you cited (done by contractors for the Edison Electric Institute and the Chemical Manufacturers Association) are not original research but rather reviews of recent research done primarily by government agencies, universities and medical schools.

Among this work, for example, is a study performed by the National Institute for Occupational Safety and Health involving more than 2,500 electrical equipment manufacturing workers, more than half of whom were exposed to PCBs on the job in excess of 20 years. This study found no excess deaths among the workers nor any increase in mortality due to cancer, cardiovascular disease or neurological disorders. Similar findings have emerged from other epidemiologic studies.

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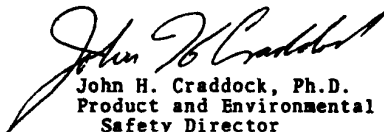
Mr. Ronald Clark

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Monsanto feels that an open-minded reading of the complete scientific record on PCB health effects leads a reasonable person to conclude that PCBs, while environmentally long-lived and a potential source of temporary dermatitis, are not human cancer agents nor are they associated with other long-term serious health effects. In short, the "sign of welcome relief" on PCBs rejected by you is entirely justified in our opinion.

Monsanto supports reasonable regulations and disposal requirements for PCBs. Again, we are not interested in going back into the PCB business. But we are concerned about overly zealous controls based upon incomplete science and an hysterical public fear of these compounds out of all proportion to their genuine risks.

Sincerely,



John H. Craddock, Ph.D.
Product and Environmental
Safety Director

/ec

enclosures 4: PCB News Release

PCB Health/Environmental Effects Fact Sheet

PCB Regulatory History Fact Sheet

PCB Production History Fact Sheet

bcc: S. G. Collins

L. J. O'Neill

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PCBs MINI SYMPOSIUM ISSUES

Session No.	Session Topic and Issues	Authors	Discussants
I	Analytical Methodologies • Current threshold concentrations for identification of PCBs in the environment using various analytical methodologies • Current threshold concentration for identification of polychlorinated dibenzofurans (contaminants of PCBs) • Need, if any, for standardized sampling procedures to reduce inter-laboratory variability in PCB residue analysis • Identification and measurements of PCBs formed in process streams • Discussion period	Dr. Edo D. Pelliazari	Dr. Mary S. Wolff
II	Exposure Studies--Environmental Residues and Bioaccumulation Environmental Residues 1. Quantity of PCBs released to environment per year from "totally enclosed systems" and other sources 2. Quantity of PCBs released from leaking condensers and transformers 3. Quantity of PCBs released through disposal processes • Efficiency of high temperature PCB disposal • Efficiency of PCB disposal in industrial boilers and impact of disposal in wider areas 4. Dispersal pathways of PCB following environmental release • Effect of release concentrations of PCBs in Great Lakes, in other open "PCB hot spots" for next 10, 20, 30 years • Impact of anticipated release on PCB concentrations in edible fish from these waters 5. Populations specifically exposed and exposure trends • Recent data concerning concentrations and stability of PCBs in various ecological environments, and the decay half-lives of these systems	Dr. Brock Neely	Dr. Mark Melancon

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PCBs MINI SYMPOSIUM ISSUES--continued

Session No.	Session Topic and Issues	Authors	Discussants
	- o Background levels of PCBs in the atmospheric, terrestrial and aquatic compartments of the environment - o Average residence times for PCBs in the three environmental compartments or, conversely, the degradation rates in air, water and soil - o Assuming no further release of PCBs, anticipated decay rate in food supplies, background levels and human tissue		
	6. Comparison of expected field levels of PCBs to effect levels in mammals		
	7. Probability of PCB transformer/condensor fires forming TCVDs and PCDFs; impact of seed fires		
B.	Bioaccumulation	Dr. Mary Jo Vodicnik	Dr. Mark Melancon
	1. Bioaccumulation rates of PCBs in fish, wildlife and humans		
	2. Excretion rates of PCBs in fish, wildlife and humans		
	3. Impact of PCB bioaccumulation in plants		
	4. General description of biotransformation patterns		
	5. Likelihood of acute lethality resulting from food chain accumulation of PCBs in aquatic environment		
	6. Likelihood of acute lethality resulting from food chain accumulation of PCBs in terrestrial animals		
	7. Recent data on bioaccumulation and persistence of PCBs in food chain		
C.	Discussion period		
III	Exposure Studies--Industrial Processes	Dr. Kent Hodges	Dr. Robert Kaley
	- o Estimation of PCBs incidentally formed in various process streams - o Worker exposure streams - o Potential for environmental release - o Relative importance of release compared to existing environmental pools of PCB - o Discussion period		
IV	Health Effects--Epidemiology	Dr. William R. Gaffey	Dr. Renate Kimbrough
	o Studies of sports-fishermen in Michigan who have consumed high concentrations of PCBs in contaminated fish		

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PCBs MINI SYMPOSIUM ISSUES--continued

Session No.	Session Topic and Issues	Authors	Discussants
	• Study on Michigan farmers exposed to PCBs from silos coated with PCBs • Recent reviews of "Yusho incident" • Other incidents involving PCB exposure • Recent studies on PCBs in human tissues • Half-lives of PCBs in humans • Discussion Period		
V	Health Effects--Laboratory Studies	Dr. Seymour Friess	Dr. Renate Kimbrough
	A. Reproductive Effects	Dr. Stephen Safe	
	1. Relevance of studies on reproductive effects in Rhesus monkeys (Allent et al.) for humans 2. Other recent studies demonstrating reproductive effects • Dosage levels • Species • Types of abnormalities • Incidence • Types of abnormalities • Incidence • Severity • Number of effect levels • Significance levels for parameters 3. Significance of animal reproductive studies and conclusions about potential effects of PCBs on human reproduction		
	B. Carcinogenicity		
	1. Recent studies on carcinogenicity of PCBs • Dose-response relationships over time • Statistical significance 2. Consensus of scientific opinion on carcinogenicity of PCBs in animals and humans • PCBs as "initiators" or "promoters" • Mode of action for reported carcinogenic effect (and specifically arene oxide formation) 3. Significance of animal studies to human population		
	C. Mutagenic Effects		
	1. Recent studies on mutagenicity of PCBs • Mutation frequencies • Statistical significance • Proposed mechanisms of action and evaluation of their appropriateness • Sensitivity of test method		

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PCBs MINI SYMPOSIUM ISSUES--continued

Session No.	Session Topic and Issues	Authors	Discussants
	2. Conclusions - o Mutagenic potential of PCBs - o Significance of animal data to human population D. Other Health Effects 1. Placental transfer rates 2. Rate of entrance of PCBs into human breast 3. Potential target organs in humans - o Neuroendocrine effects on thyroid, adrenals, gonads and hypothalamic-pituitary axis hepatotoxicity - o Others 4. Dermal and inhalation absorption rates in humans 5. Significance of observed persistent chloracne and skin pigmentation changes 6. Relevance for humans of studies by Allen et al. in demonstrating learning disabilities in Rhesus monkeys and low PCB dosages 7. Evidence of detrimental effects on learning in species other than monkeys 8. Other health effects observed for PCBs - o Effect - o Species - o Dose - o Statistical significance E. Discussion period		
VI	Environmental Effects A. Recent studies on ecotoxicity of PCBs in various fish and wildlife species 1. Reported effects 2. LD50s 3. Statistical significance B. Impact of impaired reproduction on phytoplankton, daphnid and fish populations 1. Potential for population changes 2. Potential for community disruption C. Reproductive impairment in exposed birds 1. Residues in bird eggs 2. Behavioral alterations 3. Relative contributions to impaired reproduction	Dr. Richard Hunter	Dr. Mark Melancon

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PCBs MINI SYMPOSIUM ISSUES--continued

Session No.	Session Topic and Issues	Authors	Discussants
	D. Relative sensitivity of mammals to reproductive and lethal effects of PCBs 1. Mink 2. Felines 3. Primates 4. Rodents 5. Others E. Modes and rates of absorption for fish and wildlife F. Comparison of field concentrations of PCBs and reported effect levels for reproductive and other chronic effects in fish, birds and mammals of economic importance 1. Water, sediment and food chain concentrations 2. Modification of PCBs' toxicity by metabolism in mammals or fish G. Significance of mutagenic effects studies in animals on fish and wildlife population H. Significance of carcinogenic effects studies in animals on fish and wildlife population I. Discussion period		
VII	Risk Assessment • Health and environmental implications of current environmental and human tissue concentrations of PCBs • Relationship of environmental and human tissue concentrations of PCBs to exposure • Possible environmental concerns for safety of monochlorinated biphenyls and other low chlorinated isomers • Impact of analytical uncertainties for PCB residue analyses on risk assessments • Potential synergistic activity of PCBs with other chemical groups, and estimates of numbers of chemicals in each group for which synergism may exist • Concern for increased susceptibility to disease in populations of animals after PCB exposure • Discussion period	Dr. Robert James	Dr. Roy Harbison

Monsanto

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April 15, 1982

Mr. Barry Sheerman, MP,
Huddersfield East
House of Commons
WESTMINSTER
London, England SW1A 0AA

Dear Mr. Sheerman:

Mr. Dan Bishop, Director of Public Affairs of Monsanto Europe, SA, asked that I respond to your letter of March 26.

It is difficult to present the scientific evidence relating to the health, toxicity and environmental effects of PCB's in a few pages; however, the task of reviewing the data from the thousands of studies (over 5,800 since January, 1976) is not impossible.

Recent thorough reviews of the health and toxicity effects of PCB's, with particular emphasis on data obtained and published since 1975 when the Toxic Substances Control Act was being drafted, have been conducted by several independent reviewers, including the scientific staff of the Department of Medicine and Environmental Health of Monsanto Company. Results of these reviews have been published and were submitted to the U.S. Environmental Protection Agency.

Results of these reviews, including an extensive scientific review of more than two dozen health studies dealing with human exposures to PCB's, fail to show a link between the chemical and human cancer (see attachments). The human epidemiology studies have shown that while exposure to PCB's can cause temporary skin problems, there are no clinically observable long-term health effects, including the occurrence of cancer.

All of the occupational studies of health effects agree that there has been no clinical illness associated with PCB exposure other than dermatitis (skin disorder). Studies of non-occupationally exposed populations have found neither dermatitis nor other clinical evidence of exposure-related effects.

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These conclusions are based on an extensive review of published and unpublished epidemiologic studies which have been performed by a number of scientists in the United States and abroad, including those from Federal and State governmental agencies, universities and medical schools.

In addition, thorough reviews of the scientific and technical literature, relating to health effects of test animals exposed to PCB's, by several independent bodies show that PCB's are not "deadly toxins" as occasionally misrepresented in the news media. On the contrary, as pointed out in the attached summary report, any impact of PCB's on the environment is so slight as to be totally insignificant.

The report of the U.S. science body of the National Research Council of the National Academy of Sciences ("Polychlorinated Biphenyls", National Academy of Sciences, Washington, DC, 1979) sums up even the most recent reviews:

"Although PCB's have been detected in the U.S. population, there have been no documented cases of PCB intoxication of humans other than those related to industrial exposure. Effects, when detectable, have been subtle rather than overt."
(Page 122)

With respect to the letter of Dr. D. J. Roberts on the subject of PCB destruction research funding, there are other areas of error in fact other than PCB health effects or in insinuations based upon partial facts.

For example, the U.S. EPA Industrial Environmental Research Laboratory at Cincinnati, Ohio, published a draft document in June, 1981, discussing "High-Temperature Degradation Characteristics of Hazardous Organic Wastes -- A Laboratory Approach." In these studies, pure PCB's were degraded under a series of controlled incineration conditions. The EPA report noted that "no dioxin structures were observed" as reaction/degradation products of the PCB's tested.

Dr. Roberts states correctly as noted also in the National Academy of Sciences report that Aroclor® brand PCB's may have contained contaminant polychlorodibenzo furans at trace levels (i.e., up to 2.0 ppm). Dr. Roberts insinuates that this may pose a significant health risk. However, the

Mr. Barry Sheerman

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recent health reviews prepared for U.S. EPA took this contaminant issue into account in their evaluation of PCB health effects. The reviewers stated:

"It is our independent professional opinion that 'any exposure to PCB's' does not pose a significant health risk to humans. These conclusions are based upon data of the primary exposure to commercial grade PCB's."

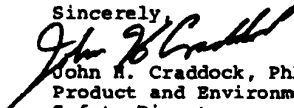
In most animal and human epidemiology studies reported in the literature which were reviewed, the form of PCB material that the subjects were exposed to was "commercial" PCB's and its concomitant impurities, if any.

Lastly, Dr. Roberts states his interest is to seek funding for research programs on methods for disposing of PCB's, particularly hydrodechlorination reactions. I sympathize with his efforts to solicit sponsorship. This area is a very active and fertile one for PCB disposal methods. Currently, in the U.S. no less than five commercial processes for dechlorination of dilute PCB's in transformer fluids have been approved or are being tested by EPA. Three of these processes are available for commercial hire now.

Enclosed are several summary packages of information on the PCB issue for your use. I have chosen summaries so as not to deluge you with tons of paper; however, details are available.

I'll be happy to attempt to answer other questions you may have on this subject.

Sincerely,


John R. Craddock, PhD
Product and Environmental
Safety Director

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enclosures: Ecology & Environment, Inc., Executive Summary
Report for Chemical Manufacturers Association
CMA Comments to ANPR (46 FED. REG. 16096),
Pages 7-18
Edison Electric Institute Comments on Use of
PCB's, Vol. I, Pages 7-14
80-015 Package

cc: Mr. D. R. Bishop - MONSANTO EUROPE, SA

bcc: C. J. Larsen


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