

SUMMARY

By

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In summary, our observations, admittedly limited, both from our laboratory data and from reports of other investigators lead us to believe with considerable confidence that PCBs do degrade in the environment. The complexity of the commercial mixtures has, however, hampered the determination of the varying rates of degradation of all the possible isomers.

Monsanto's sales actions have definitely reduced the amount of PCBs that could be introduced into the environment.

In those applications in which the use of PCBs is considered essential, namely transformers and capacitors, further actions will assure strict environmental control on PCBs.

In transformers the use of the lower chlorinated biphenyls along with proper handling during manufacture, use and repair and proper disposal of waste fluid by high temperature incineration should result in acceptable control.

For the capacitor application the development of Aroclor 1016, which satisfied all of the industry's requirements relating to dielectric characteristics and handling properties as well as having Underwriter Laboratory fire-resistance approval, permits the continued use of PCBs in this important hermetically sealed application but with a fluid that has a significantly lower content of the slower degrading isomers. The use of this material accompanied by proper handling and disposal of the scrap fluid by high temperature incineration represents in our considered opinion a significant step forward in our efforts to control the impact of PCBs on the environment.

PLAINTIFF'S
EXHIBIT

506

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low chlorinated PCBs but not in the high chlorinated compounds. Even though their analysis did not adjust for age, it suggests that the relationship between blood PCB levels and duration and recency of exposure may be a function of the level of chlorination of the PCBs. Smith et al however, in an elaborate analysis of high and low chlorinated blood PCBs versus present and past exposure, found no "evidence either to support or refute different accumulation kinetics in humans for the lower and higher chlorinated biphenyls". Nevertheless, they found a significant correlation between current personal air PCB levels and low chlorinated blood PCBs, but no significant correlation with high chlorinated blood PCBs.

In summary, body burdens of PCBs are clearly related to the level of exposure to environmental PCBs. Observations of a decrease in the burden of PCBs after exposure is eliminated or decreased are not consistent. The lack of consistency may be due to the short periods of observation of some of the studies, or possibly to differences in the average chlorination of the PCBs involved. Studies of the relationship of PCB burden to duration of exposure again are not consistent. There is a suggestion that this may be due to the confounding effects of age and sex, or to differences in the metabolism of high and low chlorinated PCBs, with the higher PCBs being more likely to accumulate in adipose tissue.

V. Epidemiologic Studies of PCBs and Health

Excluding mortality studies, there are 17 epidemiologic studies of health effects related to PCB exposure. The accident report of Meigs et al is included since it did not differ in design from many of the studies that were not motivated by accident reports.

These studies are listed in Table 4 with a summary of the findings by major category. Five of the reports are in Japanese [13,14,15,16,18]. The details of those studies are taken from the NIOSH criteria document for PCBs [34].

Two of the studies, Kappanen and Kolhol and South Carolina Department of Health and Environmental Control are not specific as to health effects. The first of these is a comparison of groups with different work exposures and different blood PCB levels (74-1900 ppb in the 12 persons with the greatest exposure) in which the authors simply state that all persons studied were in good health. The second is a study of 32 workers in a capacitor plant, 10 of whom were exposed regularly to PCBs. The authors state that there is "no evidence of physical harm resulting from working with PCBs".

The remaining 15 studies in Table 4 are reviewed below with respect to their findings in each major category of health effects. The studies are considered in the order of their publication.

Dermatologic effects. There are 11 studies of dermatologic effects associated with PCB exposure. The first is Meigs et al

described in Section II above, who found that 7 of 14 exposed workers got chloracne where the PCB concentration in their breathing zones averaged 0.1 mg/cum. Hasegawa et al reported an unstated number of cases of hyperpigmentation of the hands, and acne-like lesions of the jaw, back and thighs in exposed workers. The average blood PCBs in the workers was 370 ppb. However, the authors state that skin complaints were unrelated to blood PCB levels and appeared to be due to skin contact. Kitamura et al reported a range of skin disorders in 10 of 13 exposed workers with an average blood level of 820 ppb. The disorders occurred on parts of the body not normally in direct contact with PCBs. Hara et al reported that about 45 percent of 118 capacitor workers complained of blackheads and other acne-like symptoms while working with PCBs. The complaints were not related to blood levels of PCBs, and virtually disappeared within a year after exposure had ceased.

Inoue et al reported one case of chloracne in an exposed worker whose blood PCBs were in the 190-210 ppb range, but no symptoms in the rest of a small work force whose blood PCBs ranged from 130 to 520 ppb. The Michigan Department of Public Health reported no relationship of any Yusho symptoms to consumption of fish with high levels of PCBs. Ouw et al reported 14 cases of dermatitis, eye irritation or burning sensations on the skin out of 34 exposed workers, where air levels of PCBs ranged from 0.32 to 2.22 mg/cum. The complaints appeared to occur more often in those with higher blood PCB levels. Fischbein et al reported that about 50 percent of 326 capacitor manufacturing workers reported a

history of dermatological symptoms, the most common symptom being a rash. Those with symptoms had higher blood levels of high chlorinated PCBs. Baker et al reported no chloracne in 18 exposed workers (average blood PCBs 75.1 ppb) or 19 members of their families (average blood PCBs 33.6 ppb). Maroni et al reported 10 cases of dermatitis (5 diagnosed as active or past chloracne) out of 80 exposed workers. The average blood PCB level in the study was 342 ppb. Smith et al found no chloracne in a study population of 324 exposed workers in capacitor manufacturing and transformer repair, whose average blood PCBs ranged from 38 to 546 ppb. However, there was a significant association of skin rash or dermatitis with blood levels of high chlorinated PCBs.

Interpretation of this mass of data is complicated by the difficulty of diagnosing chloracne, the uncertainties of blood PCB determinations, and the changing technology for making such determinations. Nevertheless, the data suggest strongly that when PCB blood levels exceed about 150-200 ppb chloracne can occur. However, most studies have shown that the occurrence of chloracne is not further associated with blood PCB levels. This suggests that (a) personal idiosyncratic factors may be involved and/or (b) that the high blood levels are an indicator of the existence of environmental contamination which actually produces chloracne by skin contact.

The reports of dermatitis other than chloracne suffer from an additional complication. According to the National Health Survey, about one-third of all Americans of working age have at least one current skin condition serious enough to warrant evaluation by a

physician [25]. Clearly, substantially more than one-third must have either a current condition or a history of such a condition in the past. The prevalence figures reported by Maroni et al and Fischbein et al are therefore not in themselves remarkable, but the agreement of Fischbein et al and Smith et al on the relationship between dermatitis and high chlorinated blood PCBs suggests that this association may be real.

Liver Function. Nine studies examined liver function. Meigs et al found one borderline abnormal liver function in 14 exposed workers. Hasegawa et al found mild disturbances in exposed workers (increased SGOT, SGPT, SAP, decreased serum cholinesterase) which they did not consider to be clinically significant. Ouw et al, Kitamura et al, Fischbein et al and Baker et al (a non-occupational study) found no abnormalities associated with exposure, except that Ouw et al found a high BSP retention in 4 out of 7 workers with blood levels above 500 ppb.

Maroni et al found 16 out of 80 workers with abnormalities in GGT, OCT and transaminases. Their blood PCB levels were higher than those in the workers with normal liver function. Kreiss et al (non-occupational study) found no relation between liver function and blood PCBs when age and alcohol consumption were taken into account. Smith et al found elevated SGOT and GGT levels in persons with higher blood PCB levels.

In summary, 5 studies of the 9 found some mild liver function abnormalities, none of which were associated with any measurable adverse health effects. The two non-occupational studies, Baker et al and Kreiss et al, found no abnormalities associated with

blood PCB level. Fischbein et al, in their study of capacitor manufacturing workers, noted that "there was a paucity of abnormal results in the biochemical studies".

Fat Metabolism. Six studies considered fat metabolism. One, Bumgarner et al, found no relationship between blood cholesterol and blood PCBs. One of the remaining 5, Hasegawa et al, found a decrease in cholesterol, glycerides, phospholipids and beta-lipoprotein in exposed workers. Of the remaining 4, Hara et al, Baker et al (non-occupational study), and Smith et al found increased triglyceride levels with increased blood PCBs. Kreiss et al found no association of triglycerides and blood PCBs when cholesterol level was taken into account. Smith et al and Kreiss et al also present contradictory findings with respect to HDL cholesterol levels; the former found an inverse relationship of HDL to blood PCBs; the latter found no relationship, but found a positive association between total cholesterol and blood PCBs.

Most studies, including one non-occupational study (Baker et al) have associated increased tryglycerides with PCB exposure. The data on cholesterol are not consistent; an increase, a decrease and no change were found (one study each). HDL cholesterol either decreased or was unchanged (one study each). Even if PCB exposure has some effect on fat metabolism, it appears to be without any apparent clinical significance.

Blood and Blood Pressure. There are five studies of blood chemistry; Bumgarner et al, Kitamura et al, Fischbein et al, Baker et al, and Maroni et al. None of them report any relationship of blood chemistry to PCB levels.

Bumgarner et al and Kreiss et al measured blood pressure in exposed persons. Bumgarner et al found no association with PCBs, but Kreiss et al found a statistically significant association between diastolic blood pressure and blood PCBs. Since there was no control group and since Kreiss et al are the only investigators to report this finding, its significance is not clear at this time.

Symptoms, Illness and Other Conditions. Six studies investigated reported symptoms in persons exposed to PCBs. Two of them reported allegedly increased symptoms of various kinds. Fischbein et al reported a history of gastrointestinal symptoms in 18 percent of 326 capacitor manufacturing workers, a prevalence of from 3.0 to 15.2 percent of various musculoskeletal symptoms, and a prevalence of from 4.8 to 27.8 of various neurological symptoms. These were, however, unrelated to duration of employment or to level of blood PCBs. Maroni et al reported 8 cases of gastrointestinal complaints in 80 exposed workers, with no indication of whether there was a relationship to duration of employment. They also reported two bleeding haemangiomas and one case of chronic myelocytic leukemia. These findings do not appear to have any significance, since they apparently are unrelated to the circumstances of exposure, and since the following 4 studies reported no symptoms related to PCBs.

The Michigan Department of Public Health compared a group of persons who consumed sport fish contaminated with PCBs to a group of unexposed controls. The incidence of 18 conditions, many of them the ones reported for Yusho disease, was measured in the two

groups. There were no health conditions that could be correlated with blood PCB levels or fish consumption. Baker et al reported that none of the following conditions were associated with blood PCB levels in a community study; fever, weight loss, anorexia, fatigue, headache, eye irritation, cough, shortness of breath, nausea, vomiting, diarrhea, abdominal pain, arthralgia, and persistent skin rash. The community study of Kreiss et al reported the same thing for prevalence of illness or weight loss in the preceding year, use of medication, use of medical care, history of heart disease, and percentage of pregnancies ending in miscarriage, stillbirth or infant death. Finally, Smith et al reported an increased prevalence of general malaise and possibly altered peripheral sensation with increased blood PCB levels among occupationally exposed workers, but found no clinical abnormalities on physical examination.

The weight of evidence, as Smith et al conclude, is that no studies to date "have shown that occupational exposure to PCBs is associated with any adverse health outcome, to be distinguished from demonstrable subclinical biochemical alterations".

Two studies considered other conditions in persons exposed to PCBs. Warshaw et al reported decreased vital capacity in capacitor manufacturing workers. However, the pulmonary function values in the study population, most of whom were current or ex-smokers, were evaluated in comparison with a standard population of non-smokers, so that the effect of smoking as a confounder was not allowed for.

Alvares et al reported that in 5 workers occupationally exposed to PCBs, the rate of drug metabolism was significantly higher than in a group of controls matched for age, sex, and smoking and drinking habits.

There appear to be no significant clinical effects associated with the occupational or environmental exposures studied in these reports.

Carcinogenicity. It is generally agreed that epidemiologic evidence for carcinogenicity should fulfill certain requirements in order to be acceptable. These requirements deal with the study design, the logic of the observed pattern, and the repeatability of the results. Table 5 lists these requirements as given by Doll [28].

There are four studies directed solely or primarily to the question of the carcinogenicity of PCBs. Table 6 lists the studies and their findings. They are reviewed here keeping in mind Doll's requirements.

The most obvious feature of Table 6 is that no study agrees with any other. That is, the requirement of repeatability is not met.

The first study, by Bahn et al, observed three melanomas in a group of 92 research and development and refinery workers. These workers had an unknown exposure to other possible carcinogens, so that there could have been confounding. In any case the study was withdrawn for revision in the definition of the exposed population, and has not yet been released [34].

Zack and Musch studied 89 workers exposed for at least six months between 1945 and 1965 inclusive. There were no deaths from cancer of the liver or cirrhosis. The excess in respiratory cancer was based on four deaths and was not statistically significant. As with Bahn et al there was confounding because of other chemical exposure at the plant and, in this case, possibly cigarette smoking.

Brown and Jones studied 2,567 workers in a capacitor plant. About half the cohort had a latency period of 20 years or more. Although there was an excess of liver cancer deaths, it was inversely related to duration and latency of exposure, which does not support an occupational explanation. There was also an excess of rectal cancer. However, the two plants studied are located in an area whose mortality from rectal cancer is greater than the U.S. average [35]. Since U.S. population rates were used as a basis for comparison, the rectal cancer excess is at least partly an artifact.

Bertazzi et al studied 1,310 workers with at least six months employment in capacitor manufacturing between 1946 and 1970. Although excess digestive cancer was observed, there were no liver cancer deaths. The total number of deaths was small (27) and the excess cancer observed was based on two or three deaths for each of the two major sites involved. There is no indication of the duration or latency of exposure for the cancer deaths. The authors state that there were no other major exposures at the plant, and propose to continue the study with a larger cohort. In spite of the statistical significance of the excesses from all

cancers, this study must be considered a preliminary report, particularly since it shares with the other studies a failure to agree on any particular pattern of mortality.

The existing mortality studies of occupational exposure do not show the agreement that would lead one to infer an excess risk of cancer. Much of the conflicting findings can be attributed to the possible effect of confounding exposures, and to the "noise level" of sporadic excesses which would be expected in the absence of any occupational hazard.

VI. Summary and Conclusions

The epidemiologic studies of exposure to PCBs show that the body burden in exposed persons, whether the exposure is by ingestion, inhalation or skin contact, is related to the environmental levels and distribution of PCB. The relation of body burden to duration of exposure is less clear, and appears to differ depending on the degree of chlorination of the PCBs. Nevertheless, the evidence is clear that higher exposures mean higher blood PCB levels, and that persons with occupational exposures have blood PCB levels that may be an order of magnitude greater than that of environmentally (that is, non-occupationally) exposed persons.

Occupational exposure to PCBs at high levels has been associated with the occurrence of chloracne, but the relationship is not straightforward, suggesting that the actual risk of chloracne is also a function of individual susceptibility and personal work habits, as well as possible exposure to other contaminants.

Dermatologic problems other than chloracne are associated with occupational exposure, and may be related to exposure to high chlorinated PCBs.

Alterations of liver function and fat metabolism associated with PCB exposure have been observed in several studies, but are characterized by investigators as mild and of no clinical significance.

The one fact on which all occupational studies of health effects agree is that there has been no clinical illness associated with PCB exposure other than dermatitis. Studies of non-occupationally exposed populations have found neither dermatitis nor other clinical evidence of exposure-related effects, with the exception of a single study which suggests that diastolic blood pressure may be related to blood level of PCBs.

Mortality studies concerned primarily with cancer present problems of interpretation due to the small sample size of some of the studies, and to the confounding effect of other exposures. However, they do exhibit a pattern, which is that none of the studies agree on the cancer sites at which an excess mortality was found, and the excesses that were found are in general not statistically significant. One must conclude that the findings of the mortality studies reflect a sporadic pattern of excess mortality at different sites which is not consistent with a carcinogenic effect of PCBs. In addition, where an examination of duration and latency of exposure was possible, no association with these variables was found [32].

Taken as a whole, 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.

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Table 1

Studies of Environmental Levels and Body Burden
of PCBs by Type of Body Burden Measure

Study	Study Type*	High & Low Chlorinated PCBs	Adipose PCBs
Baker, E et al [11]	A	No	No
Bumgarner, JE et al [12]	C	No	No
Hara, I et al [13,14]	B,C	No	No
Hasegawa, H et al [15]	A,B,C	No	No
Inoue, Y et al [16]	A,C	No	No
Karppanen, E, Kolho, L [17]	A	No	Yes
Kitamura, M et al [18]	B	No	No
Maroni, M et al [19]	A,C	Yes	No
Ouw, HK et al [20]	A,B	Yes	No
Smith, AB et al [21]	A,C	Yes	No

* A = comparisons of groups with different exposure levels

B = evaluation of results of decreasing or removing exposure

C = comparisons of groups with different durations of exposure.

Table 2

Studies of Blood PCB Levels Before and After Exposure
Levels Changed, and Interval from Exposure
Change to Remeasurement

Study	Exposure Change	Interval to Remeasurement	Decrease in Blood PCB Level
Hara et al [13,14]	Ceased	1 year	~75%
Hasegawa et al [15]	Ceased	1 month	None
Kitamura et al [18]	Ceased	3 months	>50%
Ouw et al [20]	Decreased	2 months	None

Table 3

Studies of PCB Levels by Duration of Exposure

Study	Relationship of Blood PCB to		
	Duration of Exposure	Age	Race
Bumgarner et al [12]	No	No	No
Hara et al [13,14]	Yes		
Hasegawa et al [15]	No		
Inoue et al [16]	Yes		

Table 4

PCB Epidemiology Studies (other than mortality) and Summary of Findings*

	Dermatologic Findings	Physiological Parameters	Symptoms and Illness	Other
Alvares et al [27]		Y		
Baker et al [11]	N	Y	N	
Bumgarner et al [12]		N		
Fischbein et al [23]	Y	Y	Y	
Hara et al [13,14]	Y	Y		
Hasegawa et al [15]	Y	Y		
Inoue et al [16]	Y			
Karppanen, Kolho [17]				N
Kitamura et al [18]	Y	N		
Kreiss et al [10]		Y	N	N
Maroni et al [24]	Y	Y	Y	
Meigs et al [3]	Y	Y		
Michigan Dept of Public Health [9]	N		N	
Ouw et al [20]	Y	N		
Smith et al [21]	N	Y	Y	
South Carolina Dept. of Health and Environmental Control [22]				N
Warshaw et al [26]		Y		Y

* Y = Findings associated with exposure

N = No findings associated with exposure

No entry = No data presented

Table 5

REQUIREMENTS FOR ESTABLISHING CARCINOGENICITY
FROM EPIDEMIOLOGICAL EVIDENCE

- Positive associations in groups of individuals with known exposure (case-control or cohort studies).
- That are not explained by bias in recording or detection.
- That are not explained by confounding.
- That are not explained by chance.
- That vary appropriately with dose.
- That vary appropriately with period of exposure.
- That are observed repeatedly in different circumstances.

Table 6

Inconsistencies in Studies of Cancer in
PCB Exposed Populations, with Findings

<u>Study</u>	<u>No. Studied</u>	<u>Findings</u>
Bahn et al [29,30]	92	Melanoma**
Zack, Musch [31]	89	Lung
Brown, Jones [32]	2,567	Liver Rectum
Bertazzi et al [33]	1,310	Digestive* Lymphatic and hematopoietic

* Significant at 5 percent level

** Significant at 1 percent level