ATTACHMENT

Excerpted From:

"Summary of the Health Effects of PCBs"
Prepared For: Chemical Manufacturers Association
November, 1981
By Ecology and Environment, Inc.
Buffalo, New York

This total document evaluates several recent reviews of the scientific literature describing the health and toxicity effects of PCB's, including three technical publications of the Department of Medicine and Environmental Health, Monsanto Company, St. Louis, Missouri.

The attachment presented here consists of only the Title Page, Table of Contents, Preface and Executive Summary. The full summary and documents cited in the Preface will be submitted to the Agency by the Chemical Manufacturers Association as part of their response to the DC Circuit Court mandate in EDF vs. EPA.

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# SUMMARY OF THE HEALTH EFFECTS OF PCBs

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Prepared for:

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# PREFACE

The technical review concerned with the effects of PCBs, as provided on the following pages, summarizes the findings reported in the following documents:

- "The Epidemiology of PCBs" by William Gaffey, a Monsanto publication, (1981).
- "A Review and Evaluation of Carcinogenicity Studies in Mice and Rats and Mutagenicity Studies with Polychlorinated Biphenyls" by George Levinskas, a Monsanto publication, (1981).
- "The Toxicity of Aroclor Products 1242, 1254, and 1260 to the Liver of Albino Rats" by George Levinskas, a Monsanto publication, (1981).
- "Human Health Effects of Electrical-Grade PCBs" by J.F. Brown, Jr., J.T. Coe, and H.D. Pocock, Jr., a General Electric publication, (1981).
- "Technical Review of the Health Effects of PCBs" by Robert James, Morris Cranmer, and Raymond Harbison, a New England Gas Association publication, (1981).
- "Assessment of Carcinogenic Risks From PCBs in Food" by Kenny S. Grump and Marjory Masterman, prepared for the United States Congress Office of Technology, contract # 933.1350.0, (1979).

The reader will note that, with the exception of the section on risk assessment, the summaries in this report contain no specific references to other documents. Since the documents listed above, which review the pertinent literature on PCB health effects to date, give specific references for further study, it was not thought necessary to repeat these same citations in the body of this report. For a more in-depth review of the pertinent PCB literature and specific citations, it is suggested that the reader refer to the documents listed above.

## EXECUTIVE SUMMARY

In this paper we examined the human health risks associated with exposure to PCBs. To accomplish this purpose, we reviewed all significant published or readily available studies of the effects of PCBs as well as the pertinent current theories of carcinogenesis, the scientific body of knowledge which supports these theories; and have provided an analysis of the chemical carcinogenesis testing performed with commercial PCBs. As a result of this review and evaluation, it is our independent professional opinion that "any exposure to PCBs" does not pose a significant health risk to humans. These conclusions are based on data of the primary exposure to commercial grade PCBs.

After reviewing the carcinogenesis test data, we have concluded that commercial PCBs do not represent a carcinogenic (genotoxic/initiator) risk and that, even if they possess oncogenic (epigenetic/promoting) activity, the risk at low exposures is insignificant. This mechanistic distinction is a very important basis from which to address the cancer risk. To paraphrase a succinct summary of this distinction by Weisburger and Williams, promoters (oncogens) share the characteristic of being active only at high, sustained doses, and up to a certain point, the lesion may be reversible. Thus, these types of carcinogens represent only quantitative hazards to humans, and safe levels of exposure may be established by carrying out proper dose-response studies.

Attempts to estimate the potential risk of cancer to man caused by PCB exposure using data developed in rodents represents a controversial but crucial dilemma. Numerous studies involving both mice and

rats have been reported, but only one study exists to date that suggests PCBs may cause an increase in hepatocellular carcinoma. When the paucity of convincing data is compared to the large number of negative tests, and when other important contributing factors are considered (e.g., the spontaneous rate of liver injury and liver regeneration, thereby promoting aberrant hepatocellular growth; etc.), it is difficult to conclude that PCBs represent a significant cancer risk in man.

Analysis of published animal data leads to the conclusion that, in animals, commercial PCBs represent a low acute exposure hazard; that mutagenic, teratogenic, and reproductive risks are minimal; and that the carcinogenic potential of this compound has not been convincingly demonstrated in an animal model relevant to man. This lack of suggestive risk based on animal data has been further borne out by the fact that neither liver nor other cancers in man have been positively linked to PCB exposure in recent epidemiologic studies utilizing large study populations.

At worst, PCBs at high or elevated doses meet some of the criteria for a chemical promoter, i.e., they enhance tumor growth through epigenetic mechanisms but do not induce new tumor growths. This distinction is of extreme importance and can be made based upon the known mechanisms for genotoxic carcinogens and those for promoting agents. PCBs demonstrate many characteristics of the latter and none of the former. A further importance of this distinction is that PCBs have only been shown to possess a weak promoting activity at most. Therefore, the thresholds both proposed in theory and observed in animal studies suggest that there are safe exposure levels for PCBs.

The occupational exposures are certainly the most extensive and longest-term human PCB exposures that we are currently aware of, and are therefore probably most representative of what adverse effects might be expected. A comparative review of these occupational-exposure studies reveals that, like other chemicals, PCBs can cause adverse health effects, but in many respects these have been minimal. While dermatitis and chloracne, which were reversible after discontinuing the exposure, have been noted in some cases, no other significant findings were routinely made. Even though several studies incorporated clinical chemistry analysis as indications of organ

dysfunction or other physical disorders, no remarkable clinical findings have been uncovered. Furthermore, several investigators have commented to the effect that there is a "paucity of abnormal results" and that "there is no evidence of physical harm resulting from working with PCBs." In spite of over 50 years of use, no causal relationship has been established for any specific type of cancer, nor has it been proved that the incidence of cancer mortality has increased. The largest study, by the National Institute for Occupational Safety and Health (NIOSH), which involved over 2,500 persons, did not detect any statistically significant excess in the cancer mortality. Since this study failed to demonstrate an excess cancer rate in a high exposure population, it provides some reassurance that it is unlikely that future studies will show any increased risk of cancer from PCBs.

In summary, epidemiologic studies have demonstrated that PCBs are not remarkably toxic chemicals after acute exposure, and that when excess exposure does occur, the usual consequences are dermatologic and not of a serious or permanent nature. Chronic exposures have added little or no additional adverse effects of note to this picture. The preponderance of studies has not identified a clinical disease associated with exposure to PCBs, nor has it provided persuasive evidence of health impairment. There is no evidence of an excess in total mortality or in mortality due to cancer, cardiovascular disease, or nervous system disease associated with occupational exposure to PCBs. PCBs have not been linked to any human cancer, and studies to date indicate it is highly unlikely future studies will establish such a link. Therefore, it appears that PCBs are not a remarkable toxicant, but a chemical which requires high doses to produce harmful effects.

The chemical analyses of PCBs have shown that they often contain polychlorinated dibenzofurans (PCDFs) at low levels. The concentrations of these toxic contaminants are generally in the parts-per-million range in pure PCB mixtures, but percent of contamination can be substantially increased as a result of industrial use. Since levels of PCBs generally found in the environment are in the parts-per-million range or lower, the concomitant concentrations of PCDFs would be expected to be unmeasurable. For this reason and because the toxicity data of all PCB exposures have probably included this

contaminant, the concern for low level exposures to PCDFs is still expected to be minimal. However, the conclusions reached in this report apply to exposure to commercial PCBs and cannot be applied to all environmental PCB exposures, which may include exposure to concentrated contaminated waste mixtures.