WHAT INDUSTRY AND GOVERNMENT KNEW ABOUT THE HAZARDS AND EFFECTS OF POLYCHLORINATED BIPHENYLS

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ABSTRACT

Polychlorinated biphenyls (PCBs) were widely used in various industrial applications for their insulating and fire retardant properties. Monsanto Chemical Company manufactured them commercially beginning in 1929 until their banning by the U.S. Congress in 1976. While a few studies were performed in the late 1930's, detrimental environmental and human health effects were ignored by the science community until 1966 when a Swedish scientist noted harmful effects on wildlife caused by PCBs. PCBs did not reach public awareness until two widespread poisoning episodes were observed in Japan and Taiwan in 1968 and 1978, respectively. Although they were initially attributed to the consumption of rice oil contaminated with PCBs, adverse health effects were in fact caused by other chemicals.

After the poisoning incidents, considerable research was carried out on the possible adverse health effects from PCB exposure has been done. The major issue pertaining to PCBs is whether or not they cause an increased risk of cancer. Thus, many occupational studies have been conducted on workers in plants, who came in direct daily contact with PCBs. From these studies, there are two contentions about PCBs, industry and government. Industry believes that PCBs do not cause an increased risk of cancer and other diseases. The government believes that although the link between PCBs and cancer has not been found, it has been suggested. PCBs do affect the environment; they biodegrade slowly and thus tend to bioaccumulate in the food chain in addition to the adverse affects on wildlife caused by PCBs.

Companies continued to use PCB-containing compounds until they were banned in 1976, despite the fact that the companies within the industry knew about the possible adverse health and environmental effects. There had been enough industry analysis, even in the late 1930's, to indicate possible harmful consequences of PCBs' on their workers and to the environment. The companies chose not to examine the possibilities and ensure public health because the manufacture of PCBs was so profitable. In addition, the lack of stringent environmental standards and regulations allowed companies to overlook possible negative effects of PCBs.

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I. INTRODUCTION

There have been many changes in PCBs since their production began in 1929. Once thought to be miracle chemicals, PCBs also were believed to be one of the worst chemicals ever. The image of PCBs is changing in 2000 in light of new and more in-depth research such as occupational studies on workers exposed to PCBs daily. Since 1929, the companies that produced and used PCB-containing compounds have maintained their innocence. (Environmental & Health Weekly #144, 1989)

Outside sources and environmental activists began to question the safety and adverse health effects of PCBs after questions and fears were raised by employees and residents around PCB manufacturing facilities in the United States and Japan. Initial research and evaluation indicated potential threats to personal and environmental health, which led to years of additional research and case development. (Flynn and Kleiman, 1991, Updated Version, 2000)

The purpose of this thesis is to determine what industry, government, and outside sources know about the effects and risks of polychlorinated biphenyls (PCBs) and when that information was obtained. (Outside sources are defined here as reports of any type of research performed by sources other than government or companies that used PCBs: specifically Monsanto, Halowax, General Electric and Westinghouse.) This study was inspired by a current legal battle between Monsanto Industrial Chemicals Company and neighbors and residents of the Anniston, Alabama area.

This thesis traces available industry studies and information from the 1930s through the demise of PCB production in the late 1970s. In addition, more recent research was included from the early 1980s when more government and EPA interaction began and extensive cleanups and regulatory suits were in progress. This study also includes current (2000) research on PCBs and the results of that research. On the following page is a timeline which maps out all pertinent PCB information found during the course of this research. (FIGURE 1)

This research began with a brief study of articles and materials obtained from the prosecuting attorneys in order to understand what Monsanto claimed to have known about PCBs during the time that it manufactured PCBs. It continued with Internet and library studies to locate additional books, journals, periodical articles, and other documents of interest. While most of this available information was recent or current, references pointed back to older articles which were evaluated. This tracing process was taken as far back as possible until several of the original seminal articles were located and evaluated. Once the relevant research documents and materials were located, a thorough appraisal was performed to determine what information was relevant.

Prior to 1960	1960 to 1980	1980 to 1990	1990 to 2000
• (1936) Wife and child developed chloracne from mere contact with a worker's clothes. • (1936) Working with PCBs caused digestive problems, burning of eyes, impotence and hematuria. • (1937) Experiments performed leave no doubt as to the possibility of systemic effects from PCBs. • (1938) Liver damage could be caused solely by dermal contact of PCBs. • (1947) Long-term exposure to PCB fumes could be fatal. • (1959) More systemic injury (above chloracne) is probable if exposure were allowed to continue.	• (1966) Damage to wildlife is actually caused by PCBs, not DDT. • (1968) Yusho Poisoning Incident – health problems found not to be attributable to PCBs. • (1971) Memo about how the health of human and animal life and the risks of ignoring the evidence [on PCBs] was inappropriate for Westinghouse. • (1971) Monsanto began requiring all of its PCB customers to sign a waiver releasing Monsanto from liability. • (1976) Congress enacted §6(e) of TSCA banning manufacture, processing and distribution of PCBs except in totally enclosed systems. • (1978) Yu-Cheng Poisoning Incident – health problems found not to be attributable to PCBs.	• (1981) NIOSH Occupational Study – Blood PCB concentrations were higher in workers, but no adverse health effects found. • (1981) NIOSH – comprehensive study of long-term health effects of PCB exposure found no statistically significant excess of individual cancers. • (1985) Study of 194 heavily exposed workers found no adverse health effects. • (1987) A mortality study of GE employees found that the overall results do not indicate any increased cancer risk because of PCBs. • (1987) Health status, cancer incidence and cancer mortality study found no evidence that cancer rates or mortality rates were excessive. • (1988) A mortality study of 6292 GE Capacitor workers found no connection between PCBs and an increased cancer risk.	• (1990) Two studies on people eating PCB contaminated fish found no significant health effects from eating the fish. • (1990) Study found adverse effects in babies whose mothers ate contaminated fish – study was disputed and proven wrong due to incorrect assumptions. • (1994) Study failed to find an association between PCBs and excess cancer risk. • (1997) Cancer has not been correlated with levels of PCB exposure and therefore, cannot be attributed to PCB exposure. • (1999) No supporting evidence between PCBs and cancer and other diseases. • (1999) Largest and longest-running epidemiology study on the effects of PCBs was published and found that PCBs do not increase the risk of cancer or other diseases.

FIGURE 1 – Timeline of PCB Knowledge

II. BACKGROUND INFORMATION

In the following paragraphs is given a brief history of PCBs, including some information about Monsanto, the major U.S. manufacturer of PCBs, and an explanation of the chemistry of PCBs and their effects. This history also includes information pertaining to PCBs obtained by means of outside or third party research, government intervention, and public documentation on PCB safety, concerns, and environmental effects. This thesis concludes with a final evaluation of whether the PCB industry knew enough information to warrant additional research into the harms and effects that PCBs had on the environment and humans.

A. Chemistry

Polychlorinated biphenyls (PCBs) were discovered late in the 19^{th} century. They are a family of compounds produced commercially by directly chlorinating biphenyl. A PCB is any one of 209 compounds of the general formula $C_{12}H_xCl_y$, where x ranges from zero to nine and y = 10 - x. PCBs are formed by heating benzene under the appropriate conditions to combine two benzene rings, creating the biphenyl compound. The biphenyl compound has 10 positions available for chlorination. (FIGURE 2)

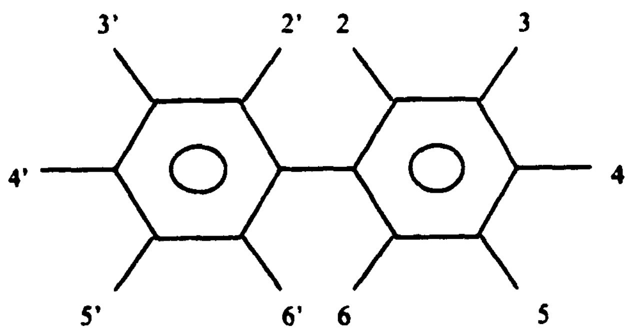

FIGURE 2 - Basic Chemical Structure of PCBs

PCBs were made by reacting anhydrous chlorine with biphenyl in the presence of ferric chloride, followed by distillation to obtain the finished product. Adding more or less chlorine gives compounds with different properties. The addition of chlorine decreases the solubility of PCBs in water. The addition of chlorine also increases the harm that the PCBs do to the environment. There are a total of 209 different congeners. (TABLE I) These compounds are all man-made and not present naturally. (Broadbank, 1991)

TABLE I

Distribution of PCBs by Level of Chlorination

Isomer Group	**Molecular Formula**	**Number of Compounds**
Monochlorobiphenyls	$C_{12}H_9Cl$	3
Dichlorobiphenyls	$C_{12}H_8Cl_2$	12
Trichlorobiphenyls	$C_{12}H_7Cl_3$	24
Tetrachlorobiphenyls	$C_{12}H_6Cl_4$	42
Pentachlorobiphenyls	$C_{12}H_5Cl_5$	46
Hexachlorobiphenyls	$C_{12}H_4Cl_6$	42
Heptachlorobiphenyls	$C_{12}H_3Cl_7$	24
Octachlorobiphenyls	$C_{12}H_2Cl_8$	12
Nonachlorobiphenyls	$C_{12}HCl_9$	3
Decachlorobiphenyls	$C_{12}Cl_{10}$	1
Total Number of Congeners		209

B. Applications

PCBs have characteristics that are desirable for many industrial applications, including dielectric heat transfer fluids, inks, dyes, paints and adhesives. Specifically, PCBs are acid-resistant and base-resistant, non-flammable, and insoluble in water, and have high boiling points and low electrical conductivity. In consistency, PCBs range from light oily fluids to greasy or waxy substances, and are clear to yellow in color. In addition, they are stable and do not change chemically over time. Since PCBs are ideal insulators for electrical transformers and capacitors, so major electrical firms like Westinghouse and GE became large users of PCBs as electricity came into widespread use during the first half of the twentieth century.

Other applications of PCBs include use as fillers in heating coils, carbonless "carbon paper", lubricating oils for industrial drills, caulking compounds for skyscraper windows, and as coolant in electrical motors in refrigerators, air conditioners, typewriters, and power saws. Over the years, a variety of products including cereal boxes, degreasers, varnishes, lacquers, waterproofing materials and bread wrappers included PCBs. The unique properties of PCBs allowed their use in the manufacturing of many common products such as plastics, adhesives, paints, and varnishes.

PCBs were discovered at the very end of the 19^{th} century when scientists were experimenting with petroleum. The Swann Chemical Company first manufactured PCBs commercially in 1929. Monsanto Chemical Company bought Swann in 1935 and continued to manufacture PCBs under the Aroclors trademark until 1975. Between 1930 and 1970, 1.4 billion pounds of PCBs were manufactured in the United States. (Broadbank, 1991). Before World War I, the Halowax Corporation began manufacturing chlorinated naphthalenes, which are related to PCBs, as coating for electric wire and companies, like General Electric and Westinghouse, began to use that coating. During the 1930s and 1940s, the Halowax Corporation often combined PCBs with chlorinated naphthalenes.

C. Environmental Effects

During their manufacture and use, PCBs were released into the atmosphere through sewers, smokestacks, weathering of asphalt and other substances containing PCBs, and open burning of PCB-containing products. PCBs continue to be released by leakage from old equipment, leaching from landfills and leaching from previously contaminated sediment. (Flynn and Kleiman, 1991, Updated Version, 2000) However, these PCB releases into the environment were considered acceptable practices in the past. For example, industries using PCBs in their processes and products discharged PCB-laden wastes into rivers and streams (often following government permits). Also, PCB-containing wastes were deposited in open landfills, and PCB-containing oil was sprayed on dirt roads for dust control. PCBs were used as extenders in some agricultural pesticides. PCBs were used in some ink formulations and were released when paper was discarded or recycled. PCBs were discharged from gas pipelines. PCBs also were released when PCB-containing equipment was damaged by accidents, fires or vandalism.

Many of the characteristics that make PCBs ideal in industrial applications create problems in the environment. PCBs are very persistent and do not readily degrade. Like many other chlorinated hydrocarbons, PCBs are soluble in fat, so they tend to accumulate in living things and to enter food webs, where they concentrate. Larger, older predators tend to accumulate PCBs in their fatty tissues, including their eggs (in the case of birds and fish) and their milk (in the case of mammals). (Environmental & Health Weekly #327, 1993) Because of bioaccumulation, the concentration of PCBs found in fish tissues moves up the food chain and bioaccumulates in higher species.

Acute toxic effects in the environment include death of animals, birds, or fish, and death or low growth rate in plants. Chronic effects from PCBs may include shortened lifespan, reproductive problems, reduced fertility, and changes in appearance or behavior. (Environmental & Health Weekly #327, 1993)

The whereabouts of 30 percent of all PCBs remains unknown. PCBs have spread to all parts of the world in some quantity. Another 30 percent reside in landfills, in storage, or in the sediments of lakes, rivers, and estuaries. About 40 percent remain in use. (Environmental & Health Weekly #327, 1993) A growing fear about PCBs in the environment is that they eventually reach the oceans. One percent of PCBs ever produced has already found its way to the oceans and is causing problems in the reproductive system of some aquatic life. PCBs enter the ocean by two routes - by deposition from the atmosphere and by drainage from rivers. Only about two percent of PCBs in the ocean have come from drainage from rivers. Thus, atmospheric deposition is by far the largest source.

D. Health Effects

In addition to the problems that PCBs cause in the environment, they also cause health problems in humans. PCBs are toxic, even at low levels. PCBs can enter humans through inhalation, ingestion or dermal absorption. Upon acute exposure, vapor can irritate the eyes, nose and throat and cause an acne-like rash called chloracne. Higher levels of exposure were once thought to damage the liver and the nervous system, causing numbness, weakness, and tingling in the arms and legs. Chronic exposure was thought to result in reproductive system problems and an increase in cancer and other diseases. However, recent research disputes a direct cause of these adverse health effects due to PCB exposure. (Flynn and Kleiman, 1991, Updated Version, 2000)

In 1976, the U.S. Congress banned the manufacture, sale and distribution of PCBs except in totally enclosed systems. PCBs were banned because of the two major food contamination incidents and have been regulated by the federal government as a "probable human carcinogen." Since 1976, many occupational health studies have been performed in order to determine the actual health risks associated with PCBs. (Flynn and Kleiman, 1991, Revised Version, 2000)

Although PCBs were important industrially due to their flame-resistant characteristics, other chemical options became available over time: silicone fluids; fluorocarbons; high molecular weight hydrocarbons; low molecular weight chlorinated hydrocarbons; as well as high boiling-point oils and esters. While these alternatives to PCBs work in electrical equipment, a transformer constructed for use with PCB fluids may not operate at the same power load with a substitute chemical; i.e., they must be "de-rated." (*Fed. Reg.*, 1985) Such transformers becomes less efficient, resulting in a higher operating cost as well as added risk of fire. Precautionary measures must be implemented to ensure fire safety and proper disposal of waste. Clearly, shifting from PCBs to alternatives has involved tradeoffs, not the *elimination*, of health and safety risks. (Flynn and Kleiman, 1991 Updated version, 2000)

III. RESULTS AND DISCUSSION OF RESEARCH

Hardly any research on PCBs was done before 1966. There is, however, evidence to prove that by 1966 the chemical companies that produced products containing PCBs had enough information about the problems caused by PCBs to warrant investigation. From this earlier information, it can be reasonably assumed that the problems caused by PCB exposures were serious and widely known, at least among the producers and users of PCBs. (Francis, 2000) Scientific knowledge about the dangers of PCBs has advanced along two tracks, one private and one public. Public knowledge on the dangers of PCBs was negligible until the 1960s.

A. Knowledge About PCBs Before 1960

A 1936 article written by Louis Schwartz, M.D., Senior Surgeon, U.S. Public Health Service, entitled "Dermatitis from Synthetic Resins and Waxes" was published in volume 26 of the American Journal of Public Health (June, 1936). Swartz wrote:

"In addition to these skin lesions, symptoms of systemic poisoning have occurred among workers inhaling these fumes. Those working with the chloro diphenyls (PCBs) have complained of digestive disturbances, burning of the eyes, impotence and hematuria. The latter symptom developed among a number of men making amino diphenyl, which is used in the manufacture of a rubber antioxidant. Causes of death from yellow atrophy of the liver have been reported among workers exposed to the fumes of the chloro naphthalenes." (PCB effect on the Lakewood neighborhood, 2000)

By the mid-1930's, workers at Halowax and at GE, and even some of their customers, were breaking out with chloracne - small pimples with dark pigmentation of the exposed area, followed by blackheads and pustules. In 1936 three workers at the Halowax Company died. Because of this, Halowax hired Harvard University researchers to expose rats to these chlorinated compounds and see if they could discover the underlying cause of the worker deaths.

The Harvard Researchers made "a number of estimates of chlorinated hydrocarbons in the air of different factories," and then designed experiments to expose rats to similar levels. They reported that "the chlorinated diphenyl is certainly capable of doing harm in very low concentrations and is probably the most dangerous (of the chlorinated hydrocarbons studied)." They also concluded "These experiments leave no doubt as to the possibility of systemic effects from the chlorinated naphthalenes and chlorinated diphenyls." (Drinker et al., 1937)

In 1937, eight years after Swann Chemical began manufacturing PCBs in commercial quantities, the Harvard School of Public Health hosted a one-day meeting on the problem of "systemic effects" of certain chlorinated hydrocarbons including "chlorinated diphenyl" which was an early name for PCBs. Representatives from Monsanto, General Electric, the U.S. Public Health Service, and the Halowax Corporation among others attended the meeting. (Environmental & Health Weekly #327, 1993)

There is also information to show that PCBs did not just affect the workers in the plants that produced PCBs. In 1936, a senior official with the U.S. Public Health Service described a wife and child, both of whom had developed chloracne merely from contact with a worker's clothes. (Environmental & Health Weekly # 329, 1993) The official also wrote, "In addition to these skin lesions, symptoms of systemic poisoning have occurred among workers inhaling these fumes." (Schroeder, 1991) After the death of the three Halowax employees in 1936, Monsanto Chemical Company started using a more pure blend of benzene to produce PCBs. After this switch, no other severe cases of chloracne were reported. It was concluded that impure benzene caused the death of the three Halowax employees.

In addition, a 1938 study of PCB-oil mixtures manufactured by Westinghouse and General Electric demonstrated that liver damage could be caused by skin contact alone, and called for the "greatest personal hygiene" in minimizing exposure. In a report on further research for Monsanto, Drinker warned that adequate ventilation was necessary when handling the chemicals. (Francis, 2000)

By 1947, E.C. Barnes of Westinghouse's medical department wrote in an internal company memo that long-term exposure to PCB fumes "may produce internal bodily injury which may be disabling or could be fatal." (Environmental & Health Weekly #329, 1993) Also, by 1959, the assistant director of Monsanto's Medical Department wrote to the Administrator of Industrial Hygiene at Westinghouse saying, "...sufficient exposure, can result in chloracne which I think we must assume could be an indication of a more systemic injury if the exposure were allowed to continue." (Environmental & Health Weekly #329, 1993)

B. Events Causing Public Awareness of the Dangers of PCBs

PCBs came to the attention of the scientific world in 1966 when studies in Sweden revealed the presence of PCBs in environmental samples (soil and water) being screened for DDT. In 1964, Soren Jensen was trying to study DDT levels in human blood when a mysterious group of chemical compounds kept recurring in his samples, interfering with his analysis. Jensen revealed that damage to birds originally attributed to DDT was in fact caused by PCBs. Jensen's research is what sparked the concern among the environmental community over environmental contamination by PCBs. (Francis, 2000)

The previously cited information was all discovered before possible problems with PCBs became public knowledge. However, two highly publicized incidents involving accidental contamination of food supplies with heating fluids containing PCBs aroused worldwide concern over potential health effects of PCBs. First, in 1968 about 1,300 people in Fukuoka, Nagasaki, and in other areas of western Japan became ill after consuming rice bran oil contaminated with 2,000 - 3,000 parts per million of thermally-degraded PCBs. These victims developed a severe, persistent form of chloracne. Further, the disease symptoms included fatigue, nausea, swelling of the arms and legs, liver disorders and neurological manifestations (primarily subjective in nature). In addition, some newborns of exposed mothers exhibited small birth size, discoloration of the skin and nails, and premature eruption of teeth. (Flynn and Kleiman, 1991, Updated Version, 2000)

Then, about 11 years following exposure, 51 *Yusho* (oil disease) patients died. The cause of death was determined in 31 cases, and 11 of these deaths were due to cancer - about 35 percent. In a similar but unexposed population, only 21 percent of deaths would have been expected to result from cancer. Ikeda et al. (1985) examined deaths among 1,761 Yusho patients through 1983. Excess mortality from liver cancer was observed in both males and females, but was statistically significant only in males. However, the geographic distribution of liver cancer deaths was markedly uneven, occurring mostly in Fukuoka, while no such excess was observed in Nagasaki. (Flynn and Kleiman, 1991, Updated Version, 2000)

The second incident of widespread effects of PCB exposure occurred in Taiwan in 1978 when approximately 2,000 people ate PCB contaminated rice bran oil. They developed *Yu-Cheng* disease, and exhibited symptoms similar to those experienced by the Yusho patients, and children of Yu-Cheng mothers exhibited symptoms of acute toxicity as well. In addition, developmental effects in children (nail abnormalities, musculoskeletal changes, behavioral problems, and cognitive deficits) were observed. Elevated mortality from liver diseases other than cancer was observed during the three years following the poisoning outbreak.

In the years following these two incidents, additional evidence suggested that PCBs might not have been the sole culprit. Indeed, subsequent investigations showed that the contaminated rice bran oil in both cases contained other toxic substances such as polychlorinated quaterphenyls and dibenzofurans. Further, dibenzofurans had previously been shown to cause the adverse health effects. Some investigators have concluded that the problems and conditions associated with the Yusho incident and the Yu-Cheng incident were not PCB related even though PCBs were found in the contamination.

C. Industry Knowledge in the 1970s

In late 1971, a group of Westinghouse staff met to discuss PCBs and they noted that PCBs concentrate in the food chain. A memo summarizing the meeting said, "It was generally concluded that the risk on the health of animal and human life and that the risks of ignoring the evidence [on PCBs] that does exist was inappropriate for Westinghouse."

Yet the 1971 memo recommended continued use of PCBs. (Environment & Health Weekly #329, 1993)

Also in 1971, Monsanto Chemical Company began requiring all of its customers of PCB-containing products to sign waivers to eliminate Monsanto's liability for improper use of PCB-containing compounds. This action informed buyers about possible dangers associated with using PCB-containing compounds. In addition, a Westinghouse biochemist named Munson claimed to have been instructed to study PCB contamination around four Westinghouse plants; the orders were said to have come directly from the CEO. In 1972, the biochemist submitted his report on the status of PCB contamination at those four plants. He urged Westinghouse to tell the local communities of the immense contamination that he found and to take remedial action. Instead, Westinghouse chose to keep the Munson report secret and continued dumping liquid PCBs directly into local environments.

D. Regulations

Concern over the toxicity and persistence in the environment of PCBs led Congress in 1976 to enact §6(e) of the Toxic Substances Control Act (TSCA) that included prohibitions on the manufacture, processing, and distribution in commerce of PCBs except in totally enclosed systems. Thus, TSCA legislated manufacture to disposal responsibility for PCBs in the United States. The Act and its subsequent regulations, resulted in comprehensive controls in the U.S. on all use of PCBs in concentrations above 50 parts per million, laying down stringent regulations for marking, record keeping, repairs to PCB-containing equipment, disposal, storage and inspection.

Manufacture of PCBs ceased in the US and the UK in 1977. And in 1986 an EC directive banned their use and that of the closely allied PCTs (polychlorinated terphenyls), together with all preparations containing over 0.01 percent by weight (100 PPM) of PCBs or PCTs. Existing transformers and capacitors were allowed to remain in service, if closed, but second-hand sale was banned. In addition, the disposal of any waste containing PCBs was brought under the Control of Pollution Act 1974 and, where PCB levels were greater than one percent, under the Special Waste Regulations of 1980. Packaging and labeling of the waste must conform to the Classification, Packaging and Labeling of Dangerous Substances Regulations of 1984. Below is an example of the type of labeling which stems from this regulation. (FIGURE 2) PCBs are the only chemical family fully regulated under any government act. This control includes the regulation of any release of PCBs into the environment, including accidental leaks or spills; specific actions are required depending upon the concentration of PCBs in soil resulting from spills.

CAUTION
CONTAINS
PCBs
(Polychlorinated Biphenyls)
A toxic environmental contaminant requiring special handling and disposal in accordance with US Environmental Protection Agency Regulations 40 CFR 761 for Disposal Information Contact the nearest US E.P.A. Office.

In case of accident or spill, call toll free the US Coast Guard National Response Center: 800-424-8802

FIGURE 2 - Example of Labeling Requirements for PCB-containing Compounds

E. Occupational Studies

Since the ban of PCBs in 1976, there have been numerous occupational health studies aimed at identifying the health impacts of PCBs. Over 50 years have passed since workers were first heavily exposed to PCBs. This is long enough to be able to detect most diseases, even cancer, reliably. The most extensive occupational studies of long-term exposure to PCBs have focused on workers employed in the manufacture of electrical equipment. These individuals had daily skin contact with PCBs for many years, inhaled relatively high levels of the chemical, and probably ingested some PCBs while eating near their workstations. Aside from occasional dermatitis, ocular irritation, and correlations of liver enzyme induction with PCB blood levels, no adverse health effects can be attributed definitely to PCBs from occupational studies, despite high serum and fat concentrations of PCBs in these workers. (GE Evaluates Health Risks, 2000)

As recently as 1981, the National Institute for Occupational Safety and Health (NIOSH) studied maintenance workers exposed to PCBs at two utility companies. This study verified that blood PCB concentrations were much higher among the workers than the national levels in people who were not directly exposed to PCBs daily. The significance of this study is that although the workers' blood PCB concentration levels were considerably higher than the norm of the general population, the workers did not exhibit any adverse health effects, even chloracne. (A Summary of Research , 1997)

Also in 1981, NIOSH performed a similar study of 224 workers exposed to PCBs at an electrical equipment manufacturing plant. Within the workers examined, the PCB blood concentrations ranged between 15 to 3,580 parts per billion (ppb), which is again much higher than the general population average. Again, no adverse health effects were observed. (A Summary of Research, 1997)

Also, in 1981, NIOSH performed the most comprehensive study of long-term health effects of PCB exposure. The study involved more than 2,500 workers employed at two separate capacitor manufacturing plants. The NIOSH researchers did not identify any statistically significant excesses over national norms of individual cancers among workers, more than half of whom had spent at least 20 years on the job. NIOSH reported that the total cancer mortality for this occupationally exposed population was slightly lower than that of the general U.S. population. Thirty-nine cancers were observed, although more than 43 would have been expected in a population with a demographic profile (e.g., age/sex/race distribution) similar to that of the 2,500 workers. Also, there was no clear dose-response relationship between length of employment in PCB-exposed jobs and risk of mortality due to cancer. NIOSH concluded in 1990: "If exposure to PCBs was associated with overt clinical disease, one would expect that the greatest effects would be seen in those individuals with the greatest exposure...The absence of either symptoms or overt clinical disease in these individuals would tend to refute concerns of adverse health outcomes associated with exposure to this chemical. (Flynn and Kleiman, 1991 Updated version, 2000)

Lawton, *et al.* (1985) studied the health of 194 workers heavily exposed to PCBs for an average of 15 years, some for as long as 35 years. A first report, on workers followed through 1976, showed no adverse effects. A 1979 re-evaluation again did not produce evidence of health effects among these workers.

Nicholson et al. (1985) reported on a mortality study involving GE employees who formed a PCB-exposed subset of the total group of capacitor employees studied. The purpose was to study the death rates in workers for whom sufficient time had elapsed between their first known exposure to PCBs and the onset of disease. Their conclusion was: "Neither the overall results of the full group nor the subgroup indicate any cancer risks. No cancer deaths occurred among males 30 or more years from the onset of exposure, whereas 5.3 would have been expected." (A Summary of Research, 1997)

The New York State Department of Health conducted a health status, cancer incidence and cancer mortality study of 289 Department of Transportation workers who were exposed to PCB-containing sediments through field or laboratory work in the 1970s. The study was published in June 1987 and concluded: "There was no evidence that rates of cancer incidence or mortality were excessive in these workers. In fact, cancer incidence was the highest in the group that Department of Health judged to be least likely to have significant exposure. No serious illnesses were believed to be due to PCB exposure. The study concluded: "Overall, the results are reassuring. Some of the sediments contained as much as 100 ppm of PCBs." (A Summary of Research, 1997)

P.R. Taylor of the New York State Department of Health and Harvard University reported in 1988 on a mortality study of 6,292 GE capacitor workers employed between 1946 and 1975. The conclusion of that work was: "Deaths due to all causes were significantly lower than expected. None of the individual cancer sites were significantly elevated. None of the estimates of PCB exposure were associated with an increase in total cancer, lung cancer or colorectal cancer. (A Summary of Research, 1997)

Greenland et al. reported in 1994 on GE workers in Pittsfield, Massachusetts. Wegman et al. said: "In brief, the epidemiological analysis did not identify any unequivocal or definitive association of the General Electric-Pittsfield work environment with excess cancer risk. With limited power the study failed to find an association between pyranol (containing PCBs) and excess cancer risk among employees." (A Summary of Research, 1997)

The American Council on Science and Health published a position paper on "Public Health Concerns about Environmental Polychlorinated Biphenyls (PCBs)" in 1997. That paper concluded: "Although PCBs are persistent in the environment and are stored in body fat, PCB levels in fish, other foods and human blood are decreasing (ATSDR, 1996). No conclusive evidence exists that background levels in the general population, or even the very high levels that occurred among some occupational groups, resulted in acute or carcinogenic effects...Cancer has not been correlated with levels of PCB exposure and, therefore, cannot be attributed to PCB exposure." (A Summary of Research, 1997)

In February 1999, the Federal Agency for Toxic Substances and Disease Registry, which is part of the U.S. Department of Health and Human Services, issued an updated draft of its toxicological profile of PCBs. The major conclusions from this report are that there are no references regarding death in humans after being exposed to PCBs by any route of exposure and that the acute lethality data do not suggest that PCBs would be acutely toxic in humans. Overall, the report found no supporting evidence between PCBs and cancer, respiratory effects, developmental effects, neurological effects, gastrointestinal effects, renal effects, cardiovascular effects and genotoxic effects. (A Summary of Research, 1997)

In March 1999, the largest and longest-running study of the epidemiology of the effects of PCB exposure was published. That study involved 7,075 men and women who were exposed to PCBs while working at General Electric's Hudson Falls and Fort Edward plants. It included hourly and salaried employees who had worked for at least 90 days in the plants between 1946 and 1977. The study compared national and regional mortality averages to the information determined within the study. The study adjusted for age and gender for the 1,195 members of the sample that died. Dr. Renate Kimbrough of the non-profit research group, the Institute Evaluating Health Risks, performed the study.

The average time since PCB exposure for the workers was 31 years, sufficient time to determine whether there was an increase in cancer mortality. The most significant finding of the study was that there was no association between PCB exposure and deaths from cancer or some 92 other causes of death. Some of the major findings in this study supported information obtained in earlier studies. The workers' exposure to PCBs resulted in significantly higher blood levels of PCBs than are found in the general population. Some of the workers in the study had PCB levels in their blood as high as several thousand parts per billion. In the United States, the average PCB levels found in the blood of people who have been tested range from 4 to 8 parts per billion, according to the Agency for Toxic Substances and Disease Registry. (IEHR, 1999)

Among the workers most highly exposed to PCBs, no statistically significant increase in deaths due to cancer or any other disease was detected, nor were statistically significant increases or decreases associated with length of employment or latency.

Based on national death rates, 699 and 420 deaths were "expected" among the hourly male and female workers, respectively. Only 586 and 380 deaths were observed among the male and female workers, respectively. Based on regional death rates, 713 deaths among hourly male workers and 449 deaths among hourly female workers were expected. Again, only 586 male and 380 female deaths were observed. Among the workers, the death rate due to all types of cancer combined was at or significantly below the expected level.

The results of this study are consistent with four prior studies of workers in the same plants. Thus, this new study combined with information from earlier studies provide strong evidence that even long-term occupational exposure, which is considerably higher than environmental exposure, does not increase the risk of cancer or other diseases. The downfall to all of the above mentioned studies is that they are all heavily influenced by industry through funding.

The Kimbrough et al. study has been disputed by the government and outside sources. Other researchers have interpreted their study findings differently. The Kimbrough et al. Study suffered from healthy worker effect bias, meaning that modern industrial workers are healthier than the general public. The study failed to account for latency, exposure misclassification, potentially insufficient dosage differences between exposed and comparison groups, and poor statistical power. (Bove et al., 1999) However, the study did find excess in three of the six cancers in interest. Although the limitations in the study approach tend to dilute any excess in cancer mortality resulting from PCB exposure, the findings still suggest a relationship between PCB exposures and excess cancer in humans. (Bove et al., 1999)

F. Environmental Health Studies

In addition to occupational health studies, environmental health studies have also been conducted. Such studies have stemmed from the worries over bioaccumulation in the environment. PCBs that have been discharged into rivers tend to concentrate in sediments at the bottoms of the rivers. Fish or other bottom-dwelling organisms take the PCBs into their systems. Fish are able to metabolize some PCBs, but those that are not metabolized are stored in fatty tissues. PCBs are then passed into the systems of other animals when they prey on fish. Thus, humans who consume fish contaminated with PCBs also bioaccumulate PCBs in their fatty tissues. For these reasons, fish are monitored for PCB concentration in contaminated bodies of water. The FDA also has established a PCB tolerance limit for resale of fish in order to lessen the possibility of bioaccumulation in the human population. (Flynn and Kleiman, 1991, Updated Version, 2000)

There have been two well-known studies within the science community of fish eaters. The Michigan Department of Public Health, under the sponsorship of the FDA, measured potential health effects of higher than normal exposure to PCBs due to consumption of fish. The study involved 182 adults, 105 of whom consumed over 26 pounds of Great Lakes fish per year. (Flynn and Kleiman, 1991, Updated Version, 2000) There was a significant correlation between PCB blood levels and the quantity of fish consumed. However, after evaluating the health histories and the current medical problems of the subjects in the study, no significant differences were found between the group that consumed large quantities of fish and the group that did not.

The Connecticut Department of Health Services conducted the other study. They analyzed the blood samples and reviewed medical histories of subjects who reported eating fish from the Housatonic River. The results of this study were consistent with the above-mentioned study. There was a correlation between the PCB blood level and the amount of fish consumed, but no link could be made between clinical observations of disease and PCB levels. (Flynn and Kleiman, 1991, Updated Version, 2000)

In 1990 a controversial study of environmental effects was published called the Jacobson study. That study described adverse effects in babies whose mothers had consumed Lake Michigan fish believed to be contaminated with PCBs. This report indicated that the babies had smaller heads, had lower birth weights and scored lower in neonatal tests. These effects were correlated with prenatal exposures but not with post-birth exposures through breast milk. (Jacobson et al., 1990 a, b) This study has been widely criticized by government and academic researchers because the effects of other potentially neurotoxic contaminants like lead, mercury and pesticides in the fish were not considered. Also, some of the mothers who consumed the fish also consumed more alcohol, caffeine and cold medicines, and weighed less on the average before pregnancy than the women in the control group. (Flynn and Kleiman, 1991, Updated Version, 2000) Also, the exposure assessment was based on maternal estimates of fish consumption over the previous six years.

Also, the concentrations of PCBs in the blood of the mothers were only slightly greater than the PCB blood levels of mothers who did not consume contaminated fish, and were within the range of normal PCB blood levels for the North American population. If such small levels of PCBs could affect the intellectual development of infants and children then there would be widespread effects across North America. Since such effects have not been noted, it seems that the results of this study are not valid. In addition, the Jacobson study did not control major factors that affect intellectual development in infants and children such as social, economic, environmental and genetic factors.

Finally there was no definite correlation between PCBs in breast milk and utero exposure and intellectual impairment. This finding was strange since the PCB levels in breast milk were about one hundred times greater than the PCB levels in maternal blood. It is thought throughout the scientific community that surely breast milk containing trace levels of PCBs would be of much greater risk to infants that lower level concentrations of PCBs in the transplancental exposure.

In defense to the controversy around the Jacobson study, Jacobson and Jacobson performed another, more in-depth study on the intellectual impairment in children exposed to PCBs in utero. This study took into account maternal drinking or smoking during pregnancy, the quality of intellectual stimulation by parents, postnatal exposure to lead, or numerous other control variables. (Jacobson and Jacobson, 1996) This study found that prenatal exposure to PCBs were associated with lower IQ scores and affected the subjects' memory and attention. Although larger quantities of PCBs are transferred by breast-feeding than in utero, this study found deficits only in association with transplacental exposure, which suggested that the developing fetal brain is particularly sensitive to these compounds. (Jacobson and Jacobson, 1996) Overall, this new study confirmed the ideas and results of the earlier 1990 study that in utero exposure to PCBs can have a long-term impact on intellectual development.

From information obtained through the occupational and environmental studies on the health effects of PCBs, the effects of PCBs cannot still remains somewhat unknown. It is obvious that the serious health problems experienced in the Yusho and Yu-Cheng incidents have not been observed as a result of occupational PCB exposure. From these occupational studies, there is more known about the potential carcinogenicity of PCBs. Although PCBs have been shown to cause liver tumors in rats that were fed high doses over a lifetime, the EPA now recognizes that PCBs are much less potent than originally thought. PCBs have not been shown to cause cancer in the most highly exposed workers, but as government studies have shown, PCBs still are a threat to humans.

Basically all of the industry funded health studies have come to the same conclusion - there is no correlation between PCB exposure and increased risk for cancer and other diseases. It is very unlikely that PCBs would act as a carcinogen in humans exposed to the levels existing in the environment today. However, many outside and governmental health studies have concluded that there is a lot of circumstantial evidence and a lot of indications that PCBs cause harm in humans, but the link has yet to be established. The contention now is that PCBs are a promoter of cancer, they cause a higher rate of cancer in the presence of a real carcinogen.

G. Environmental Studies

Until recently, there have not been many studies on the effects of PCBs in the environment, except for bioaccumulation in the food chain. How PCBs affected humans has been much more important since the two "PCB poisoning" incidents, than PCB effects on the environment. Once research had shown that there is no direct correlation between exposure to PCBs and an increased risk of cancer and other diseases, the focus has switched more to cleaning up the contamination.

Although PCBs have been shown to have relatively low toxicity, the correct disposal of PCB-containing waste is still very important. PCBs are very stable and remain in the environment for a very long time, causing PCBs to bioaccumulate in the food chain. But most worrying of all are the consequences of low temperature combustion of PCBs, either deliberately or in accidental fires, which leads inevitably and directly to the formulation of dioxins.

The threat of dioxin formation is especially problematic in low temperature combustion. Low temperature combustion occurs when PCB fluids are removed from electrical equipment and replaced with other fluids. The combination of these fluids and PCBs can cause the formation of dioxins if a fire occurs or if low temperature incineration is performed on the fluid for disposal. Dioxins do not occur naturally and are the most toxic chemical produced by man in quantity. Thus, the formation of dioxins from PCBs very well poses a large human health threat indirectly. As long as PCBs remain in the equipment, they pose virtually no threat. (Broadbank, 1991)

H. Cleanup of Environmental Contamination

There have been fears about cleaning up contamination and causing more harm to the environment and humans. It was once thought that lakes and rivers contaminated with PCBs should be left alone. The contention now is that it is better to find ways to remediate the PCB contamination. For example scientists from General Electric and the New York State Department of Environmental Conservation have reported that polychlorinated biphenyls are undergoing extensive biodegradation in nature. Many strains of natural bacteria including both aerobic and anaerobic types are causing degradation of PCBs. Each strain attacks PCB mixtures in their own distinct way. These findings contradict the earlier held idea that PCBs are virtually indestructible and will not naturally leave the environment. (Flynn and Kleiman, 1991, Revised Version, 2000)

It was initially suggested (and is maintained by GE) that leaving contaminated rivers and waterbeds alone would allow for natural restoration and remediation of PCB-laden waters. Bacterial dechlorination of PCBs in buried sediments in the upper Hudson River has occurred (Brown and Jones, 1981), but currently there is no practical means to accelerate this process. The time frames for "natural" remediation were estimated as being 20-30 years longer than for active remediation, but it was argued that natural remediation would be far cheaper and less disruptive to the ecosystem than remedial measures such as dredging. However, any remediation that does not address the continued seepage of PCB oil droplets from the fractured bedrock beneath the dredgible portion of the Hudson River will not be effective in the long term.

Most sites have been cleaned up by soil excavation and disposal in EPA-approved landfills, although soil incineration also has been used. These efforts, along with the ban on PCB manufacture, ensure that exposure to PCBs in the U.S. will continue to decline. EPA is currently overseeing several Superfund sites containing significant levels of PCBs, where complete remediation has been delayed by various factors, including lack of suitable technology (a particular problem for sediments) and local opposition to landfills or incinerators. Before actual remediation can occur, remedial investigation and feasibility studies (including cost analysis) must be performed. (Flynn and Kleiman, 1991, Revised Version, 2000)

Remediation techniques and disposal technologies continue to evolve. Many approaches have been tested but none has emerged as a technically and economically viable solution for the wide variety of environmental situations encountered. A useful method for cleaning water will probably not be effective in treating soil. Highly chlorinated PCBs will not be as readily decomposed as less-chlorinated PCBs. These types of factors contribute to the challenges of effective and cost-efficient remediation of PCB contaminated sites. Bacterial degradation or biodegradation of PCBs in soil and sediment is a potentially useful technology that is receiving much attention (Shannon, 1996; Brenner *et al.*, 1994; Furukawa, 1995; Abramowicz, 1994; Anon., 1997). Preliminary results on the biodegradation of soil samples, including those taken from the Hudson River, show promise. A "thermal blanket" approach, in which soil is heated from the surface downward and volatilized PCBs are removed under vacuum, is also under investigation. (Flynn and Kleiman, 1991, Revised Version, 2000)

It is now known that PCBs in the environment, while persistent, are not permanent. PCB levels have been declining significantly in almost every environmental segment, including human serum and adipose tissue. The concern now is how to fix the PCB contamination problem since PCBs do cause detrimental effects on some species of wildlife. In addition, although the link between PCBs and human health effects has not been proven, it has not been totally overruled either. Basically after all of the studies to date, PCBs still remain somewhat of a mystery.

IV. SUMMARY AND CONCLUSIONS

The purpose of this thesis was to determine what the chemical industry and science communities knew about PCBs during their manufacture and after their banning in 1976. Information was traced back to 1936, seven years after The Swann Chemical Company (later bought by Monsanto Chemical Company) began commercial production of PCB-containing products. Overall, the industry made the mistake of not researching problems. There was ample information about the possible problems associated with PCBs. The Halowax Company even experienced some fatalities in 1936 which were thought to be linked to PCBs.

Information on potential problems existed, but companies like Monsanto, Halowax and General Electric chose to ignore it. The problems associated with PCBs were passed off as not problems with the PCBs themselves, but problems with using impure benzene to manufacture PCBs. Even if that explanation was indeed true, Monsanto and the other companies involved should have investigated the problem in order to ensure that they were not causing any undue harm to the environment or humans.

With the exception of a few references dating back to when PCBs were first being manufactured, there was no scientific concern over the effects of PCBs until 1966. Once PCBs became linked in a sense to the problems associated with DDT, Monsanto and other companies were obligated to investigate. Testing of PCBs started to emerge. Numerous lawsuits are under way pertaining to companies hiding information that they had on PCBs.

When the two PCB poisoning incidents occurred, there was a public outcry and demand to find what was causing the poisoning. Although it was later proven that the poisonings were not PCB-related at all, this poisoning is what sparked the PCB debate and in the end caused the downfall and ban of PCBs in the United States and throughout the world. In 1976, the EPA banned the manufacture, processing and distribution of PCBs except in totally enclosed systems. The EPA labeled PCBs as probable carcinogens.

Subsequent industry funded or based studies on the health effects associated with PCBs all seem to say the same thing - PCB exposure does not cause an increase in cancer and other diseases. Most of the health studies have been done in occupational exposure settings, on employees who worked for years in direct contact with PCBs. The PCB blood levels in these workers are significantly higher than those in people who have not been directly exposed to PCBs on an occupational level. The contention is that if studies prove that there is no link between PCBs and increased cancer and other disease levels in humans with occupational PCB exposures, then there is also no correlation in cancer rates of humans not exposed to PCBs at work.

The industry contention that PCBs are not harmful in any way to humans is overstated. There is not one study that totally disproves the association between PCBs and human health effects. It is government contention that although there have been many industry based studies which attempt to prove that PCBs are harmless, the health effects due to PCB exposure are still unknown. All of the studies whose findings claim to prove no excess cancer mortality resulting from PCB exposure instead have done nothing more than suggest a relationship between PCB exposures and excess cancer in humans.

In addition to PCBs harmfulness in terms of adverse human and animal health effects, thére is also concern about their presence in the environment. PCBs are very stable and tend to remain intact for a long time, allowing bioaccumulation in the food chain and other problems. A recent study indicates that PCBs are biodegrading. This finding is very promising since PCBs were thought to be virtually indestructible so that they unlikely to leave the environment naturally.

In the end, the problems with PCBs have been known from almost the beginning of commercial production. The companies who relied on PCBs either as users or as producers, chose not to pursue any investigation of the effects of PCBs either on the environment or on humans. It seems to be negligent to know that there is a potential problem with a product and then not investigate the problem.

Overall the debate about PCBs is still unsettled. Industry believes that PCBs are not the monstrous chemicals they were thought to be in the late 1970s, that in fact they do not cause an increased risk of cancer and other diseases. The government and many outside sources believe that although the link between PCBs and adverse human health effects is still not clear, it is definitely suggested. In addition, PCBs definitely have adverse effects in the environment. If more research had been done initially or once potential problem was identified, maybe there would be less PCB pollution throughout the world.

V. RECOMMENDATIONS

It would have been very useful and helpful to have been able to contact someone at the EPA in regards to the information presented in this thesis. Attempts were made to contact someone, but for some reason, the EPA does not seem to want to answer questions or inquiries about PCBs. Ample time needs to be allotted in order to ensure that all of the information is found. After hunting for a considerable amount of time, information was found pertaining to early research performed on PCBs.

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