

Environmental Roundup

New Study Raises Doubts About Earlier Work on Health Effects of PCBs

In a paper released in mid-September, William R. Gaffey, an epidemiologist with Monsanto Co., made public the findings of examinations of 24 epidemiologic studies of human exposure to polychlorinated biphenyls (PCBs). The results of the paper are sure to prove controversial in the current regulatory setting, in which the Environmental Protection Agency is engaged in an effort to revise PCB regulations which were overturned by the federal Court of Appeals for the District of Columbia in 1980. Gaffey concluded, after examining the 24 studies:

Alterations in liver and fat metabolism were found in most studies that examined these functions, but there was no clinical illness associated with these alterations or with level and duration of exposure to PCBs. Studies of mortality rates in exposed populations have shown no pattern of cancer deaths related to PCB exposure.

For many years, PCBs have been accused of causing illnesses ranging from acne to cancer. Widely used in heat-resistant dielectric fluids for transformers and capacitors, as well as hydraulic systems and electrical motors, PCBs are not biodegradable. Only recently have acceptable methods of PCB destruction been developed, through incineration at exceedingly high temperatures or through a chemical process which breaks down the PCB molecular structure into harmless components. The push to eliminate PCBs from the environment was given strong impetus when Congress passed the Toxic Substances Control Act (TSCA) in 1976. TSCA gave broad regulatory authority over chemicals to the EPA, but mentioned only one specific chemical as a target for regulation: PCBs.

Behind the regulatory and legislative drive to regulate was a series of animal and human studies on health effects of PCBs. Gaffey did not attempt to review every such study, but concentrated on three types of studies:

- 1) Studies of accidental heavy exposures to PCBs and resulting acute and chronic effects.
- 2) Studies of the relationship between exposure to PCBs and the resulting body burden of PCBs in serum or adipose tissue.
- 3) Studies done because the populations in question were known or suspected to be exposed to PCBs.

Gaffey characterized other studies, particularly clinical studies of the effects of heavy exposure to PCBs, as "extremely useful in identifying the kinds of effects that should be studied." He did not

review such studies, however, because those studies "do not address the question of the risk of incurring such effects."

Accidental Heavy Exposure

There were two studies of such exposure reviewed by Gaffey. In the first, involving 14 workers in a plant where a process change had introduced an unspecified PCB compound into the plant environment, Gaffey agreed that seven of the 14 had developed chloracne as a result of their exposure to the PCB compound. The acne condition later disappeared upon treatment, while improved plant controls prevented any further recurrence.

The second "heavy exposure" incident is the now-famous "Yusho incident," in which a thousand Japanese suffered illness after eating cooking oil which had been contaminated with Kanechlor 600, a PCB compound manufactured in Japan. The symptoms included hyperpigmentation, acne-like lesions, discharge from the eyes, central nervous system symptoms, vomiting and diarrhea. Nine of ten babies born to women involved at Yusho displayed hyperpigmentation and increased eye discharges, although these symptoms later disappeared. Among the Yusho patients, an increase in cancer deaths was noted, exceeding the norm for that locality.

Nevertheless, Gaffey concludes the relationship of these symptoms and effects of PCBs is highly questionable for a number of reasons. With regard to the cancer deaths, Gaffey notes that the criteria for diagnosis of Yusho had changed after the original incident, so that in determining percentages of cancer deaths it was impossible to determine how the earlier researchers were able to reach their conclusions. Secondly, in comparing Yusho cancer deaths to cancer deaths in the immediate locality, no adjustments had been made for age. Finally, the time from exposure to death was less than ten years, which Gaffey concluded "may well be too short a period for cancers resulting from the exposure to show up."

The most important evidence throwing the Yusho incident into a new light, however, is more recent reanalysis of the cooking oil ingested by the victims. These more recent examinations of oil showed that PCBs were not the only contaminants. In fact, polychlorinated dibenzofurans (PCDFs) and polychlorinated quater-phenyls (PCQs) were ingested in amounts roughly equivalent to the amount of PCBs consumed by the victims. Not only does this fact make it

difficult to establish any clear cause-and-effect relationship, it also makes it nearly impossible to generalize on lower level environmental or occupational exposure to PCBs, based on the role of PCBs in the Yusho incident.

Environmental Levels and Body Burdens

Gaffey believes that epidemiological studies on this topic have clearly shown that there is a relationship between the amount of PCBs in blood and fatty tissue and the amount of PCBs in the environment to which the subjects are exposed. Once exposure to PCBs is eliminated or decreased, however, the decrease in the body's burden of PCBs is not consistent. Gaffey cannot explain conclusively these inconsistencies, but does point to a number of possible factors:

- 1) Inconsistency may be due to the short observation periods in some of the studies.
- 2) Inconsistency may be due to differences in the average number of chlorine molecules in the PCBs involved.

Gaffey noted additional inconsistencies among studies which attempted to establish a relationship between the amount of PCBs in the body and the length of exposure to PCBs. While this could be due to the confusing effects of a subject's age and sex, it also could be due to the differences in the metabolism of high and low-chlorinated PCBs. More highly chlorinated PCBs are more likely to accumulate in adipose or fatty tissues than are the less highly chlorinated PCBs.

Epidemiologic Studies of PCBs and Health

In reviewing these studies, Gaffey divided his examination along lines of major categories of health effects.

Dermatologic effects. There is great difficulty in diagnosing chloracne, in determining blood PCB levels, as well as rapidly developing technology for making such determinations. In spite of these obstacles, Gaffey believes that the studies strongly suggest that chloracne can occur when PCB blood levels exceed roughly 150-200 parts per billion. Besides chloracne, there also appears to be a relationship between dermatitis and high chlorinated blood PCB levels.

Liver function. This is one health effect which has been widely publicized by those promoting the regulation of PCBs. Yet when he reviewed nine studies on this particular effect, Gaffey concluded that four of the studies could find no liver abnormalities associated with exposure to PCBs. In the other five studies, some mild liver abnormalities were noted, but none of them could be associated with any adverse health effects.

Fat metabolism. Gaffey notes that most studies have associated PCB exposure with increased triglycerides, a blood

component consisting of fatty acids. The data remains inconsistent however, and Gaffey concludes that "if PCB exposure has some effect on fat metabolism, it appears to be without any apparent clinical significance."

Blood and blood pressure. One study has reported a "significant association between diastolic blood pressure and blood PCBs," but Gaffey believes that, because there was no control group with which to compare the subjects and since this was the only study to report a relationship, the significance of the study's findings are not clear.

Carcinogenicity. Of the four studies devoted specifically to this health risk, Gaffey finds that no study agrees with any other, therefore demonstrating that one of the prime requirements for an acceptable cancer study—repeatability—is lacking. In several of the studies, other potential carcinogenic agents could have been present, including cigarette smoking, but these factors were not accounted for by the studies. In one study which reported an excess of liver cancer deaths among workers at a capacitor plant, the deaths were inversely related to duration and latency of exposure. Occupational causation would therefore appear unlikely.

In short, concludes Gaffey, the existing studies "do not show the agreement that would lead one to infer an excess risk of cancer."

Importance of Gaffey's Work

Gaffey does not equivocate in summing up his findings. He argues that "the epidemiologic studies find that high occupational exposures to PCBs may cause dermatitis of various kinds, but that there are no other clinically observable effects, including the occurrence of cancer."

Gaffey has not conducted any new research, nor has he demonstrated that PCBs are harmless or relatively harmless. The importance of his paper is that it lays open to serious question some of the scientific underpinnings of the current PCB regulations, as well as the basis of Sec. 6(e) of the Toxic Substances Control Act.

It is unlikely that his report will receive a very warm reception within certain environmental groups or perhaps even within the Environmental Protection Agency. Nevertheless, since EPA is currently attempting to repair the damage done to its PCB regulations by environmentalists' legal challenges, Gaffey's report is particularly timely. There is no doubt that his findings, and the questions implied therein, will be raised and must be answered. If the EPA is to establish regulations that are both scientifically well-founded and capable of withstanding judicial scrutiny.

—Roderick T. Dwyer