PCBs: A PERSPECTIVE FOR THE DIE CASTING INDUSTRY

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Polychlorinated biphenyls (PCBs) have received considerable attention over the last 15 years because of concerns about their environmental persistence and their possible effects on human health and the environment. They are pervasive and misunderstood. PCBs have come to be among chemicals most feared by many persons.

PCBs are now highly regulated. They are the only chemical substances singled out by Congress for "immediate" regulatory action under the Toxic Substances Control Act of 1976 (TSCA).(1) In July of 1979 regulations covering the manufacture, distribution in commerce, use, marking, storage and disposal of PCBs became effective in the United States.(2)

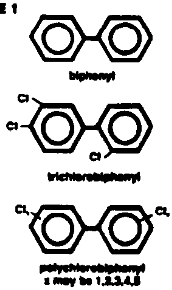
The die casting industry has used PCBs for many years in hydraulic fluids for safety reasons. Because PCBs are relatively non-flammable, apparatus containing them is essentially free from fire and explosion hazards associated with usage in proximity to high temperature and open ignition sources. Thus the die casting industry is particularly affected by the PCB regulations under TSCA.

This article will describe the use of fire-resistant hydraulic fluids containing PCBs in the die casting industry and the actions taken, both by industry and the government, after PCBs were discovered in the environment in the late 1960's. The article also will discuss the current federal PCB regulatory framework and the latest studies assessing the possible environmental and human health effects of PCBs.

1. <u>History And Uses Of PCBs</u>(3)

PCBs are a class of organic chemicals known as chlorinated aromatic hydrocarbons. They were introduced into United States industry in 1929. Chemically, PCBs are composed of carbon, hydrogen and chlorine atoms in various combinations (see Figure 1).

FIGURE 1



The unique chemical and physical properties of PCBs led to their widespread use. PCBs are chemically inert, stable and fire resistant, and they have a very low vapor pressure (BP ranges 275° - 425°C). PCBs function uniquely as dielectric insulators to act as non-conductors of direct electric current. These properties made them ideally suited for electrical applications where high-voltage arcing could occur and could result in fires and/or explosions, damage to equipment and significant hazards to health and life. Thus, since the early 1930's, PCBs have been used in transformers, capacitors, and other electrical equipment.

The fire-resistant nature of PCBs also made them well-suited for use in hydraulic and heat transfer fluids. Industrial hydraulic operations began using PCBs for fire protection in the late 1940's and early 1950's. Usage increased in typical industrial applications where fire-resistant properties were both desirable and necessary. PCB hydraulic use concentrated in primary metal production and metal working industries which utilized high temperatures and power usage for producing and forming metals and related products.

MONS 015279

Hydraulic power is used extensively in the basic steel and aluminum industries, in foundries, and is the primary means of transmitting large forces in die casting, forging and extrusion. Metal temperatures in or near hydraulic equipment for such uses range from 800°F to 3000°F and the fire hazard is severe.

In addition to fire safety, PCB hydraulic fluids offered additional performance characteristics such as lubricity, anti-rust and corrosion properties and favorable physical properties, e.g., vapor pressure and viscosity, to facilitate equipment design and operation.

PCBs were also used in a variety of other industrial products, including items such as lubricants, inks, plasticizers, adhesives, coatings and carbonless copy paper. However, the bulk of all PCB sales were for electrical, heat transfer and hydraulic fluid applications.

Monsanto Company entered the chlorinated biphenyl business in 1935 with the purchase of Swann Chemical Company and eventually became the major producer of PCBs in the United States. PCBs also were produced in a number of other countries and are still produced and used in many European countries.

2. Growing Awareness Of Potential Concerns Associated With PCBs

The use of PCBs resulted in industrially superior products. Because of their widespread use they have been distributed throughout the environment. However, their persistent presence in the environment was unsuspected before the late 1960's.

Scientific knowledge about the presence of PCBs in the environment, and about its possible significance, began to evolve during the late 1960's. That evolutionary process began with two events, one in Sweden and the other in Japan.

MONS 015280

In Sweden, Soren Jensen, using new analytical technology to investigate DDT residues in the environment, reported the possible presence of PCBs in fish tissue.[4] Following preliminary news media reports in late 1966, Monsanto and others began immediately to study the Swedish work. Before the findings could be confirmed or duplicated in the United States, analytical methods had to be refined in order definitively to separate PCBs from other chlorinated hydrocarbons that were known to be present in the environment. New techniques were required to enable researchers to detect and identify these chemicals in the trace level ranges being reported. The advent and development of refined gas liquid chromatography analytical techniques during this time period and since have made routine analyses in the part per billion (ppb) range possible.

In Western Japan, in 1968, about 1,000 people became ill as the result of an unfortunate industrial accident in which rice oil was contaminated with PCBs when a heat exchanger ruptured and leaked into the food product.[5] The illnesses which came to be known as "Yusho" or rice oil disease, initially were blamed on the presence of PCBs. Several years later, however, it has been learned that most, if not all, of the toxic Yusho effects were not caused by the PCBs but were actually caused by extraordinarily high trace levels of impurities in the Japanese PCB fluid.

The presence of PCBs in the United States environment was confirmed by 1970, but little was known about their potential impact. Based on these early studies and reports, Monsanto voluntarily terminated sales of PCBs in 1970 for use in "open" applications, such as plasticizers and carbonless copy paper.[6] Monsanto also advised food processors using PCB heat transfer fluids to change to alternative heating methods. Monsanto re-emphasized the need for improved monitoring of finished food products to preclude contamination by any heat transfer fluid. In 1971 Monsanto terminated all heat transfer fluid sales of PCBs, substituting other products with equivalent thermal stability but less fire resistance.

MONS 015281

The development of replacement hydraulic fluids also began in 1970. In 1970 and 1971 Monsanto contacted customers in various industry segments, including the die casting and metals producing industries who used PCB hydraulic fluids as well as other PCB formulations, to inform them of PCB environmental concerns. Monsanto alerted users of PCB hydraulic fluids to manage wastes in order to eliminate PCB discharges to the environment. As new hydraulic fluids were developed in 1971, sales of fluids containing PCBs were terminated.

The only uses for which Monsanto continued to produce and sell PCBs were certain enclosed applications in the electrical industry, such as in capacitors and transformers. No suitable replacements for PCB dielectric fluid were available in the early 1970's. The electrical industry and the government suggested that the benefits to society of continued chlorinated biphenyl dielectric use outweighed the low risk of uncontrolled releases from sealed applications. The Government's Interdepartmental Task Force on PCBs recommended in their May, 1972 report that "the use of PCBs should not be banned entirely." "Their continued use for transformers and capacitors in the near future is considered necessary because of the significantly increased risk of fire and explosion and the disruption of electrical service which would result from a ban on PCB use." They requested that Monsanto continue producing PCBs for these applications, in order not to stop the production of equipment essential to the safe and efficient distribution and use of electrical energy.[7] Therefore, Monsanto agreed to continue supplying PCB products to manufacturers of electrical power distribution equipment for use <u>only</u> in capacitors, transformers and other sealed systems. In continuing to sell to such customers, however, Monsanto emphasized that the key to managing the risk was sound maintenance practice and disposal control. Monsanto also required assurances that the materials would be safely handled and properly disposed of.

By 1977, replacement dielectric fluids were available, and Monsanto halted all production of PCBs. (PCB manufacture and sales were finally prohibited in July, 1979 by Federal regulations.)

MONS 015282

3. Government Regulation Of PCBs

In the fall of 1971, the federal government established an Interdepartmental Task Force on PCBs to study the environmental presence and health effects of PCBs.(7) Among the Task Force recommendations was passage of a federal statute to restrict use and distribution of PCBs and to collect information about their effects.

Congress passed the Toxic Substances Control Act (TSCA) in 1976.(1) The act singled out PCBs for regulation and authorized EPA to promulgate rules governing the disposal, marking, manufacture, processing, distribution in commerce and use of PCBs.

EPA's final PCB regulations, published in July, 1979, are found in Title 40, Part 761 of the Code of Federal Regulations (CFR).(2) In summary, the provisions:

- Prohibit all manufacturing of PCBs unless specifically exempted by EPA.
- Prohibit processing, distribution in commerce and use of PCBs except in a "totally enclosed manner."
- Authorize certain processing, distribution in commerce and use of PCBs in a non-totally enclosed manner.
- Define marking, storage and disposal rules.
- Define recordkeeping requirements.
- Establish a 50 parts per million (ppm) minimum PCB concentration for regulation.

Of particular interest to the die casting industry are those provisions of the regulations dealing with the use of PCBs in hydraulic systems, as well as the marking, storage, disposal and recordkeeping regulations. Provisions dealing with uses of PCBs in electrical transformers and capacitors also may be applicable to the die casting industry.

MONS 015283

The use of PCBs in hydraulic systems in a non-totally enclosed manner is specifically authorized until July 1, 1984, provided the conditions of 40 C.F.R. § 761.30(e) are met. These conditions require initial sampling and analysis of all hydraulic systems that <u>ever</u> contained PCBs with subsequent flushing and draining of equipment. For each year that tests indicate a PCB concentration of at least 50 ppm, each hydraulic system must be drained and refilled with fluid containing less than 50 ppm PCBs. When the annual test indicates that the fluid in a system contains less than 50 ppm PCBs, no further testing is required.

Thus the key checkpoint for hydraulic systems in the die casting industry is the 50 ppm minimum cutoff level. The required sampling, analysis, draining and disposal of fluids, in addition to storage, marking and recordkeeping requirements, are very expensive. In many cases multiple drainings and flushings have failed to achieve PCB levels less than the 50 ppm regulatory cutoff level.

There is no known technology that will universally remove PCBs from hydraulic systems and will systematically achieve the required 50 ppm level by following a prescribed program. A major frustration of the industry is the failure to understand why simple dilution techniques such as multiple drainings and flushings with fresh fluid will not achieve the mathematically calculated reduced PCB levels.

The current regulatory scheme is complicated by a lawsuit brought by the Environmental Defense Fund (EDF) against EPA, challenging the validity of the 1979 PCB rules. In a decision handed down in 1981, the United States Court of Appeals for the District of Columbia Circuit held that there was insufficient evidence to support certain provisions of the regulations authorizing "totally enclosed" uses of PCBs. The court also found the evidence insufficient to support the 50 ppm regulatory cutoff level. The Court directed EPA to develop new PCB regulations but allowed the 1979 regulations to stand until such time as new PCB rules are promulgated. Thus EPA faces the task of establishing a new regulatory cutoff level and/

or authorizing additional non-totally enclosed PCB uses at low PCB levels, such as in hydraulic systems containing low but measurable PCB levels. This rulemaking procedure is taking place at this time.[9]

4. Health Effects of PCBs

Since Congress passed TSCA in 1976, much new scientific information has been published on the health effects of PCBs in both humans and animals. A search of the published literature indicated that over 5,000 scientific and technical papers on PCBs have been published since 1976.[10]

Of particular significance are those reports relating to human exposure or epidemiology studies. Within the last two years results of a number of published human PCB exposure studies have shed significant new light on the PCB health effects issue.[11] In addition, two independent groups of scientists have recently re-reviewed the total body of PCB health and toxicity literature with particular emphasis on the human exposure studies.[12] [13] These reviews have been in conjunction with the new EPA rulemaking procedure required by the Court of Appeals in the EDF case. The Chemical Manufacturers Association (CMA) sponsored one group of reviewers, Ecology and Environment, Inc. (E&E), an independent environmental consulting firm from Buffalo, New York. The E&E report was submitted to CMA and EPA in November, 1981 entitled "Summary of the Health Effects of PCBs."[12]

A second independent review of the PCB health effects and environmental effects literature was sponsored by trade associations in the utilities and electrical equipment industries, Edison Electric Institute (E&E) and the National Electrical Manufacturers Association (NEMA). The EEI/NEMA study was performed by the firm Drill, Friess, Hays, Loomis and Shaffer, Inc., Consultants in Toxicology of Arlington, Virginia. The Drill, Friess et al report was submitted to EPA in February, 1982.[13]

MONS 015285

The independent conclusions of both of these groups of scientists, which are supportive of and consistent with each other, may be summarized as follows:[12] [13]

(1) Current exposures to PCBs generally do not pose any serious risk of injury to human health.

(2) PCBs are not human carcinogens.

(3) PCBs have not been shown to affect human reproduction adversely or to cause birth defects. PCBs are not mutagens or teratogens.

(4) The only proven adverse human health effects resulting from PCBs are two skin conditions, dermatitis and chloroacne, which are reversible after discontinuance of exposure.

Ecology and Environment, Inc. (E&E) concluded in their report submitted to EPA that in its "independent professional opinion that 'any exposure to PCBs' does not pose a significant health risk to humans." E&E concluded "that PCBs do not represent a carcinogenic (genotoxic/initiator) risk and that, even if they possess oncogenic (epigenetic/promoting) activity, the risk at low exposures is insignificant."

Recent epidemiological studies also have failed to find any serious health effects caused by exposure to PCBs. A 1981 study by the National Institute of Occupational Safety and Health (NIOSH) focused on 2,500 electrical equipment manufacturing workers[14] who had been occupationally exposed to PCBs for several years. Many of the workers were routinely exposed to PCBs for over 10 years. The study found no excess in total mortality or in mortality due to cancer, cardiovascular disease or neurological disorders.

A recent review by Dr. William Gaffey of Monsanto Company of epidemiology studies published to date found that during occupational exposure, PCBs can cause temporary skin problems, but that there were

MONS 015286

no clinically observable long-term human health effects, including the occurrence of cancer.(11) Studies of non-occupationally exposed populations found neither dermatitis nor other clinical evidence of exposure-related effects.

Many of the recent epidemiology studies include data on large numbers of industrial workers, who, over many years, were occupationally exposed to PCBs. In most cases, these were chronic occupational exposure to PCBs at levels far greater than any reasonably foreseeable exposure level under existing regulations. The studies have shown that, like other chemicals, PCBs can cause dermatitis and chloracne, although these skin disorders were reversible after discontinuing the exposure. In spite of over 50 years of PCB use, no causal relationship has been established for any specific type of cancer, nor has it been proven that the incidence of cancer mortality has increased due to PCB exposure.

5. Environmental Levels Of PCBs

Recent measurements of environmental levels do not support the conclusion that PCBs have exhibited a significant irreversible impact on the ecosystem. In May, 1983, EPA released the results of a study showing "a sharp decline in the percentage of the U.S. population having levels of polychlorinated biphenyls (PCBs) above three parts per million in their fat tissue."(15) The study continued:

> Results of the National Human Adipose Tissue Survey (NHATS) conducted by the Office of Toxic Substances indicates that the estimated fraction of the national population having greater than 3 ppm of PCBs have decreased from 8 to 1 percent between 1977 and 1981 after increasing from 2.7 to 8 percent between 1972 and 1977. This indicates that exposure of the U.S. population to PCBs is decreasing.

Data on PCB contamination of fish and natural bodies of water have shown that environmental levels are still decreasing at a significant rate. Levels in fish in three different areas of the United States (Great Lakes(16) (17) (18), New York(18) (19) and Alabama-Georgia(20)) were in

MONS 015287

the range of one to five ppm in 1980-81, as contrasted with levels ranging from 60 ppm in 1973 to 18 ppm in 1975.

In addition, recent publications have demonstrated that the more highly chlorinated PCB homologs are not as persistent as predicted. Although their persistence had been predicted to be on the order of a hundred years, one study has shown that their average persistence is in the range of 40-50 months. (20) These data are based upon half-life values of PCBs in the tissues of environmentally exposed fish.

Data published by the National Academy of Sciences in 1979 (21) also have shown a significant reduction of PCB concentrations in the air over the North Atlantic Ocean. These data have demonstrated an order of magnitude decrease in PCB concentrations in the air ranging from 0.76 ng/m (±0.55 ng/m) in 1973 to 0.074 ng/m (±0.099 ng/m) in 1977.

These downward PCB trends are the result of voluntary industry actions taken in the 1970's to reduce usage of and possible exposure to PCBs. These responsible industry actions were taken before the enactment of TSCA in 1976 and far earlier than the actual PCB regulations in 1979.

6. Summary

Recent studies indicate that PCBs are not human carcinogens and that while they may produce reversible skin conditions, they do not pose serious risk of injury to human health. Also, as a result of voluntary efforts to reduce the use of PCBs, the level of PCBs in the environment continues to decrease.

To preserve and continue these environmental improvements, the die casting industry must continue to use special care in the handling of any item containing PCB, including hydraulic machinery, capacitors, and transformers. Good industrial hygiene work practices should be employed by all workers who may come into conctact with PCBs. Although the regulatory environment governing PCBs is in a state of flux, regulations are in effect governing all aspects of the use, distribution in commerce and disposal of equipment containing more than 50 ppm PCBs. These regulations are detailed and require the die casting industry to continue to reduce the concentration of PCBs in hydraulic fluids.

MONS 015289

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MONS 015290

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MONS 015291

OBSERVATION AND CONCLUSIONS BASED ON A STUDY ON THE HEALTH OF CAPACITOR WORKERS WITH HIGH PRIOR EXPOSURE TO PCBs

PRESENTATION AND DISCUSSION BY:

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July 11, 1983

THE HEALTH OF CAPACITOR WORKERS WITH HIGH PRIOR EXPOSURE TO PCB's: A CLINICAL CROSS-SECTIONAL STUDY

GENERAL ELECTRIC COMPANY
CORPORATE ENVIRONMENTAL PROGRAM

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J. BROWN, JR., PHD.

OBJECTIVES OF STUDY

1. CHARACTERIZE HEALTH STATUS OF EXPOSED POPULATION
   - OVERALL ASSESSMENT (HISTORY, PHYSICAL)
   - 75 QUANTITATIVE PARAMETERS

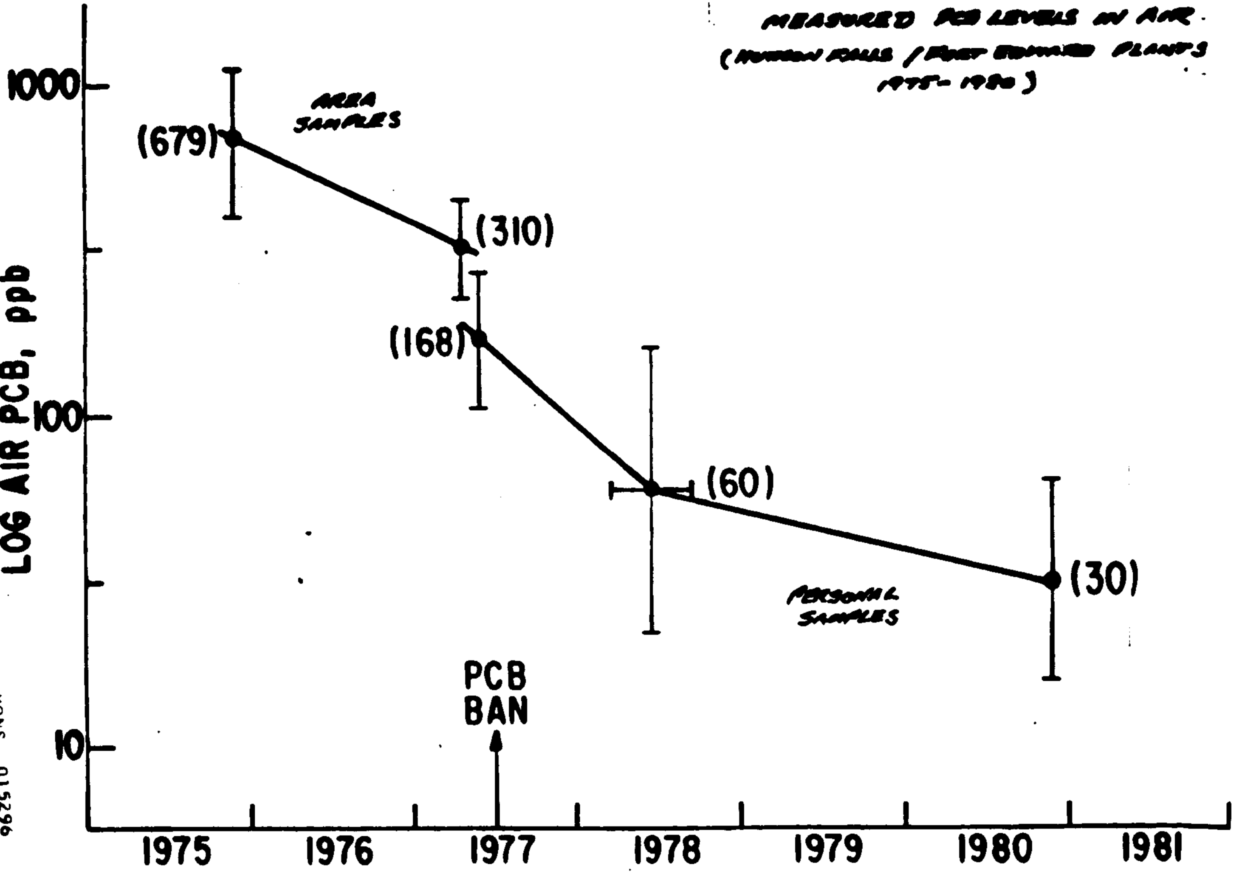
2. CHARACTERIZE EXPOSURE LEVELS
   - JOB ANALYSIS AND CATEGORIZATION
   - PCB AIR LEVELS
   - SERUM PCB MEASUREMENTS
     - ACTIVITY INDICATORS
     - PCB BODY BURDEN

3. ASSESS HEALTH EFFECT - EXPOSURE CORRELATION
   - CHECK REPORTED CORRELATIONS
   - LOOK FOR NEW ASSOCIATIONS AMONG VARIABLES

SIGNIFICANT BACKGROUND FACTORS

(GE HUDSON FALLS / FORT EDWARD PCB EXPOSURES)

- LARGEST U.S. PCB USER
  (15% OF TOTAL PCB CONSUMPTION (1966-1974)
- COMPOSITION OF PCB'S USED
  - 95% OF PRODUCTION
    AROCLOR 1254: 1946-1952
    AROCLOR 1242: 1952-1971
    AROCLOR 1016: 1971-1977
- DEFINEABLE EXPOSED POPULATION
  - LONG CONTINUOUS SERVICE
  - MANY WITH HEAVY EXPOSURE
- BEST OPPORTUNITY TO DEFINE ACTUAL EFFECTS OF PCB EXPOSURE IN HUMAN


MEASURED PCB LEVELS IN AIR
(HUDSON FALLS / FORT EDWARD PLANTS
1975-1980)
LOG AIR PCB, ppb
1000
100
10
AREA SAMPLES
PERSONAL SAMPLES
(679)
(310)
(168)
(60)
(30)
PCB BAN
1975
1976
1977
1978
1979
1980
1981

MULTIPLE PRIOR INVESTIGATIONS

- FISCHBEIN, SELIKOFF ET AL
- WARSHAW, SELIKOFF ET AL — MT. SINAI
- WOLFF, SELIKOFF ET AL
- BROWN ET AL : NIOSH, CINCINNATI, OHIO
- TAYLOR: NYSDH, HARVARD SCHOOL PUBLIC HEALTH

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HEALTH STATUS ANALYSIS

- STUDY POPULATION AND SELECTION
- CLINICAL MEASUREMENTS
- MEDICAL FINDINGS

DESCRIPTION OF GE STUDY POPULATIONS

1976:	DIRECTLY EXPOSED CAPACITOR WORKERS (~ 10% OF WORKFORCE)	194
1979:	REPEAT STUDY	174
1981:	SMALL GROUP STUDIES	
	• HIGH EXPOSURE	12
	• CLERICAL AND ADMIN.	18
	• NEW EMPLOYEES SINCE 1977 (HIGH EXPOSURE ZONE)	16

MONS 015299

POPULATION SELECTION (194)

	No.
• BASED ON CURRENT EXPOSURE (1976)	
• CONTINUOUS IN HIGH EXPOSURE ZONE	55
• CONTINUOUS IN PERIPHERY • INTERMITTENT HIGH EXPOSURE	139

PLANT PCB USE AND EMPLOYMENT DATE

• 1946-1954: AROCLOR 1254	51
• 1954-1971: AROCLOR 1242	93
• 1971-1977: AROCLOR 1016	50

MT. SINAI SCHOOL OF MEDICINE STUDY
(FISCHBEIN ET AL)

1976 : VOLUNTEERS	326
1979 : REPEAT STUDY	
• WORKERS IN COMMON	33
• ADIPOSE TISSUE BIOPSY	61

[illegible]

Population and Exposure (16)

- Sex
- Age
- Service
- Job Code
- Job Status
- Plant
- Ex/non-E
- Disease Status

- Blood PCB
  - 1242
  - 1254
  - 1260
- DDE
- Exp. Est.
- Air PCB
- Mt. Sinai
- Fast/non-Fast (1976)

Metabolic Responses (10)

- Height
- Frame
- Pre-Empl. Wt.
- Body Wt.(76 & 79)
- Max. Ref. Wt.
- Body Wt/Height*

- Triglycerides
- Cholesterol
- Blood Sugar
- Uric Acid

Cardiovascular (3)

- ECG
- Blood Pressure
  - Systolic
  - Diastolic

Hepatic Responses (12)

- Total Bilirubin
- Direct Bilirubin
- SGOT
- SGPT
- GGTP
- Alkaline Phosph.
- LDH
- Total Protein
- Albumin
- Globulin
- A/G Ratio
- Amylase

Renal Responses (18)

- Bun
- Creatinine
- Bun/Creat. Ratio
- Na^+
- K^+
- Cl^-
- Ca^{++}
- Pb^-
- Mg^{++}

- Urinalysis
  - Appearance
  - pH

  - Sp. Gr.
  - Acetone
  - Albumin
  - Glucose
  - RBC
  - WBC
  - Casts

Hematology (13)

- Iron
- RBC
- HGB
- HCT
- MCV
- MCH
- MCHC
- WBC
- Differential
  - Polys
  - Lymphs
  - Monos
  - Eosins
  - Baso.

Pulmonary Function (4)

- FVC
- FEV_1
- FEV_1/FVC
- Chest x-ray

History (5)

- Smoking
- Alcohol use
- Drug use
- Diagnosis
- Surgery

Symptomatology (6)

- Dermatological
- Neurological
- Cardiovascular
- Respiratory
- Gastrointestinal
- Musculo Skeletal

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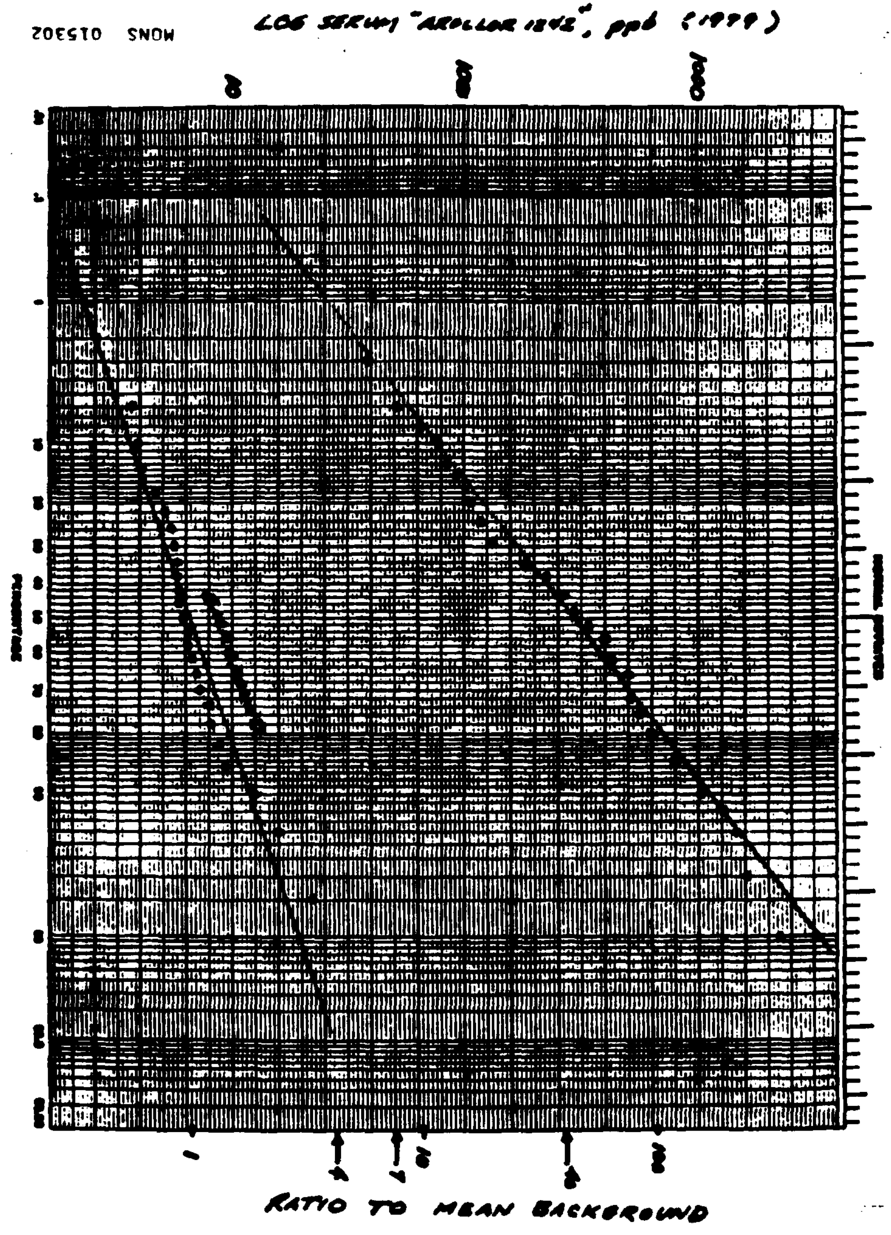
MONS 015302


LOG SERUM "AROCLOR 1242", ppb (1979)
10
100
1000
RATIO TO MEAN BACKGROUND
1
4
7
10
40
100
NORMAL DEVIATES
PERCENTAGE

Clinical Findings in PCB-Exposed Capacitor Workers

1. Dermatological Findings

Medical record review (1970-1975) 1500-1800

Non-Exposed Employees	No.	
Skin irritations or dermatitis	70	(4.2%)
Occupationally related	16	(23%)
Non-occupational	54	

Medical record review (1960-1975)

PCB-Exposed Employees	
Contact dermatitis to dielectric fluid	49
Nausea, dizziness, eye and nasal irritation, etc. on short initial exposure	16

Medical History of Study Population

Rash		45
PCB-related	1	
Seborrhea		12
Infections		19
Eye complaints		7
Old acne		4
Other		13

Chloracne not observed

Plant Physician

CLINICAL FINDINGS IN PCB-EXPOSED CAPACITOR WORKERS (CONT.)

2. CHRONIC OBSTRUCTIVE LUNG DISEASE

- RESTRICTIVE PATTERNS (3) 1.8%
  OBSTRUCTIVE PATTERNS (26) 15.3%
  MIXED PATTERNS (3) 1.8%
- 65% OF POPULATION SMOKERS OR X-SMOKERS

3. OBESITY

- 50% OF POPULATION OVERWEIGHT
- MANY OBESE BY ANY STANDARD

4. HYPERTENSION

- HISTORY OF HYPERTENSION 22.7%
- DIASTOLIC BP ≥ 90 14.7 → 19.6% SINCE EMPLOY

5. GLUCOSE INTOLERANCE

- 45 CASES (20%): 5 DIABETICS, 10 OTHERS
  30 NORMAL POST PRANDIAL

6. ELEVATED CHOLESTEROL LEVELS

- 1976 - 41%; 1979 - 29% USING LRCP AGE ADJUSTED PERCENTILES
- INCIDENCE OF GALLSTONES, FATTY FOOD INTOLERANCE, ETC. 10%
- TRIGLYCERIDES 1976-9% : 1979-18%

7. OTHER BIOCHEMICAL VARIABLES
   IN NORMAL RANGES EXCEPT SGPT

3. Statistical Association Between Health Status Indicators and Measures of PCB Exposure

- Statistical procedures used
- Correlations observed
- Comparison of findings with others
- Conclusions

STATISTICAL PROCEDURE:

MULTIPLE LINEAR REGRESSION

- EXAMINE VARIABLE DISTRIBUTIONS
  - LOG TRANSFORMATION AS REQUIRED
  - W-TEST OF DISTRIBUTIONAL ASSUMPTIONS
- SELECT CONFOUNDERS
  - ~~% BODY FAT~~ urinary Specific Gravity, SEX, SERVICE TIME
- TEST EACH VARIABLE FOR DEPENDENCE ON PCB'S AND CONFOUNDERS:

  (VAR1) = A + B(VAR2) + C(VAR3)+ .....

DEPENDENT VARIABLE	INDEPENDENT VARIABLES

- STATISTICAL CRITERIA

  MODEL : $F > 3.84$; DF = 140-170

  COEFFICIENTS: 95% CONFIDENCE INTERVAL $\neq 0$

TWO MEASURES OF PCB LEVELS USED

1. GROSS PCB CONCENTRATION IN SERUM
   - (WEIGHT PCB) / (WEIGHT SERUM)

2. CHEMICAL ACTIVITY OF PCB'S (a)
   - (WEIGHT TISSUE PCB) / (WEIGHT TISSUE LIPID)
   - AT EQUILIBRIUM, A TOXICANT MUST REACH SAME CHEMICAL ACTIVITY (a) IN ALL TISSUES OF THE BODY, INCLUDING ANY SITES OF PHARMACOLOGICAL ACTION. THIS ACTIVITY FUNCTION CORRELATES WITH TOXIC EFFECT.

FERGUSON, 1939

PCB EQUILIBRIUM IN BODY

- NO EVIDENCE OF ACTIVE TRANSPORT
- EQUILIBRIUM ESTABLISHED WITHIN DAYS
- PCB CARRIERS IN SERUM HAVE BEEN IDENTIFIED:
  - PRIMARILY, NEUTRAL LIPID (NL) MICROPHASES OF SERUM LIPOPROTEINS
  - SECONDARILY, ALBUMIN (ALB)
- EQUILIBRIUM BETWEEN ADIPOSE TISSUE (A) AND SERUM (S) PHASES DEFINED BY CHEMICAL ACTIVITY **a**:

$$a = \frac{[PCB]_A}{[NL]_A} = \frac{[PCB]_S}{b[NL]_S + K[ALB]_S} \sim \frac{[PCB]_S}{b'[NL]_S}$$

- LITERATURE DATA INDICATE MEAN VALUES OF b' CLOSE TO 1.0, IF $[NL]_S$ BE EXPRESSED AS SUM OF SERUM TRIGLYCERIDES PLUS CHOLESTEROL, OR AS EXTRACTABLE LIPIDS.

RESULTS OF LINEAR REGRESSION ANALYSIS

- SIGNIFICANT ASSOCIATIONS AMONG OBSERVED CLINICAL FINDINGS
  - OBESITY, HYPERLIPIDEMIA, HYPERTENSION, ETC.
  - SMOKING AND PULMONARY FUNCTION
- ONLY THREE CLINICAL MEASUREMENTS CORRELATED WITH GROSS SERUM PCB CONCENTRATIONS
  - SERUM TRIGLYCERIDES
  - SERUM TOTAL CHOLESTEROL
  - SERUM Y-GLUTAMYL TRANSPEPTIDASE
- SIMILAR CORRELATIONS REPORTED PREVIOUSLY

Association of Clinical Indicators with Serum Level and Pharmacological Availability of Lipophilic Agents

Measure of Lipophilic Agent	N	Clinical Measurement* Triglyc.	Chol.	GGTP
Gross conc. in serum				
Aroclor 1242	156	+	+	+
Aroclor 1260	126	+	+	N.S.
DDE	156	+	+	N.S.
Chemical Activity				
Aroclor 1242	156	N.S.	N.S.	N.S.
Aroclor 1260	126	N.S.	N.S.	N.S.
DDE	156	N.S.	-	N.S.

* Controlled for sex, service, sp. gr. (urine)

Clinical Parameters Significantly Associated with Gross Serum PCB Concentrations in PCB-Exposed Populations

Author (PCB)	Clinical Measurement					
	TRI	CHOL	GGTP	SGOT	SGPT	HDLC
Present study	+	+	+	N.S.	N.S.	
Chase et al (1254)	+	N.S.	N.S.	+	N.S.	N.S.
Smith et al						
L-PCB	+	N.S.	+	+		N.S. (-)
H-PCB	+	+	+	+		-
Baker et al (1254)	+	+ (drinkers)	+ (drinkers)	N.S.	N.S.	N.S. (-)
Kreiss et al (1260)	N.S.	+	+		N.S.	N.S.

SUMMARY

- RESONABLY LARGE POPULATION WITH HIGH PRIOR OCCUPATIONAL EXPOSURE TO PCB's
- HEALTH PROBLEMS OF THE POPULATION ARE THOSE OF THE MODERN AFFLUENT AMERICAN WORKER; E.G., OBESITY, HYPERLIPIDEMIA, HYPERTENSION, SMOKING
- THE STATISTICAL ASSOCIATIONS BETWEEN GROSS SERUM PCB CONCENTRATION AND SERUM LIPIDS AND LIVER ENZYMES FOUND TO BE THE CONSEQUENCE OF PCB EQUILIBRATION BETWEEN SERUM LIPOPROTEIN AND ADIPOSE TISSUE RESERVOIRS OF NEUTRAL LIPIDS

$$\frac{[PCB]_A}{[NL]_A} = \frac{[PCB]_S}{b'[NL]_S}$$

DESCRIPTION AND COMPARISON OF PCB EXPOSURE LEVELS

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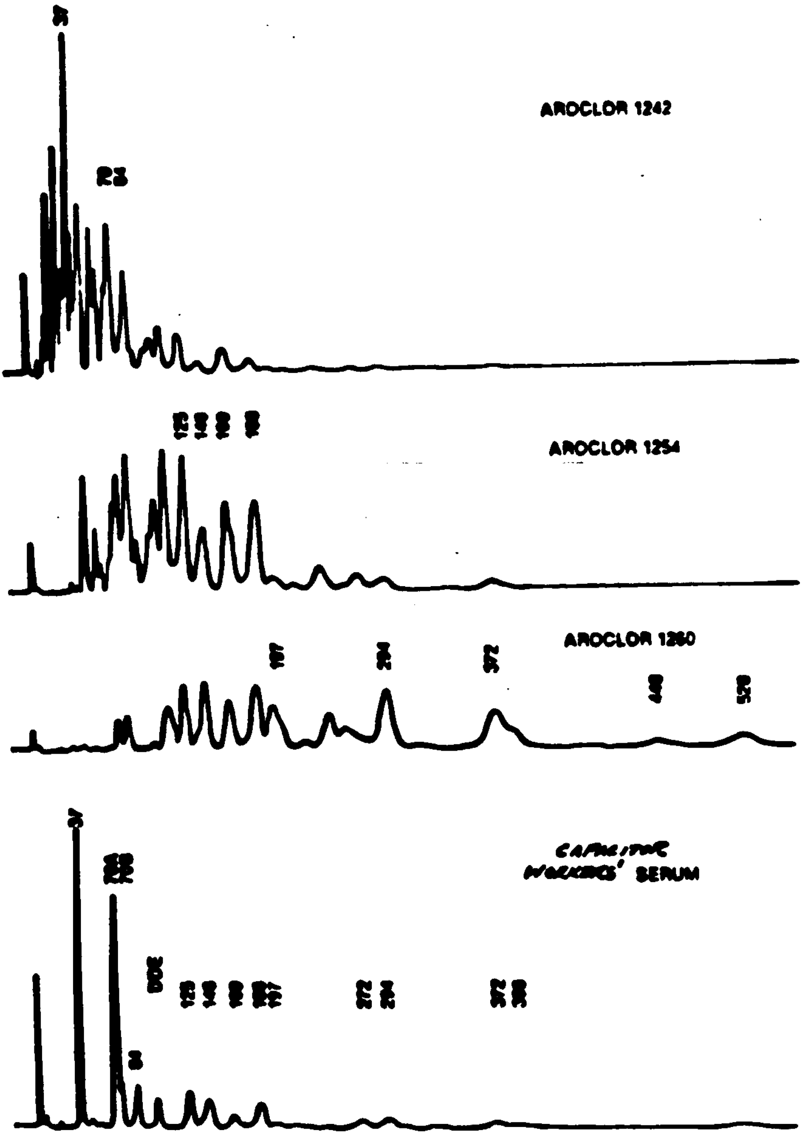
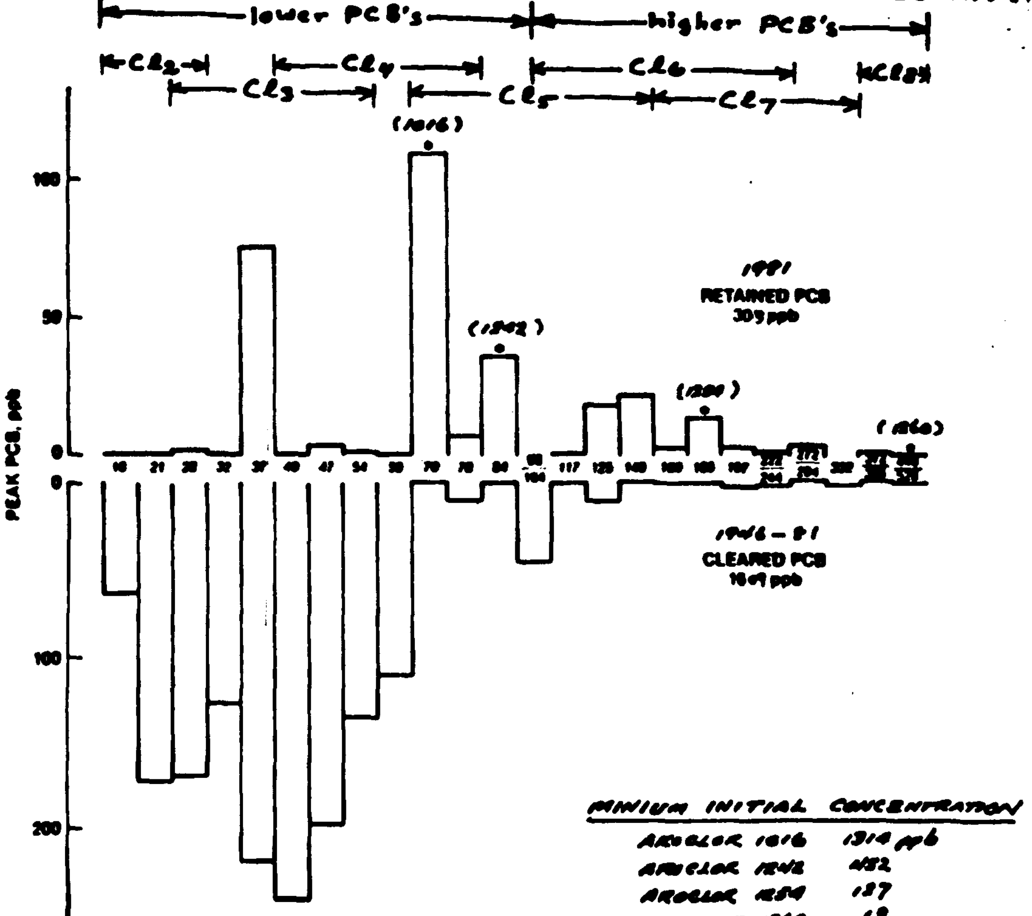
TOPICS TO BE DISCUSSED

1. REPORTING OF PCB ANALYTICAL DATA
2. ESTIMATION OF CUMULATIVE UPTAKE AND CLEARANCE
3. CALCULATION OF BODY BURDENS
4. HUMAN VS. ANIMAL UPTAKE COMPARISONS
5. CAPACITOR VS. OTHER OCCUPATIONAL EXPOSURE
6. AMBIENT PCB LEVELS IN CAPACITOR MANUFACTURING VS. CURRENT ENVIRONMENTS


AROCLOR 1242
AROCLOR 1254
AROCLOR 1260
CAPACITOR WORKERS' SERUM

OBSERVED (1981) LEVELS OF PCB's IN CAPACITOR WORKERS EXPOSED 1953-77



MINIUM INITIAL CONCENTRATION	
AROCLOR 1016	1314 ppb
AROCLOR 1242	452
AROCLOR 1254	127
AROCLOR 1260	19

TABLE II. Alternative Ways of Reporting Same Analytical Date on PCB Levels in Capacitor Worker's Sera

Reportable PCB Aggregate		Reportable Parameter (ppb)		
Description	Peak Numbers	Actual PCB's present	Analy-tical "Aroclor"	Minimum Initial conc.
~2-4 Cl-BP	11-70	195	-	1739
~5-6 Cl-BP	78-197	101	-	166
~7-8 Cl-BP	222-528	7	-	7
Total	11-528	303		1912
LPCB's	11-98	237	-	1807
HPCB's	104-528	66	-	105
Total	11-528	303		1912
Aroclor 1016	11-70	-	-	1314
Aroclor 1242	11-146	-	1000	452
Aroclor 1254	47-244	-	150	127
Aroclor 1260	70-528	-	93	19
Total	11-528	303	1093[a]	1912

a. Sum of values for "Aroclor 1242" and "Aroclor 1260"

PCB EQUILIBRIUM IN BODY

- NO EVIDENCE OF ACTIVE TRANSPORT
- EQUILIBRIUM ESTABLISHED WITHIN DAYS
- PCB CARRIERS IN SERUM HAVE BEEN IDENTIFIED:
  - PRIMARILY, NEUTRAL LIPID (NL) MICROPHASES OF SERUM LIPOPROTEINS
  - SECONDARILY, ALBUMIN (ALB)
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$$a = \frac{[PCB]_A}{[NL]_A} = \frac{[PCB]_S}{b[NL]_S + K[ALB]_S} \sim \frac{[PCB]_S}{b'[NL]_S}$$

- LITERATURE DATA INDICATE MEAN VALUES OF b' CLOSE TO 1.0, IF $[NL]_S$ BE EXPRESSED AS SUM OF SERUM TRIGLYCERIDES PLUS CHOLESTEROL, OR AS EXTRACTABLE LIPIDS.

PCB Levels in Workers Directly Exposed (1946-1977)
(N = 12)

PCB's Present (1981)	Mean	Range
Serum	303 ppb	150-450
Tissue (est.)	44.9 ppm	23-67
Body Burden (22 kg fat)	1.0 gram	0.5-1.5

Minimum Initial Concentrations and Uptake		
Serum	1912 ppb	925-2775
Tissue (est.)	277 ppm	136-402
Uptake	6.1 grams	3.0-8.8

Minimal Clearance 84%

COMPARISONS BETWEEN PCB UPTAKES IN DIRECTLY EXPOSED CAPACITOR WORKERS AND ANIMALS USED IN CHRONIC TOXICITY TESTING

LOWER PCB'S (AROCLORS 1016, 1242)

MINIMAL TOXIC DOSE IN RATS [a]	> 4.	G/KG
MINIMUM UPTAKE IN DIRECTLY-EXPOSED CAPACITOR WORKERS	0.1	G/KG

HIGHER PCB'S (AROCLOR 1260)

PRODUCING HEPATOCARCINOMA IN RATS [b]	1.6	G/KG
UPTAKE IN DIRECTLY-EXPOSED CAPACITOR WORKERS	0.003	G/KG

a. BURSE, KIMBROUGH ET AL., 1974; GOLDSTEIN, 1975

b. KIMBROUGH ET AL. 1975

REPORTED ABSENCE OF CONSISTENT HEALTH EFFECTS IN INDIVIDUALS OCCUPATIONALLY EXPOSED TO PCB's USED AT MODERATE TEMPERATURES

AUSTRALIA

OUW ET AL, 1976

FINLAND

KARPPANEN AND KOLHO, 1972

ITALY

MARONI ET AL, 1981

JAPAN

HASEGAWA ET AL, 1972
HARA ET AL, 1974
KITAMURA ET AL, 1973

US

FISCHBEIN ET AL, 1979
BROWN AND JONES, 1981
SMITH ET AL, 1982
WARSHAW ET AL, 1979
CHASE ET AL, 1982
LAWTON ET AL, THIS STUDY

OBSERVATIONS OF HEAVY PCB EXPOSURE IN CAPACITOR WORKERS

AMBIENT PCB OR "AROCLOR" LEVELS 100-1000 μG/M^3

SERUM PCB OR "AROCLOR" LEVELS 100-1000 PPB

HASEGAWA ET AL, 1972
KITAMURA ET AL, 1973
FISCHBEIN ET AL, 1979
SMITH ET AL, 1982
KARPPANEN AND KOLHO, 1972
OUW ET AL, 1976
MARONI ET AL, 1981
LAWTON ET AL, THIS STUDY

US PCB USAGE AND OCCUPATIONAL EXPOSURE 1930-75

APPLICATIONS		EST. NO. INDIVIDUALS EXPOSED	
LOW TEMPERATURE USES	(MM LBS)	PERIPHERALLY	DIRECTLY
CAPACITORS	630	32,000	4600
TRANSFORMERS	335	-	-
MISCELLANEOUS	163	-	-
TOTAL	1228	~65,000	~9000
HIGH TEMPERATURE USES			
HEAT EXCHANGERS	20	-	-
MISCELLANEOUS	5	-	-
	25	~1300	~200

CONCLUSION 1

1930-1977 OCCUPATIONAL EXPOSURES TO PCB'S WERE WIDESPREAD

- CAPACITOR MANUFACTURING
- TRANSFORMER MANUFACTURING AND SERVICE
- PLASTICIZER AND PRINTING INK USERS
- MANY THOUSANDS DIRECTLY EXPOSED

CONCLUSION 2

1930-1977 OCCUPATIONAL EXPOSURES TO PCB'S WERE <u>HIGH</u>

- AMBIENT AIR LEVELS
- UPTAKE RATES
- RETAINED PCB'S

PAST AND PRESENT ENVIRONMENTAL PCB LEVELS

	NG/M^3
CAPACITOR MANUFACTURING (1955-77)	~1,000,000
CAPACITOR MANUFACTURING (1979)	30,000
BINGHAMTON OFFICE BLDG, AFTER DISRUPTION OF PCB TRANSFORMER (1983)	800 TO 1,600
VAULT CONTAINING PCB TRANSFORMERS (1982)	700 TO 900
AIR NEAR PAPER RECYCLING MILL (1977)	6 TO 120
AIR IN PCB-USING LABORATORY (1977)	40 TO 50
AIR IN OFFICE USING DATASCREEN TERMINALS (1982)	56 TO 81
OUTDOOR AIR, NORWAY, 1982	0.5 TO 1

<u>CONCLUSION 3</u>

IN VIEW OF PAST PCB EXPOSURE LEVELS AND UPTAKES IN CAPACITOR WORKER POPULATIONS, PRESENT ENVIRONMENTAL LEVELS PRESENT LITTLE CAUSE FOR CONCERN.

PROPOSITION:

YUSHO INCIDENTS DON'T PREDICT HEALTH EFFECTS RESULTING FROM ORDINARY, LOW TEMPERATURE PCB USAGE

- DIFFERENT CHEMICAL COMPOSITION
- DIFFERENT IDENTIFIED TOXICANT
- HEALTH EFFECTS NOT SEEN IN OTHER EXPOSED POPULATIONS

COMPOSITIONS OF PCB MIXTURES PRESENTED TO HUMAN STUDY POPULATIONS

US CAPACITOR WORKERS

MAINLY LOWER PCB'S (AROCLORS 1016, 1242)

SOME HIGHER PCB'S (AROCLOR 1254)

PCDF/PCB 0-2 PPM

US TRANSFORMER WORKERS

MAINLY HIGHER PCB'S (AROCLORS 1254, 1260)

SOME LOWER PCB'S (AROCLOR 1242)

PCDF/PCB 0-5 PPM

JAPANESE YUSHO VICTIMS

PYROLYSED LOWER PCB (KANECHLOR 400)

~50% PCQ, PCBP, PCDF, ETC.

PCDF/PCB 2250 PPM

US PCB USAGE AND OCCUPATIONAL EXPOSURE 1930-75

APPLICATIONS		EST. NO. INDIVIDUALS EXPOSED	
LOW TEMPERATURE USES	(MM LBS)	PERIPHERALLY	DIRECTLY
CAPACITORS	630	32,000	4600
TRANSFORMERS	335	-	-
MISCELLANEOUS	163	-	-
TOTAL	1228	~65,000	~9000
HIGH TEMPERATURE USES			
HEAT EXCHANGERS	20	-	-
MISCELLANEOUS	5	-	-
	25	~1300	~200

REPORTED OBSERVATIONS OF CHLORACNEGENIC DISEASE IN INDIVIDUALS EXPOSED TO PCB's USED AT HIGH TEMPERATURES

<u>OCCUPATIONAL CHLORACNE</u>	PUCCINELLI, 1954
(APPEARING IN HIGH PROPORTION	MEIGS ET AL, 1954
OF EXPOSED WORKERS)	HOFMAN ET AL, 1962
	BIRMINGHAM, 1964
<u>YUSHO DISEASE</u> *	~40 JAPANESE PAPERS, 1969-
	~10 TAIWANESE PAPERS, 1980-
* PRIMARY TOXICANT IDENTIFIED AS 2,3,4,7,8-PENTACHLORO-DIBENZOFURAN	MASUDA ET AL, 1982

COMPARISONS BETWEEN YUSHO VICTIMS AND CAPACITOR WORKERS
IN PCB AND PCDF UPTAKE

	Yusho Victims: Mean Dose	Yusho Victims: Minimum Toxic Dose	Directly Exposed Capacitor Workers
Total Accumulation			
PCB's (g.)	0.63	0.11	>6
PCDF's (mg)	3.4	0.6	<0.01 (a)

a. Assuming <2 ppm PCDF in PCB absorbed

COMPARISONS BETWEEN YUSHO VICTIMS AND RATS IN PCB AND PCDF UPTAKE

	Minimum Toxic Dose	
Substance	Yusho Victims	Rats
Lower PCB's (g./kg)	0.002	> 4 (a)
Mixed PCDF's (μg/kg)	11	~10 (b)

a. Goldstein, 1975

b. Oishi, 1978

PROPOSITION:

YUSHO INCIDENTS DON'T PREDICT HEALTH EFFECTS RESULTING FROM ORDINARY, LOW TEMPERATURE PCB USAGE

- DIFFERENT CHEMICAL COMPOSITION
- DIFFERENT IDENTIFIED TOXICANT
- HEALTH EFFECTS NOT SEEN IN OTHER EXPOSED POPULATIONS