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Dr. Ed DeNike
Bio/Chem Investigations Section
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7272 Cleanwater Lane, LU-11
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Dear Dr. DeNike:

First, let me apologize for the delay in responding to your phone and written requests for PCB information. However, I finally pulled together and sorted these documents, hopefully to minimize volume and not reduce broad technical content.

The following comments relate to your letter and questions and the documents I have enclosed:

1. Most of the information in the attachments will relate to PCB health effects/testing. As noted in several of the reviews (e.g., CMA Review, Drill, Friess et al,) most testing of PCBs published in the literature, including all the rat chronic feeding studies, used commercially available Aroclor® PCB fluids obtained from Monsanto. These fluids were tested "as is" with any attendant incidental impurities that might be present such as the PCDFs. Also, the retrospective epidemiological studies on various workers groups or environmentally exposed populations, studied groups primarily exposed to these same grades of commercial Aroclor® fluids and formulations with other chemicals such as tri/tetrachlorobenzenes in the case of electrical equipment workers/dielectric fluids.

   As the authors of the two major reviews (CMA and Drill, Friess et al for NEMA-EEI) note such impurities/mixtures had little influence on the outcome of the studies since no significant chronic human health effects except skin problems were noted.

2. I think your observations and conclusions that PCPFs and PCDDs are rather ubiquitous is correct from data that I've seen published. The Dow paper published in Science (Attachment 4) is a good reference on this subject. Another more recent document is the Choudhry and Hutzinger publication (Attachment 5) which gives in detail, decomposition products of various hydrocarbons and halogenated hydrocarbons and discusses thermal decomposition, including incineration. Again, I agree with your conclusions



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that proper incineration at sufficiently high temperatures could probably provide adequate control for this problem. This is the basis for EPA's PCB incineration/disposal rule. I think your temperature range of 4000°-5000°F is "over kill" based upon EPA's laboratory and stack sampling studies performed in conjunction with permitting commercial PCB incineration disposal sites (e.g., Rollins at Deer Park, TX and ENSCO at El Dorado, AR). These studies are available from Reg. VI EPA and I have copies somewhere in my files if you can't locate them).

3. Your observation that the key to this dilemma is "what creditable scientific investigation could be used to establish cause for removal?" is right on target. Anything any of us can do to put this problem in the realm of scientific and medical evidence, instead of emotionalism and politicism will go far towards resolving these issues and regaining public confidence.

   I (and other scientists, physicians and health professionals) believe that where available, human health studies should be used to help arrive at a responsible decision. Although these are almost always retrospective studies that involve many other variables, in many cases a weight of evidence is being built up. I don't think such human exposure data can be lightly and summarily dismissed in favor of a few laboratory animal studies in some cases. Being in St. Louis I am quite familiar (from the press and news media) with the Missouri Dioxin issues, particularly Times Beach. This has turned out to be a political circus involving little, if any, true scientific discussions.

4. There have been some scientific realizations in U.S. EPA that the PCB issue is not actually as bad as it was originally perceived when the Toxic Substances Control Act of 1976, which regulates PCB manufacture, use, storage, etc., was passed. Up to that time there was really only one large scale human exposure incident (Yusho) that was investigated.

   Since 1976 continuing epidemiological study of Yusho and its victims and other exposed populations have led to publication of a dozen or so articles of human PCB exposure studies many of which were not published in peer review journals until after TSCA. These are reviewed quite well by Dr. Gaffey (Attachment 6), CMA (Attach 1) and the Drill, Friess Group (Attachment 2).

   Recent Federal Regulations related to PCBs (Attachment 7 and 8) have recognized that every PCB exposure is not necessarily significant and harmful and that there are levels of PCB that do not pose a significant risk to humans. For example, in the recent PCB regulations, 40 CFR 1761, published in the Federal Register November 8, 1984 (FR 49, p. 44634-44638 at p. 44635) the U.S. EPA deleted the previous definition of "significant exposure" and states "further rulemakings by EPA have established that there may be exposures to PCBs which are not significant." Thus, EPA amended the rule as follows:



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> "that any exposure of humans or the environment to PCBs, as measured or detected by any scientifically acceptable analytical method may be significant, depending on such factors as the quantity of PCBs involved in the exposure, the likelihood of exposure to humans and the environment, and the effect of the exposure." (emphasis mine)

In addition, the PCB regulations (40 CFR 1761) were amended effective October 1, 1984 by new rules published in the Federal Register July 10, 1984 (FR 49, p. 28172-28193 at p. 28176, Col 2) which allows certain PCBs in new products at an average level (annually) up to 25 ppm and a maximum excursion level up to 50 ppm. These levels are based upon exposure assessments conducted by EPA for hypothetical levels and situations. EPA concluded "that the risks associated with these exposure situations are not unreasonable." These exposure scenarios should be available from U.S. EPA Office of Toxic Substances. Again, I may have them if you have trouble getting copies.

The following publications are enclosed for your review and use. They provide a basis to support the above conclusions and also may provide some material to fill in your outline. The references in publications A-1, A-2, A-3, A-6, A-9 and A-10 are probably the most pertinent of the numerous PCB health effects articles published. (Over 5000 PCB health/environmental effects articles have been published since 1976 according to one estimate.)

These references do not contain many papers that deal with specific PCB congeners and their toxicity etc. or similar articles for PCDFs and PCDDs. In the past 3-4 years numerous congener-specific articles have been published, however, it would be a scientific and regulatory morass to try to analyze and regulate the several hundred specific congeners in these three classes of compounds. I personally attempt to deal with them on a "family" basis while noting interesting papers on specific congeners.

I hope this information helps your report. I would be happy to discuss any of these or other references with you. Give me a call after you've had time to digest this information.

Sincerely yours,

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

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## LIST OF ATTACHMENTS

1. Exerpts (including Executive Summary) from Chemical Manufacturers Association, "Summary of the Health Effects of PCBs." (This Review and Reference Material are available from Chemical Manufacturers Association, Washington, D.C. or U.S. EPA, OTS, Washington, D.C., Nov. 1981.

2. "Highlights of the Potential Health Effects in the Human From Exposure to Polychlorinated Biphenyls (PCBs) and Related Impurities" prepared by Drill, Friess, Hayes, Loomis and Shaffer, Consultants in Toxicology for Edison Electric Institute (EEI) and National Electrical Manufacturers Assn. (NEMA), Feb. 1982.

3. "Literature Update on Potential Health Effects from Exposures to Polychlorinated Biphenyls and Related Chlorinated Heterocycles" prepared by Drill, Friess, et al, Dec. 1983.

4. "Trace Chemistries of Fire; A Source of Chlorinated Dioxins", Bumb et al (Dow Chemical Co.).

5. Title pages of Mechanistic Aspects of Thermal Formation of Halogenated Organic Compounds Including Polychlorinated Dibenzo-p-Dioxins. Choudhry and Hutzinger. 1983.

6. "The Epidemiology of PCBs", W. R. Gaffey, 1983.

7. Federal Register, 49, p. 44634 ff.

8. Federal Register, 79, p. 28172 ff.

9. Material Safety Data Sheet - Polychlorinated Biphenyls - PCBs, Monsanto, 1980.

10. PCBs: Is the Cure Worth the Cost? American Council on Science and Health, Jan. 1985.

11. Polychlorinated Biphenyls - PCBs, A Report on Uses, Environmental and Health Effects and Disposal, Monsanto Co., Nov. 1979. (Summary of presentations and data submitted to U.S. House of Representatives Committee.

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