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COMMENTS IN RESPONSE TO TWO ADVANCE NOTICES OF PROPOSED RULEMAKING RELATING TO THE MANUFACTURE OF PCBs BELOW 50 PARTS PER MILLION PUBLISHED MAY 20, 1981, BY THE ENVIRONMENTAL PROTECTION AGENCY [46 FED REG 27617, 27619]

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TABLE OF CONTENTS

EXECUTIVE SUMMARY 2

I. INTRODUCTION 8

II. BACKGROUND 10

III. HEALTH AND TOXICITY EFFECTS OF PCBs 17

IV. NATURE AND FATE OF THE INCIDENTAL MANUFACTURE, PROCESSING, DISTRIBUTION AND USE OF PCBs AT CONCENTRATIONS BELOW 50 PPM 29

V. WORKER PROTECTION AND IN-PLANT EXPOSURES TO PCBs 34

VI. ANALYSIS OF INCIDENTALLY GENERATED PCBs 39

A. Problems, costs, and uncertainties in analyzing chemical industry processes for low concentrations of PCB 40

B. [Insert discussion of CMA-EPA Round Robbin Survey] 43

C. Regulations Directed toward control of PCB in products can probably be supported analytically at the current state-of-the-art 43

D. The state-of-the-art in PCB detection and quantification limits the ability to study methods of controlling incidental generation 47

VII. COST FACTORS IN THE ANALYSIS OF PCBs 49

A. Chlorobiphenyl analysis in process streams requires advanced equipment and methods 49

B. Factors involved in routine monitoring of process 52

VIII. PROBLEMS, RESOURCES AND COSTS TO REDUCE OR REMOVE INCIDENTALLY GENERATED PCBs 56

A. Introduction 56

B. Considerations in reducing generation 57

C. Example of efforts to reduce the formation of PCB 61

D. Reducing PCB concentration after generation 62

1. Standard Separation Processes 63

(a) Distillation

(b) Extraction

(c) Adsorption

(d) Absorption

2. Special Processes 64

(a) Examples of company efforts to remove PCBs after incidental generation

IX. POTENTIAL IMPACT OF EXEMPTION PETITIONS ON INDUSTRY AND EPA 72

X. AMBIENT PCBs 92

XI. EPA's PROPOSED EXCLUSION FOR CLOSED MANUFACTURING PROCESSES/CONTROLLED WASTE PROCESS. 98

XII. AN ANALYSIS OF THE LEGAL, PROCEDURAL AND POLICY ISSUES IN EPA's REVIEW OF THE RECORD IN THIS PROCEEDING 104

A. Introduction and Summary

B. The legislative and regulatory history of PCBs under the Toxic Substances Control Act.

C. Environmental Defense Fund v. Environmental Protection Agency: The 50ppm regulatory cut-off.

D. CMA's agreement to conduct an intensive, expedited information gathering effort.

E. EPA's development of a regulatory program for incidentally generated PCBs.

1. The general nature of EPA's authority and discretion to fashion a regulatory program for incidentally generated PCBs.

2. Sole reliance on the exemption petitions process will impose unreasonable administrative burdens on EPA.

3. Regulation of PCBs below 50ppm would yield trivial or deminimus benefits.

F. EPA must interpret Section 6(e) together with other provisions of the Act.

G. EPA's assessment of the benefits of regulating incidentally generated PCBs: The Health Effects of PCBs; Risks to be Addressed in Proposal Regulations.

H. EPA's obligation to consider the effects of other regulatory controls of PCBs.

1. Other provisions of TSCA

2. The Occupational Safety and Health Administation Exposure limits for PCBs

3. The Clean Water Act.

4. The Resource Conservation and Recovery Act of 1976 (RCRA)

5. The United States Department of Agriculture - Food Establishment Controls.

6. The Food and Drug Administration - Food and Drug Controls.

7. Agency proceedings held in abeyance

I. EPA should review any proposed regulation of incidentally generated PCBs in accordance with Executive Order 12291

XIII. CONCLUSIONS 143

APPENDICES

REFERENCES

ATTACHMENTS: (not included)

Previously submitted documents:

·Analytical Dissertation

·Report on Incidental Generation Survey

·Ecology and Environment, inc. Report, and literature references

EXECUTIVE SUMMARY

When Congress enacted Section 6(e) of TSCA in 1976 it was concerned with the need to ban or severely limit commercially produced PCBs. Persistent and known to accumulate in body tissue, these PCBs were viewed as a relatively narrow group of products used as dielectric, heat transfer, cooling and hydraulic fluids.

But neither Congress, industry or others concerned about PCBs at that time knew that a wide range of industry processes incidentally and unintentionally generated extremely low concentrations of PCBs. Consequently, they also did not know that many of these PCBs were in significant respects different in chemical composition and physical characteristics from, commercially produced PCBs, and that many of them were significantly different in the nature and extent of the potential health risks they posed.

Accordingly, Congress could not have considered whether Section 6(e) was an appropriate means of regulating such PCBs. Congress could not have addressed the practicality or feasibility of the narrow and limited provisions by which certain PCBs could be exempted or excluded from regulation.

Information submitted to EPA by CMA demonstrates that:

1. PCBs are not as toxic to humans as they were believed to be when Congress enacted TSCA or when EPA promulgated its PCB Ban Regulations. They do not present the carcinogenic risks once believed. Epidemiologic studies have not demonstrated a causal relationship between PCB exposure and excess in total mortality, or in mortality, due to cancer, cardiovascular disease or neurologic disorders. Certainly not every human exposure to PCBs can be deemed significant. The large number (thousands) alone of newly published studies on the health effects of PCBs justifies a reassessment by EPA of its position that any exposure to PCBs presents a signficant risk.

2. While a large number of chemical industry processes generate low concentrations of PCBs, the vast majority of those PCBs:

(a) are safely controlled in wastes regulated by EPA;

(b) are in processes from which discharges other than wastes are subject to other controls which eliminate or significantly minimize human exposures;

(c) are destroyed within the processes which generate them; or

(d) are otherwise in a form or status which effectively prevents significant human exposure.

3. Because of the minimal opportunities for in-plant exposure to workers and the worker protections and practices employed by the chemical industry, workers do not experience significant exposure to incidentally generated PCBs.

4. Because of the complex nature of the PCB family of chemicals, the limitations and costs of available analytical equipment, and the exotic and little understood science and technology involved in conducting analyses of complex chemical streams, the analysis of such streams to determine whether and what concentrations of PCBs they may contain is enormously expensive and uncertain.

5. Similarly, the alteration of chemical processes to reduce or remove concentrations of incidentally generated PCBs is expensive, difficult and uncertain.

Extensive information supplied by CMA provides substantial evidence to support the following conclusions:

1. There is no basis for concluding that incidentally generated PCBs below 50 ppm should be regulated. In fact, evidence may exist to demonstrate that materials containing higher concentrations of PCBs do not merit regulation.

2. Reliance upon the exemption petition procedure provided in Section 6(e)(3) of TSCA as the means by which industry can obtain relief from regulation of incidentally generated PCBs is patently inappropriate:

(a) Congress did not know of the existence of widespread, low concentrations of incidentally generated PCBs and could not have intended to subject either EPA or industry to the uncertainties, costs and burdens of a case-by-case, rule-by-rule, year-by-year petitions procedures.

(b) Because of the pervasiveness of low concentration incidentally generated PCBs, the petitions process will subject small manufacturers or <u>any</u> sized manufacturers of <u>low volume</u> products to uncertainties, costs and burdens which will very likely shift or eliminate innovation and investment in product development. Because such PCBs exist in a range of processes which are common in the chemical industry, the uncertainties of the petitions process can be expected to adversely impact the business plans of suppliers and customers of the generators of such PCBs.

3. The Agency's 50 ppm regulatory cutoff has already disadvantaged U.S. firms competing with foreign companies whose processes are not similarly regulated.

4. EPA should exclude from regulation all processes producing any concentrations of PCBs where:

a. all wastes or discharges are handled or disposed of in accordance with all applicable regulations;

b. the PCB concentration in products of such processes do not exceed 50 ppm (or such higher level as EPA may establish by rule); and,

5. Because of the physical, chemical and toxicological properties of monochlorobiphenyl and dichlorobiphenyl, these compounds should not be classified as PCBs for regulatory purposes. In any event, monochlorobiphenyl should not even be classified as a PCB because it has only one chlorine atom.

I INTRODUCTION

These comments and data are submitted to EPA by the Special Program Panel on PCBs of the Chemical Manufacturers Association (CMA) in response to:

- commitments which the Association made to voluntarily provide information to assist the Agency in developing new "PCB" regulations under the Toxic Substance Control Act, a project prompted by the fact that the DC Circuit Court of Appeals set aside certain of the Agency's PCB regulations in Environmental Defense Fund v Environmental Protection Agency; and

- EPA's advance notices of proposed rulemaking, published May 20, 1981, 46 Fed. Reg. 27617, 27619.

CMA is a nonprofit trade association whose approximately 185 United States member companies account for more than 90 percent of the total domestic production capacity for basic industrial chemicals. Many of our members will be directly affected by EPA's regulations and policies under the Toxic Substances Control Act generally, and Section 6(e) of that Act specifically.

CMA's submission contains information of a type and quantity not previously available to Congress or EPA -- information which will provide the Agency with substantial evidence to develop effective and not unreasonably burdensome regulations of PCBs.

II. BACKGROUND

A detailed description of the history of this matter is contained in Section ____, infra. What follows is a general description of the events leading up to CMA's submission to EPA.

In enacting the Toxic Substances Control Act (TSCA) in 1976, Congress separately identified by name only one chemical for special regulatory control -- polychlorinated biphenyls. In Section 6(e) of that Act, Congress established a phased program for the disposal of PCBs, the phase out of its manufacture, processing and distribution, and stringent limitation of the use of PCBs. That program was to be implemented by a series of EPA rulemakings.

Certain of the Agency's subsequent rulemaking efforts were challenged by the Environmental Defense Fund (EDF) and on October 30, 1980, the DC Circuit Court of Appeals sustained EDF's challenge that EPA had failed to support two of those regulations with substantial evidence. It directed the Agency to proceed expeditiously to develop new regulations.

The parties to that litigation realized, however, that regulating PCBs on the basis of the sweeping statutory language alone, and absent regulations which more precisely defined the nature and scope of the control of PCBs, might be to the disadvantage of the general public interest, the regulated industries and the EPA. Accordingly, the litigants negotiated an expedited data collection and rulemaking schedule and jointly filed motions with the DC Circuit Court of Appeals to stay the mandate of its opinion. A "stay of mandate" would leave the challenged regulations in effect during that cooperative, industry-government effort. The Court subsequently granted those joint motions, after which EPA published advance notices of proposed rulemaking (ANPR) in order to solicit data from the public to supplement information being collected by the industry litigants.

CMA was not a party to the litigation. However, it voluntarily stepped forward and participated in the negotiations among the litigants. It then agreed to assist the Agency by expending considerable resources in an intense effort to obtain data from its members and to provide narrative technical dissertations on various issues facing the Agency in its Court-directed effort to develop PCB regulations. The information submitted herewith is the result of CMA's efforts in meeting those commitments to the Agency, and in addition, contains information beyond that which the Association agreed it would provide.

Information is also provided in response to the additional questions posed by the Agency in ANPR's published in the May 20, 1981, *Federal Register*, which called for the submission of information by November 16, 1981._/

CMA's submission contains a great deal of information -- in both type and quantity -- which was not available to EPA when it promulgated its challenged regulations. Obviously, this

_/ An extension of time until November 25, 1981 was granted to CMA to complete portions of this submission other than the report on the questionnaire survey and review of toxicity. Those two documents were submitted to the Agency in final draft form on November 16, 1981.

information was also not available to Congress when it enacted TSCA. In order to provide an overview of the importance of this information it is necessary to provide a brief summary of the language and legislative history of Section 6(e) of TSCA, the nature and basis of EPA's challenged regulations, and the holding of the DC Circuit Court of Appeals while this information is detailed later in these comments, this overview may provide a helpful context in which to review the CMA's submission.

When Congress enacted the PCB regulatory scheme set forth in Section 6(e) of TSCA and when EPA promulgated its regulation limited or preliminary information was available concerning important respects about PCBs.

The focus of Congress's concern in adding §6(e) to TSCA during its passage in 1976 was on those PCBs that had been manufactured intentionally. Historically, PCBs had been sold for a variety of applications amoung which were, in descending order, capacitor or dielectrics, plasticizer applications, transformer coolants, hydraulic and lubricant fluids, and heat transfer media. During 1971 and 1972, all sales except fluids for capacitors and transformers had been ended by voluntary industry action and total domestic sales were about half of the peak reached a year earlier; yet the feeling in Congress was that additional controls were desirable and that they should be of a mandatory nature.

The focus of <u>EPA's</u> concerns in promulgating its 1979 regulation was also primarily these same PCBs, but the regulations also covered PCBs incidentally and unintentionally generated within industrial processes. Specifically, the Agency proposed an exclusion from its regulations for such materials containing PCBs in concentrations below 50 ppm. However, the only chemical processes incidentally significant generating low concentrations of PCBs which received any significant attention in the course of the rulemaking related to dye pigments.

The DC Circuit Court of Appeals, in setting aside EPA's "50 ppm" regulation as unsupported by substantial evidence, adopted EPA's view that Section 6(e) of TSCA encompassed incidentally generated PCBs, and observed that not only had EPA failed to show that its regulatory cutoff did not pose unreasonable risks for health or the environment, but failed to identify the amount of PCBs left unregulated by the 50 ppm cutoff._/

CMA's submission fills these important gaps of information. It provides significant new information on the nature, poundage, fate and exposure characteristics associated with PCBs incidentally generated in concentrations below 50 ppm in chemical processes. In general, CMA's submission supports the following:

a. While the total quantity of low concentrations, incidentally generated PCBs is extraordinarily small, the PCBs occur in types of processes which CMA believes are common with SIC 28 and within industry at large.

b. The vast majority of these PCBs are either destroyed or controlled to the extent that there is little if any human or environmental exposure, including in-plant worker exposure.

c. Analyzing and quantifying low concentrations of incidentally generated PCBs in the complex matrices of chemical processes involve a range of uncertainties hitherto unidentified and a significant resource burden on large as well as small corporations.

d. Reducing concentrations of PCBs to levels below 50 ppm is difficult, uncertain, and expensive.

Perhaps the single most important issue facing the Agency in this matter is the need for it to obtain the best scientific information regarding human effects of exposure to PCBs.

When Congress passed Section 6(e) of TSCA, PCBs were viewed as a "mad dog chemical", a life threatening chemical and an animal and human carcinogen.

When EPA promulgated its PCB regulations it held to a position which became a pivotal finding for the DC Circuit Court of Appeals -- a conclusion that any exposure to PCBs was significant.

New scientific information indicates that not only was EPA's conclusion in error, but that PCBs are not the threat to human health as was previously believed. Furthermore, recent information indicates that certain chemicals within the chlorobiphenyl family do not exhibit the same potentially adverse effects as others.

The fact of this new information is itself important. In the ten years prior to the 1976 passage of TSCA, some 2,000 scientific articles had been published on PCBs. Since 1976, 5,800 additional scientific and technical papers have been published. In an effort to help EPA evaluate the significance of this new wealth of information, CMA is submitting a number of critical reviews of significant studies in that body of published literature.

CMA urges EPA to direct that its own scientists carefully review any significant new information on the human health effec of exposure to PCBs and that, in addition, it utilize its curren authority to solicit the views of respected scientists from outside the Agency on an expedited basis, regarding their latest views on the human health effects of PCB exposure.

III. HEALTH AND TOXICITY EFFECTS OF PCBs

PCBs have been singled out in the legislature and news media of this country as posing a general threat to human health. Environmentalists, legislators, and the media dubbed PCBs as "deadly toxins," "human and animal cancer causing agents" and "life threatening chemicals resulting in a general belief by the US population that the slightest presence of PCBs represents a significant potential hazard."

PCBs are the only chemical substance which Congress specifically mandated in TSCA as requiring immediate regulatory action by the EPA Administrator. The PCB regulations written thus far appear to have been premised on EPA's belief that any exposure of PCBs to humans is significant and may present an unreasonable risk. In promulgating PCB regulations, EPA must utilize <u>substantial evidence</u> in determining whether any unreasonable risk to health or the environment are associated with PCBs at various levels of exposure. Substantial evidence should comprise good scientific evidence relating to the effects of PCBs on human health. CMA believes that substantial evidence exists to support the contrary conclusion that low level exposures to PCBs do not present a risk to human health or the environment.

In developing regulations to implement Congress's statutory mandate, the EPA Administrator relied upon adverse effects information contained within 4 reports identified in EPA's Support Document. All of these were published in either 1976 or 1977.

Much new information has been published on the health effects of PCBs since that time. A recent CMA search of the literature (TOXLINE, MEDLINE, and Chemical Abstracts) shows that over 5800 scientific and technical papers on PCBs have been published from 1976 to date. At most, Congress and EPA had available less than 2800 scientific articles which were published during the 10 year period prior to 1976. On this basis alone, CMA requests that EPA evaluate this new information and reassess its position that any exposure to PCBs is significant.

The probability that a chemical will result in an adverse effect is a function of exposure to the compound and its inherent toxicity. As noted elsewhere, low vapor pressure minimizes the potential for exposure even at concentrations of several thousand ppm. Animal toxicity literature documents that PCBs are not a highly toxic compound. Utilisation of standardized criteria for acute toxicity classifies PCBs as only slightly toxic to non-toxic (Table 1). This ranking is based in part on the fact that doses required to produce short term toxic effects in some test species are so high that the dose necessary to cause similar effects in humans would exceed 1 quart. A comparison of the acute toxicity of PCBs with other commonly known chemicals is shown in Table 2.

Chlorinated biphenyls have been evaluated for mutagenic potential in several systems, ranging from bacterial test systems to intact animal studies. They have been found to be negative in the Ames test with the exception of one positive mutagenic response for the 4-chlorobiphenyl isomer. Repeated attempts to duplicate the results of this early study have not been able to confirm a mutagenic potential for 4-chlorobiphenyl in the Ames test. This lack of reproducibility in the early findings reported by Wyndham et. al. (1976) can only lead to the conclusion that their findings are unfounded. Chlorinated biphenyls also exhibit negative responses in the dominant lethal test (a test for heritable damage leading to embryotoxicity) and are not clastogenic (capable of causing gross or morphological damage to chromosomes of blood or sperm cells of rats or cultured human blood cells). Collectively, the results of these studies indicates that ambient levels of chlorinated biphenyls do not present a mutagenic risk.

PCBs have produced embryotoxicity and spontaneous abortions in laboratory animals but only at doses which are high enough to produce maternal toxicity. PCBs are no more toxic to the fetus than most chemicals when given at toxic doses to the maternal

Tables

animals. PCBs (at high levels?) produce minimal changes in newborns and are much less toxic than some common vitamins and hormones.

CMA contracted with the independent consulting firm Ecology and Environment, Inc. (E&E) to prepare a review of the latest health effects information on PCBs. Several newly completed studies were given to E&E and these and other significant published or readily available studies were reviewed. It is E&E's "independent professional opinion that 'any exposure to PCB's' 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./ In other words, PCBs share the characteristic of being active only at high, sustained doses, and up to a certain point, the lesion may ba reversible. Therefore, safe levels of exposure may be established by carrying out proper dose-response studies."

Numerous studies involving both mice and rats have been reported, but only one study exists to date that suggests PCBs may cause an increase in hepatocellular carcinoma. Two other chronic tests in rats, as well as tests in the mouse, did not reveal a statistically significant increase in liver cancer or any other cancer with PCB treatment. A recent bioassay, performed by the National Cancer Institute, did not demonstrate that PCBs produced cancer in the rat. (ref.) A comparison of the one positive study with the large number of negative tests, and consideration of other important contributing factors, such as the spontaneous rate of liver injury and liver regeneration which can lead to aberrant hepatocellular growth, leads to the conclusion that PCBs do not represent a cancer risk to people.

At worst, PCBs at high or elevated doses meet some of the criteria for a chemical promoter, i.e., they enhance tumor growth through epigenetic mechanisms. PCBs do not induce new tumor growths. At most, PCBs have only been shown to possess a week promoting activity. Therefore, the thresholds both proposed in theory and observed in animal studies suggest that there are safe exposure levels for PCBS.

The most meaningful information for assessing a chemical's chronic health effects can be derived using human data from properly designed epidemiology studies. Epidemiological studies are often possible in situations where people have been exposed for many years.

A recent review of twenty-one epidemiology studies found that during occupational exposure, PCBs can cause temporary skin problems, but that there are no clinically observable long-term human health effects, including the occurrence of cancer (ref.). Studies of non-occupationally exposed populations found neither dermatitis nor other clinically evidence of exposure-related effects.

Many of the recent human epidemiology studies include data on large numbers of industrial workers who were occupationally exposed to PCBs over many years. These occupational exposures, in most cases, involved chronic PCB exposures which are orders of magnitude greater than any which can reasonably be foreseen under existing regulations. A comparative review of these occupational-exposure studies reveals that, like other chemicals, PCBs can cause adverse health effects, but in most respects these have been minimal. While dermatitis and chloracne, which were reversible after discontinuing the exposure, have been noted in some cases, no other significant findings were routinely made. In spite of over 50 years of use, no causal relationship has been established for any specific type of cancer, nor has it been proved that the incidence of cancer mortality has increased.

In a recent NIOSH study involving about 2500 electrical equipment manufacturing workers, over half of the cohort was occupationally exposed in excess of 20 years. Some of the workers were exposed to PCBs for as long as 40 years. The study found no excess in total mortality, nor in mortality due to cancer, cardiovasular disease or neurological disorders. Since this study failed to demonstrate an excess cancer rate in a high exposure population, it provides some reassurance that it is unlikely that future studies will show any increased risk of cancer from PCBs. As additional data have been accumulated on the Yusho incident, it appears that it was NOT the PCBs which were responsible for the adverse health effects observed but the extraordinarily high levels of impurities in the used commerical Japanese manufactured PCB mixture. (1)

The conclusions from these epidemiologic studies are in distinct contradiction to statements appearing in the present

Court of Appeals Decision that "PCBs are extremely toxic to humans," (re ıce) and "epidemiology data and experiments on laboratory a ls indicated that PCBs pose carcinogenic and other risks humans."

Although most recent scientific literature reviews have focused on human health effects studies, recent publications on the effect of environmental contamination by PCBs do not support the conclusions that PCBs have exhibited a significant irreversible detrimental effect on the ecosystem. Early reports documented that PCBs are both persistent in the environment and that they bioaccumulate in some species. CMA agrees that the higher PCB homologs are persistent and bioaccumulate to some degree. However, at present available scientific evidence does not support the alleged health and environmental consequences of this behavior.

Fear of dire ecological consequencies caused the Administrator of EPA to find "that any release of PCBs into the environment will eventually result in widespread exposure of wildlife including some of man's food sources, and humans and that such exposure may have adverse effects." In 1976, EPA presented data on PCB contaminated levels in food for the years 1973-1975. (Table 3). These data clearly indicate a significant downward trend in PCB levels, including the highly publicized fish levels. These downward trends in the data are the results of voluntary industry actions in 1971 to reduce usage and possible exposure of PCBs by eliminating all "open" uses. These responsible industry actions were taken prior to promulgation of TSCA in 1976 and certainly much earlier than the actual PCB regulations which became effective in mid 1979.

Very recent data on environmental contamination of fish and natural bodies of water (4,5,6,7)* have shown that environmental levels are still decreasing at a significant rate. Levels in fish in three different areas of the U.S. (Great Lakes, New York State, and Alabama-Georgia) were in the range of 1 to 5 ppm in 1980-81, as contrasted with the pre-1976 data which ranges from 60 ppm in 1973 to 18 ppm in 1975. In addition, at least two recent publications (5,7) demonstrate that the earlier prediction of extreme persistence of the higher chlorinated homologs in the environment is not of the order of a hundred years but is measureable and is on the average in the range of 40-50 months. These data are based upon half-life values of PCBs in the tissues of fish environmentally exposed. In addition, recent data published by the National Research Council (1979) have shown a significant reduction of PCB concentrations in air over the North Atlantic Ocean. These data have demontrated a decrease in PCB concentrations in air ranging from 0.76 ± 0.55 ng/m^3 in 1973 to 0.074 ± 0.099 ng/m^3 in 1977. [should this be left in??, need to check with NAS].

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* Note: Numerous other references to individual studies in the same time frame are available in the literature. These studies were selected since they present summary and overview of various geographical regions and include a comparison of analyses of PCBs over a period of years.

Uncontrolled waste disposal practices of commercial mixtures of PCBs have resulted in human exposures and environmental contamination. Since some PCBs were widely dispersed and are persistent (especially the higher homologs), they became ubiquitous in our environment. Concern over the adverse health effects were largely due to the possibility of effects from long-term exposure to PCBs and not based upon scientific observation and fact. Drastic regulatory measures were considered necessary in 1976 due to the then existing great scientific uncertainty concerning health effects. Compounding this uncertainty is the fact that the effects of PCBs vary greatly with the degree of chlorination and that commercial mixtures of PCBs, upon which most health effects studies are based, were contaminated with incidental contaminants such as polychlorinated dibenzofurans.

CMA believes that a thorough evaluation of the toxicological literature substantiates the conclusion that under most conditions of exposure PCBs have not been demonstrated to be hazardous to the public and that intermittent, low exposures will not lead to harmful consequences. CMA requests that the Administrator review the most recent scientific data and evidence available and the previous determination that any exposure to PCB's may present an unreasonable risk of injury to health or the environment or that any exposure to PCBs is significant. Following such an assessment, the Agency should review its current regulations and establish new regulations based on an evaluation of risk which are more consistent with the true properties of PCBs.

Table 3

TOXICITY RATING CHART

		Probable Oral Lethal Dose for Humans*	
	Rating	Animal LD_{50}	Expected Human Dose
1.	Nontoxic	15,000 mg/kg	≥ 1 Quart
2.	Weakly Toxic	5,000-15,000 mg/kg	1 Pint-1 Quart
3.	Moderately Toxic	500-5,000 mg/kg	1 Ounce-1 Pint
4.	Toxic	50-500 mg/kg	1 Teaspoon-1 Ounce
5.	Extremely Toxic	5-50 mg/kg	7 Drops-1 Teaspoon
6.	Supertoxic	≥ 5 mg/kg	Less Than 7 Drops

* Average Adult of 70 kg
Adapted from Doull et al. 1980.

Table 2

ACTUAL TOXICITY AND THE TOXICITY RATING CHART

OF SOME SELECTED CHEMICALS

Agents	Animal LD_{50}	Expected Human Dose*
PCBs	14,000 mg/kg	1 Quart
Alcohol	10,000 mg/kg	1 Pint-1 Quart
Table salt	4,000 mg/kg	1 Pint
Iron	1,500 mg/kg	1 Ounce-1 Pint
DDT	100	1 Teaspoon-1 Ounce
Strychnine	2	4 Drops
Nicotine	1	1 Drop
TCDD	0.001	Less Than 1 Drop
Botulinus toxin	0.00001	Less Than 1 Drop

* Average Adult of 70 kg
Adapted from Doull et al. 1980.

Table 3

PCBs IN FOOD

Products	Percent of samples with PCBs 1973	1974	1975	Maximal Concentration (ppm)
Fish	60.4	44.0	17.8	123.0
Milk	2.2	2.6	0.7	2.3
Eggs	1.1	4.2	0.0	11.0
Cheese	0.9	2.6	0.0	2.8
Feed Components	12.7	0.0	0.3	9.0
Animal Feed	7.2	0.0	0.0	199.5
Processed Fruit	4.5	0.0	0.0	19.2
Baby Food	1.1	0.0	0.0	trace
Meats, Poultry	1.9	1.2	0.3	> 5 ppm

Adapted from Jelinek and Corneliussen 1976.

IV NATURE AND FATE OF THE INCIDENTAL MANUFACTURE, PROCESSING, DISTRIBUTION AND USE OF PCBs AT CONCENTRATIONS BELOW 50 ppm.

CMA surveyed its membership to determine the nature, fate, poundage and other characteristics of the incidental manufacture, processing, distribution and use of chlorinated biphenyls at concentrations below 50 ppm. The complete report is appended.

The poundage of chlorobiphenyls reported represents data submitted by 85 firms, 26 of whom found 135 processes to report. These 85 firms represent between 36 to 37.6 percent of all U.S. chemical industry sales in Standard Industrial Classification Code 28, based on 1978 sales data. Moreover, they represent a large percent of basic industrial chemical sales, since firms in this group are members of the Chemical Manufacturers Association. It is this segment of the industry where incidental generation of PCB is most apt to occur.

Accurate projections to the chemical industry as a whole cannot be made without a high level of uncertainty. Attempting to project to the total chemical industry by multiplying the reported poundage by a factor of three would not be reasonable and result in vastly overstating the total produced.

The reported data show that only about 13,800 pounds of chlorobiphenyls are incidentally generated per year of which 13,100 pounds or 95 percent are disposed of as controlled waste. Of the 13,100 pound disposed of as controlled waste, 9100 pounds (66 percent) is incincerated, 1800 pounds (13 percent) is in a salt water wash discharged to a salt water reservoir surface landfill, 1600 pounds (12 percent) goes to landfill, and 600 pounds (2 percent) goes to ground injection.

The survey also found that on the order of 660 net pounds per year of chlorobiphenyls are contained in products produced by the chemical industry. Of this amount, approximately 500 pounds or 75 percent are enclosed in solid products such as paint films and polymers, or destroyed, thus minimising human contact and exposure in the environment. No chlorobiphenyls were reported as going into consumer products. About 490 of the 660 pounds were reported to be in products which were listed as captive intermediates, intermediates, or industrial products. Commercial products were reported as containing 68 pounds per year.

It is believed that the reported data represented the bulk of the chlorobiphenyls incidentally generated in the chemical industry. This is based on the coverage of the basic industrial chemical production represented by the firms responding to the survey.

The most important feature to consider in evaluating the results of the survey are the demonstrated patterns of production and fate of the chlorobiphenyls incidentally generated. Since 95 percent of the incidentally generated chlorobiphenyls are disposed of as controlled waste, even large errors in the estimates of quantities produced would mean that there is a minimal potential for human or environmental exposure.

Furthermore, of the remaining 5 percent found in products, about 4 percent is encapsulated in some solid matrix such as a paint film or polymer. Therefore incidentally generated PCBs does not present a real potential for exposure.

While it is believed the poundage reported is representative of the total, the number of processes reported is probably small in relation to the total ~~amount~~ of number, processes? products "incidentally generated chlorobiphenyls." The types of processes reported are widely and extensively used, and many small manufacturers could employ them to produce low-volume products. While this would not add significantly to the total poundage, ~~therefore~~, the number of individual processes incidentally generating chlorobiphenyls may be understated by a factor of ten or more. The data provide no basis for estimating the exact number.

The opportunity for workplace occupational exposure material containing chlorobiphenyls is also extremely low. At least 99 percent of the poundage reported is generated and processed in enclosed process systems or process systems where any release or removal occur under carefully controlled conditions.

The survey data show that only 8 of the 135 processes reported had been chemically altered to operate below a 50 ppm concentration level. The survey did not request information on physical changes which were necessary in order to operate processes below 50 ppm.

The data reported by survey respondents were based on analytical tests for 44 percent of the poundage, on informed opinion based on some analytical evaluation for 13 percent, and on best-theoretical-estimages for 43 percent of the poundage.

Several of the respondents reported the "firms's known or estimated detectable limits of PCBs." These data are tabulated in the survey report. The responses do not appear to be in complete concordance with the CMA Analytical Report previously submitted to EPA.

The survey requested information on the limits of detection (LOD) of chlorobiphenyl in process streams. The principal purpose for requesting those data was to provide additional information on the accuracy of the poundage reported. In other words, low values of LOD would indicate that firms were able to estimate the quantity of chlorobiphenyl generated with greater certainty. The instructions in the survey did not provide scientific criteria for defining LOD, such as that currently offered by the proposed standard of the American Chemical Society that the LOD be defined as at least three times quarter than the instrument signal-to-noise ratio. In the absence of such criteria, it would be expected that reported LOD's would be lower than that established by the standard since (1) the proposed standard is new and not yet widely adapted, and (2) the purpose of the standard is to correct a problem in overstatement of detectable limits (i.e.low values) and to provide comparability between laboratories.

The survey instructions requested that LOD be reported for the specific process stream where chlorobiphenyl was being reported. The implication was that firms would report on the basis of their own analytical data. It is not possible to be sure that all firms reported on this basis. It is possible that some firms reported literature values for LOD rather their own. Reporting of literature values for analysis of PCB in water would explain the very low LOD values reported by some firms.

While the LOD provides some information on the level of uncertainty regarding the presence of unobserved chlorobiphenyl, it is nota usefull concept for evaluation of analytical capability to measure chlorobiphenyl. The LOQ is greater than the LOD. The Proposed ACS standard is that the LDQ should be ten times the instrument signal-to-noise ratio, compared to three times the signal-to-noise ratio for the LOD. The LOQ level is higher because of the accuracy errors introduced into the analysis by use of lower signal values. As the analytical paper provided to EPA by CMA states, regulation should be based on the ability to measure chlorobiphenyl, not the ability to detect.

Further information on LOD and LOQ will be provided in CMA's report on its round robin analytical study.

[The supposition here is that the round robin survey results will be relevant and persuasive on this point]

WORKER PROTECTION AND IN-PLANT EXPOSURES TO PCBs

In two of its three May 20, 1981 Federal Register notices on PCBs, EPA posed the following questions soliciting information relating to worker protection requirements:

> II. What worker protection requirements might be appropriate with respect to closed manufacturing process? (46 Fed. Reg. at 27618)
>
> 5...What precautions are being taken now, or are planned to protect workers who may be exposed to PCBs? (46 Fed. Reg. at 27621)

CMA believes that imposing additional protection measures on top of those now employed by industry would duplicate existing efforts and/or contribute little if anything to the goal of worker protection. First of all, as discussed above, it is important that EPA bear in mind the latest scientific information on the law toxicity of PCBs, disucssed supra at ________.

Secondly, the low vapor pressure of PCBs makes it highly unlikely that workers will be exposed to significant amounts of PCBs. The accepted scientific physical laws of solutions, especially Raoult's law, dictate extremely small levels of PCB inhalation exposure from solutions containing low levels of PCB. The vapor pressure of PCBs over a water solutions

50 ppm of PCBN will be reduced by a factor of about 0.000003 as compared to the PCB itself. In every situation where an OSHA standard exists for the primary chemical involved in incidental manufacture of PCB's, control of exposure to that primary chemical gives orders of magnitude of safety relative to the OSHA PCB standard if the PCB concentrations is below a few thousand parts per million. For example, chlorobenzene exposure is regulated by OSHA.

If a worker is exposed to vapors from a chlorobenzene solution containing 1000 ppm PCB's, and the chlorobenzene exposure is at the regulatory limit, the PCB exposure will be below the OSHA PCB standard by a factor of 160. (For further discussion see App. A.)

Thirdly, before PCBs were recognized as a potential risk and before they were discovered to be incidentally generated in chemical manufacturing processes, the chemical industry employed proper protective clothing and good management practices to protect workers from exposure to the primary chemicals with which PCBs have now become associated as incidental contamination. EPA recognized this fact in the Preamble to the May 31, 1979 Final Ban regulations. 44 Fed. Reg. at 31527 (1979). However, in that preamble EPA erroneously asserted that the use of protective clothing and good management practices to control worker exposure to the primary chemical often left the exposure to PCBs uncontrolled. Id. As demonstrated in these comments (see Appendix A), it is CMA's belief that control of the primary chemical insures control of the PCB contaminants. In this connection, it is important to note that the EPA has already proposed, and the DC Circuit Court of Appeals upheld various authorized uses of PCBs based on the Administrator's findings that protective clothing and good management practices employed by industry reduced certain PCB exposures to low levels, thus presenting no unreasonable risks. Specifically, the Court upheld EPA's authorization of continued servicing of PCB transformers- those containing PCB concentrations greater than 500ppm, and the servicing and rebuilding of contaminated transformers-those containing PCB concentrations between 50 and 500ppm.

The potential for worker exposure to PCBs incidently generated at some point within a chemical process facility is much less than the potential for workers servicing and rebuilding electrical equipment. In any event, there are a wide range of protection measures currently utilized by industry either becuase of a need to protect against toxic or corrosive primary chemicals or as a result of specialized mandatory federal or state requirements relating to those primary chemicals.

It is important to note that "proper protective equipment" and "good management practices" are difficult to define in terms which would be uniformly applicable or appropriate. Particular definition will frequently depend upon the nature of the manufacturing process involved.

For example, safety glasses, gloves, and long-sleeved shirts are generally used in the chemical industry when unintentional contact with a toxic or corrosive chemical may occur. If the risk of contact is higher, for example, during sampling of a pressurized stream or drumming-off of waste, then additional protection is appropriate. This protection would generally include splash goggles or shields, gloves, and protective outer clothing such as rainsuits or aprons.

Food, drink and tobacco products are frequently prohibited from work areas; employers may also be instructed to wash their hands and faces prior to eating or smoking. If eye contact with a toxic or corrosive chemical may be involved, chemical showers and eyewash facilities are provided.

Equipment or process engineering and design considerations may also be important, for instance, in minimizing the potential for inadvertent releases and to control <u>intentional</u> removal of a chemical from a process. For instance, sample points are generally designed to be easily accessible to purge systems. Drum filling stations generally provide for proper ventilation. Pump seals and other likely leak points are generally shielded and drained to an appropriate point for clean-up and disposal. Further, the chemical industry today deals routinely with the proper design and operation of spill prevention control and countermeasure (SPCC) systems for storage and handling of toxic chemicals. Under other regulations, best management practices (see 40 CFR 125) and SPCC plans (see CFR 112 and proposed 40 CFR 151 at 43 F. R., 39276 (September 1, 1978) either are or will be required. These regulations currently address many of the primary chemicals with which incidentally generated PCBs are associated. Therefore, additional spill control requirements addressing incidentaly generated PCBs are unnecessary.

As discussed in our legal, procedural and policy discussion infra at ________, Section 9 of TSCH requires the Administration, before taking regulatory action, to coordinate the Agency's various authorities and to consult and coordinate with other Agencies in order to avoid duplicative or insufficient regulatory action. Congress also indicated that the results of such review and coordination were to be published with a proposed regulation. Accordingly, before EPA proposes any additional worker protection requirements on the chemical industry it should review existing proposals, consult with other Agencies including the Occupational Safety and Health Administration and carefully consider all applicable existing requirements and practices.

In conclusion, because of recent information on the law toxicity, of PCB, the chemical's inherently low vapor pressure, and the extensive use of a wide range of worker prevention and good management measures already in place within industry for a wide range of reasons, and because of EPA and the DC Circuit's previous conclusions that such measures appropriately reduce risks to PCBs, it is not clear what purposes EPA would serve by layering another regime of protection measures on top of those which exist.

VI. ANALYSIS OF INCIDENTALLY GENERATED PCBs

A. Problems, Costs And Uncertainties In Analyzing Chemical Industry Processes For Low Concentrations Of PCBs.

Among the issues which CMA voluntarily agreed to address as a part of its information gathering efforts for EPA was:

> "[A]n explanation of the problems, costs and state of the art of sampling and analysis for the identification of the pressure and concentrations of PCBs below 50 ppm in complex chemical streams*/

As CMA further agreed, that information was submitted within four months of the Court's approval of the February 20, 1980, joint motion filed by the litigants in EDF v. EPA. On ________, CMA sumitted a 38 page single spaced report, with attachments, entitled The Analysis of Chlorinated Biphenyls, (hereinafter: CMA's Analytical Report). This document represents the first publicly available effort to identify and describe analytical problems associated with the type of chlorinated biphenyls incidentally generated within chemical processes. It presents a number of important conclusions:

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*/ Letter from David Forsyth Zoll to Ruth Greenspan Bell, February 20, 1981, attached to Joint Motion for Further Stay of Assurance of the Mandate, EDF v. EPA, No. 79-1580, (D.C. Cir. filed February 20, 1981).

A. Chlorinated biphenyls are in reality some 209 individual, indentifiable "isomers";

B. Virtually every one of these isomers has differing chemical and physical properties;

C. Analysis of process streams requires the individual indentification and measurement of each of these;

D. The various instruments which can be used to measure chlorobiphenyls have different sensitivities to these isomers;

E. The variability in the sensitivity of the instruments requires that each instrument be calibrated against the specific chemical compound to be measured or that the variations from the standards used to calibrate the instrument are known;

F. The absence of commercially available standards for all isomers prevents instrument calibration or determination of the difference in instrument sensibility between a number of these isomers;

G. The chemical composition of process streams, or the "matrix," has a large impact on the ability of available instruments to detect and measure low PCB concentrations.

MONS 013471

Limits of detectability and quantification in general are lower in product streams than in more complex contaminated waste product streams. Limits of measurement can range from less than one ppm per isomer in some product streams to several hundred ppm per isomer in some complex waste streams;

H. Development of an analytical protocol to analyze the set of output streams from a process have been reported to cost on the order of $120,000, A protocol for analyzing a comparatively clean product stream would be materially less expensive.

CMA's analytical report describes how the absolute level of chlorobiphenyl in a process could be large yet, because of the number of other isomers present as well as the limits of detectability of available instruments, those PCBs <u>could still be undetectable.</u>

These findings, of course, are of great importance for EPA's consideration of its regulatory approach to PCBs. As currently implemented, the agency's 50 ppm regulatory cut-off applies to <u>each part</u> of a chemical process, and its waste streams. At or below 50 ppm the currently available technology cannot, in many instances, provide reliable assurances to <u>either</u> the manufacturer or EPA as to whether PCB concentration in a particular process or waste stream are within a particular concentration range.

The analytical problems and uncertainties caused by the mix, or matrix of various chemicals associated with a chemical process and the limits of detectability of instrument methods may vary widely. For instance, product streams are comparatively "clean", although they may still contain on the order of 50 separate chemicals. On the other hand, waste streams can be extraordinarily complex, containing many substances which have not been thoroughly characterized, or who by their nature may absorb or "lack" the PCBs in tarry mixtures or solids. These physical characteristics increase the chance that the ~~pressure of~~ presence of PCBs in a stream will be masked, and/or that the level of detectability and quantification will be raised.

The extent of this masking can be significant. Data in CMA's analytical report that in some situations the level of detection of a single isomer can be raised to 100 ppm in some matrices.

Unfortunately, there is no published data on the precision (meaning the repeatability of an analytical procedure) or acuracy (meaning the variation between a true value and what is seen) of chlorobiphenyl analysis in process streams as opposed to analysis for aroclors, or intentially manufacuted PCBs. The few literature references indicate a precision on the order of ±20 percent for a given protocol using gas chromatography/mass spectrometry.

Again, it is the matrix effect which can have the most impact on precision. Significant decreases in the relative response of the mass spectrometer occur as a result of sample mix [citation]. Data reported in CMA's analytical dissertation indicated recovery of spiked samples as low as 65 percent.

In sum, given the facts that (1) multiple isomers are known to occur in many process streams, (2) the uncertainty in the limit of detection (LOD) of a given isomer under the best of circumstances is less than one to five ppm; (3) the limit of quantification (LOQ) per isomer is on the order of five to ten times the limit of detection value, and (4) matrix effects confound and increase both LOD and LOQ values, then the ability to observe, identify, and measure accurately the concentration of chlorobiphenyl present in a process or waste stream at the current state-of-the-art will often be far above a 50 ppm concentration level.

B. [Insert dicussion of CMA-EPA Round Robbin project]

C. Regulation Directed Toward Control ~~of~~ PCB In Products Can Probably Be Supported Analytically at the Current State-~~of~~-The-Art.

On a theoretical basis, if chemical processes had the potential for generation of all 209 chlorobiphenyl isomers simultaneously, then the analytical methods used to determine PCBs would have to be capable of measuring the quantity present to a level of 50/209 or 0.239 ppm/isomer. Such a limit is well below the current state of the art in analytical capability for detection alone in the type of process streams generally analyzed. Available information from the CMA incidental generation survey, and information reported on analytical methods development and shown in Figure X of the CMA analytical report, both show that the number of isomers in a given process and product are apt to be few in number.

Three basic types of reactions can yield chlorinated biphenyl: (1) coupling reaction starting with chlorinated aromatics, (2) chlorination reactions, and (3) degradation reactions where hydrocarbon radicals are gengrated in the presence of chlorine radicals.

In the first type of reaction, the point of coupling is well defined and the number of chlorinated biphenyls determined by the structure of the starting materials(s). For example, 3,4-dichlorobenzoyl peroxide is decomposed in benzene under certain conditions to 3,4,-dichlorobiphenyl. Impurities in the starting material could lead to other chlorinated biphenyls and some self-coupling of the peroxide and isomerization could occur under the conditions of the reaction, but a single product would dominate all others.

When chlorinating aromatics, the second basic reaction type, it is well known that a phenyl or a chlorine substitute will direct subsequent substituent to the ortho or para position. For example, the normal iron chloride catalyzed chlorination of monochlorobenzene will yield about 55% paradichlorobenzene, 40% orthodichlorobenzene, and only 5% metadichlorobenzene. Conditions can modify the ratios slightly, but the basic selection will continue to exist. It is also will known that chlorine will deactivate a benzene ring. That is, it is more difficult to get the second chlorine on tha ring than it was to to get the first chlorine. This means that the second chlorine will usually go into the second ring in a biphenyl molecule, futher enhancing the selection process. The review by

Hutzinger(1) amply demonstrates the degree of selectivity in the chlorination of biphenyl. One example is the major components of Aroclor 1221.

Major Components of Aroclor 1221

Compound	% in Aroclor 1221
biphenyl	12.7
2-chlorobiphenyl	28.4
4-chlorobipbenyl	18.7
2,2'-dichlorobiphenyl	9.2

(continued)

(1) Hutzinger, O., Safe S., and Zitko V., The Chemistry of PCB's (1974), CRC Press, Inc.

2,4'-dichlorobiphenyl	3.5
2,4'-dichlorobiphenyl	13.6
4,4'-dicblorobiphenyl	6.2

All of the chlorine are in the o,p position (to the phenyl-phenyl bond). Ninety percent of the dichlorobiphenyls have one chlorine on each ring. Hutzinger also notea that there are 5 major components of Kanechlor-400 (a tetra-penta chlorobiphenyl mixture) and 7 major components of Phenoclor DPG (a hexa-hepta chlorobiphenyl mixture). These data clearly indicate that chemical reaction selectively will limit the total number of components and will severly restrict the number of major constituents.

The third basic type of reaction leading to chlorinated byphenyl is degradation. Such high temperature processes will yield components based on thermodynamic stability and the relative concentration of reactants. Steric and electronic effects dictate that different structure will have different thermodynamic stability and the relative concentration of reactant will dictate the approximate degree of chlorination. The two factors will combine to determine that a few components will predominate.

Therefore, the level of uncertainty in the estimation of total PCB in a <u>product</u> is less than it might otherwise have been if such processes produced large numbers of homologs and isomers.

Matrix effects are greatly reduced when analyzing clean product streams. While such individual product streams may contain a variety of chemical substances defined as "product," they tend to be better characterized than waste streams and therefore are easier to analyze. This is not to say that they are free of interferences; they are not. In addition, some products are solids, such as polymers and pigments, and these matrices can be quite difficult to analyze for PCBs. However limits of detection of 1 ppm or less per isomer are achievable in clean streams. On many instances, therefore, the available analytical technology is capable of providing greater assurance that a product did not contain in excess of 50 ppm PCB. A regulatory cutoff at less than 50 ppm for products, depending on the level, may or may not be supportable at current state-of-the-art of analytical technology, depending on the nature of the interferences caused by product in the analysis as well as the number and type of isomers present.

D. The State-of-the-Art in PCB Detection And Quantification Limits The Ability To Study Methods Of Controlling Incidental Generation

The thickness of a piece of paper cannot be measured with a yardstick. Similarly, if the operating conditions of a process are changed, today's state-of-the-art in analytical methods cannot measure how this changes the minute concentrations of chlorobiphenyls present. As noted in preceding parts of this discussion, many chlorobiphenyls may be present which are not detected at all, and a process change could merely push or pull isomers above or below the limit of detection. Moreover, the available levels of accuracy and precision are not capable of the accuracy required to correlate the changes which may be occurring with changes in process conditions.

As has been noted above, matrix effects create great uncertainty in the analytical determination of PCBs in the complex chemical systems found in waste streams and reactors. However, there is an even more important analytical problem which prevents study of factors for controlling incidental generation in a number of instances. For example, there are many mechanisms for the formation of benzene which create PCBs in relatively high concentrations in the process reactor, and at measurable levels. On the other hand, some incidental generation processes produce concentration in the process reactor which are well below instrument detection limits, and are estimated to occur in the parts per billion range. In such processes, PCBs are observed only at a point in the process where they are concentrated in a waste stream, such as still bottoms, where matrix effects are often most severe. Thus, the problem of monitoring a process analytically is doubly compounded because the analytical methods are not capable of observing the changes in concentration at the point of PCB generation, only at a point later in the process where they are concentrated and more heavily masked by matrix effects.

MONS 013479

A further problem that PCBs may not be generated by the primary production process at all, and may occur through secondary effects in the process. Examples include refluxing a chlorinated aromatic solvent, a side reaction with a solvent or with a catalyst. In such instances the limits of the capability of analytical methods may prevent even the identification of that portion of the process responsible for PCB generation.

Until science produces a better "yardstick", one cannot seriously consider attempts to modify the chemistry of a process to control chlorobiphenyl incidental generation. You cannot change or control that which you cannot measure.

VII COST FACTORS IN THE ANALYSIS OF PCBs.

The discussion of the economic "impact of exemption petition procedures" later in this document, presents rough, order of magnitude estimates of the costs associated with that approach to control incidental generation of PCBs. What follows is a discussion of the cost factors involved in the analysis of PCBs.

A. Chlorobiphenyl Analysis In Process Streams Requires Advanced Equipment and Methods.

As has been shown in the CMA analytical report the only procedure for the effective quantitative analysis of chlorobiphenyls in process streams is the combination of gas chromatography with mass spectrometry. This statement is based on the following facts.

First, the levels of concentration of interest require the most responsive detector systems, and detector systems which react specifically to the isomers of chlorobiphenyl likely to be present. This limits the choicas to gas chromatography with electron capture or electroconductivity detectors, and to mass spectrometry.

Second, matrices in process or waste stream samples are likely to contain substances which intenfere with the use of electron capture detectors. This detector will respond to any halogenated substance, as well as to many oxygenated and sulfur containing compounds. Many of the process or waste streams where chlorobiphenyl may be generated result from processes which contain these interfering substance, particularly organochlorine compounds. Such compounds tend to illute with the same retention times as the chlorobihpenyls, and therefore mask the signal. Therefore, in order to be certain that the material being measured is a chlorobipheyl, a detector which responds specifically to the chlorobiphenyl in a masked signal must be used; in this case a mass spectrometer. Further, the response of the electron capture detector to halogen compounds is so intense that the detector is easily "saturated", and loses its ability to respond or discriminate between halogen compounds when concentration of one compound is large with respect to the other.

Third, there is now ample scientific evidence that the signal response of the electron capture detector varies significantly from one chlorobipheni isomer to another, even within the same homolog. The scientific literature now states unequivocally that the electron capture detector cannot be used in quantative analysis unless or until the detector can be calibrated against the specific isomer being quantitated [citation]. There are at present only 80 standards for 209 isomer, thus effectively eliminating this detector for serious use unless the isomer of interest is among the 80 standards or until more standards are available. This absence of standards is also a most serious problem when using mass spectroscopy, but the relative error level seems to be less (on the order of a factor or two, rather than a factor or several thousand with the electron capture detector.)

Fourth, the pattern recognition analytical methods developed for analysis of Aroclor fluids using the electron capture detector, are not applicalbe to process stream analysis.* Chlorobiphenyls in process streams do not exhibit the familiar Aroclor fluid pattern of isomers. Isomer distributions in process streams tend to be unique for each process in which they are observed.

In conclusion, it should be noted that the availability of more standards could make the electron capture detector more applicable in this area of analysis if the matrix is non-interfering or the chlorobiphenyl can be removed from the matrix. Much additional original research on methods of a standard preparation must be conducted before a full set of standards can be produced. It is believed that such an effort will require several calendar years to execute, unless a special effort is initiated to accelerate the process.

β ~~7~~ Factors Involved In Routine Monitoring of Processes

There are no rules-of-thumb which apply generally across all chemical processes, which tell one how often a process must be monitored to determine if it is in "control". Quality assurance monitoring can occur hourly, per shift, or per day, or once per week, depending on the

* It should be noted that pattern recognition methods are not appropriate for analysis of environmental samples either, but they may have some limited application to analysis of transformer oils.

stability of the process, its degree of automation, and other factors.

When in-process concentration is used as the control mechanism for incidental generation, then the closer the control level is to the estimated level of observed process stream concentration, the greater the effort required to monitor the process for chlorobiphenyl. How often one would have to monitor to determine if chlorobiphenyl levels were in "control," given a specified concentration level, is unknown since the measurement methods available are not capable of reliably detecting variation as a function of process change. Moreover, since chlorobiphenyl concentrations have has been observed to vary in different parts of an overall production process, the average number of samples which would be required is also unknown. It is therefore difficult to predict the level of effort and cost of monitoring with confidence for any change in the concentration level for a regulatory cutoff. Firms who have had reasonable confidence that the current level of chlorobiphenyl generation is well below 50 ppm, probably have not (1) expended the time and effort to develop analytical protocols or (2) purchased the additional instrumentation necessary to support the added laboratory workload that routine monitoring caused by a lower regulating cutoff would generate. The CMA incidental generation survey has shown that reports on 53 of the 137 reported processes were based on other than analytical testing. This is supporting the hypothesis that not all firms have found it necessary to monitor processes routinely at the current 50 ppm cutoff level.

The CMA analytical report has shown that the development of an analytical protocol for an entire process (i.e. all process streams) costs on the order of $120,000. If the current regulatory cutoff were to be reduced below 50 ppm, then more firms would be required to develop such protocols for their processes, the number depending on the relationship between the new cutoff limit and the expected concentration levels of PCB in these processes. Alternatively, if only products containing PCB were to be regulated, the cost of analytical protocol development would be expected to be less. If only products containing PCBs were regulated at a 50 ppm concentration cutoff, then there may be no additional significant industry analytical protocol cost impact.

It should be noted, that irrespective of the regulatory approach selected by EPA, a reduction in the 50 ppm PCB concentration cutoff will create cost impacts which will fall most heavily on the small manufacturer or the low volume product lines. The cost of the gas chromatography/mass spectrometer instrumentation is approximately $250,000, and requires $12,000 per year in maintenance support. Many small manufacturers do not have such equipment, or the trained staff to operate it. The protocol development is an additional significant cost burden. Routine monitoring expenses using the equipment and protocol is a further cost burden. The result would be that few small firms or firms supporting low volume product lines would find it possible or profitable to operate those chemical processes subject to regulation. Given the fact that the CMA incidental generation survey has disclosed the wide breadth of the processing situtation where PCB is incidentally generated, including processes widely used in the industry, small firms with small production operations could find themselves force out of entire lines of chemical processing. This could have a severe impact on new chemical substance innovations by small firms. This loss in innovation would be felt in the chemical industry, the related manufacturing industry served by these firms, and the general public.

PROBLEMS, RESOURCES AND COSTS TO REDUCE OR REMOVE INCIDENTALLY GENERATED PCBS

A. INTRODUCTION

The purpose of this section is to present the technical and economic aspects of developing and operating chemical processes in which the concentration of PCBs must be controlled to less than 50 ppm.

The discussion focuses on two specific examples: one, a process adjusted to reduce generation of PCBs to less than 50 ppm; the other a process in which removal after generation is the only known way to comply with existing regulations. Further concentration reduction in either of these cases would require considerable additional research with little confidence of success. The limitations of current analytical technology poses a not inconsiderable barrier to this research.

In this section are included theoretical considerations in the reduction or suppression of PCB formation, processes for removal of incidental PCBs and the two case histories. It should also be noted that limited, valuable manpower and financial resources must be diverted into extensive research and development programs, which, even if successful, do not benefit health or the environment.

For purposes of this section, it is presumed that the maximum PCB content permitted in any commercial product will be <50 ppm. Any additional incidental PCBs produced will be disposed of in accordance with existing EPA regulations.

B. CONSIDERATIONS IN REDUCING GENERATION

Little information is available about manufacturing processes or chemistries leading to the formation of low concentations of PCBs. It is an area of trace chemistry which has not been substantively addresses in published literature--and for good reason. As thermally and chemically stable compounds, PCBs, even at significant impurity concentrations in other chemicals, are not more than diluents exerting little if any influence on uses of the contaminated chemicals. The existence of a regulatory cutoff level at 50 ppm may be the only reason for concern about PCBs as impurities in chemical materials. Hutzinger, et. al., in The Chemistry of PCBs (CBC Press, 1974) illustrates 41 different reactions that can form PCBs. An engineer in EPA's OPTS reportedly said (Chemical Week, January 14, 1981) that PCBs can be formed anytime a material containing hydrocarbons is chlorinated in the presence of heat.

By EPA definition, PCBs are any level of chlorination to the biphenyl molecule (from one chlorine atom to ten). The incidental generation and contamination of chemical processes by

9

PCBs can come from many diverse sources. It is necessary to examine the physical properties of PCBs to understand their appearance in chemical processes.

The molecular weight of a PCB isomer can vary from 188.5 to 499. Boiling points range from 273°C for the mono homolog to over 400°C for the deca isomer. In general, PCBs ar not very soluble in water, but are soluble in oils and other organic solvents. PCBs, with the exclusion of the lower homologs, are not readily biodegradeable compounds and, once formed, are extremely persistent. These characteristics give an indication as to whether ~~when~~ PCBs may be found in processes, i.e., frequently in high boiling waste streams.

PCBs can find their way into chemical processes through two main routes; chemical reaction and contamination. Since chemical reaction types that form PCBs are already documented in the exemption petition files and the CMA survey, they will not be discussed here. Suffice it to say, when chlorine exists in a reactive form (Cl_2, HCl, Chloride salts, etc.) and carbon or hydrocarbon are present with sufficient temperature and/or catalyst (such as iron, copper, or zinc), it is possible that PCBs can form at very low concentrations. This commonly takes place in a reactor, furnace, distillation column, tarpot, phase separator etc. PCBs can even be formed at extremely low concentrations by breaking down a chlorinated solvent in a high temperature heat exchanger. PCBs can also find their way into processes by incidental contamination. Feedstocks may be contaminated at relatively low concentrations. A manufacturing process may destroy the PCBs or they may pass on through unchanged. Water contaminated with PCBs can easily introduce PCbs into a process since PCBs are more soluble in organic compounds. Water wash steps in processes readily transfer trace amounts of PCBs to the organic material.

PCB contamination of chemical processes due to incidental reactions or incidental contamination usually occurs at very low concentration. These concentrations may be below the detectable limits for clean chemical streams; however, the point of contamination will <u>rarely</u> be a clean chemical stream.

The analytical problems associated with detecting PCBs at low concentrations in interfering matrices is documented in CMA's analytical report. Since PCBs boil at high temperatures. Most processes concentrate PCBs into the waste streams. For energy and environmental reasons, most processes concentrate wastes to as great a degree as possible and have one or more recycle streams. This has the tendency of contributing to PCB buildup. For example, if PCBs are generated at a level of 100 ppb in a chemical reaction process and are concentrated in the wastestream by a factor of 100 (1% yield loss to high boiling waste), the concentration of PCBs in the waste stream will be 10 ppm.

Correspondingly, if a PCB free material is washed with water containing 10 ppb PCB at a 10 to 1 water/organic ratio, then the organic product will contain 100 ppb PCB. Again, using a concentration factor of 100 (1% yield loss) the high boiling waste stream will be contaminated at a level of 10 ppm. Both examples illustrate that by incidental generation or contamination, a waste stream (the hardest place to analyze) can be concentrated to a level of 10 ppm PCB with an entry concentration of only 100 ppb.

Once PCBs are identified in a process, it is a significant research undertaking to try to eliminate them. Besides the analytical problems of finding PCBs at extremely low levels, the reactions which form them are unknown. The reaction kinetics of trace contaminants is a relatively unexplored field of science. Interferences, competing reactions, etc., make it extremely difficult to determine the precise mechanism of PCB production. There are many interacting variables to consider such as reactant concentrations, order of reactant addition, process temperature, pressure, hold-up time, catalytic effects, mixing, etc. For example, lowering the process temperature 10°C should theoretically halve the reaction rate. Thus, PCB production <u>may</u> be halved. However, the primary reaction rate <u>may</u> correspondingly be halved. To get the same amount of production, the throughput must be doubled. The ratio of PCBs per pound of primary product may remain the same or may increase due to a larger recycle stream associated with more throughput.

To date, there has been little success in reducing the formation of PCBs in extremely low concentrations. Each process represents an entirely different research project with at time a negligible effect on the amount of PCB generated PCB generation. The lack of success in reducing PCB generation can be supported by examining the exemption petitions filed with EPA. Significant reduction in the formation of PCBs at concentrations greater than

50 ppm have been reported in very few instances. Most of the success in reducing PCB concentrations has been made by making (engineering) process modifications. These do not reduce the total poundage of PCBs formed but rather just the concentrations at various stages in the process. This has been accomplished at substantial capital investment and energy costs. In other words, companies often have the capability to make modifications to comply with the regulation but not necessarily to reduce the total amount of PCBs formed.

I. <u>Example of efforts to reduce the formation of PCB</u>
During the development of a process for the manufacture of a key specialty chemical intermediate, it was recognized that the potential existed for the formation of by-product PCBs. This was confirmed by analysis, with up to 2000 ppm detected in a process stream. Following is a summary of the technical efforts employed to define and minimize the quantity of incidental PCBs formed, and the consequent adverse impact on the commercial manufacture of the required intermediate.

(1) The analytical research program needed to support this project was estimated to have cost $200,000. The development of practical analytical procedures was facilitated by the availability of advanced analytical equipment at a central research facility. This equipment is not commonly found in most company analytical control laboratories. Before the commerical production of the required chemical intermediate could be established at a major chemical manufacturing site, established, it was necessary to purchase and install additional analytical equipment at the site for a cost of $50,000.

(2) Research programs were initiated to study ways to reduce incidental PCB formation. The company investigated:

(a) the influence of reaction variables on the rate of incidental PCBs produced in the process, and,
(b) alternative chemical routes to the desired intermediate.

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After an effort which took 2 1/2 person years of technical time and an expenditure of $500,000, the company was able to reduce the concentration of PCBs in the process stream by a change in reaction conditions from 2000 ppm to between 30 and 50 ppm. A pilot plant was constructed at an additional cost of $50,000 demonstrate the revised process. As noted below in Section (3) this reduction in incidental PCB formation was achieved only with a significant economic penalty. It is also emphasised that in this case, the degree of response to change in reaction conditions is extraordinary and one would not expect this solution to be broadly applicable to other processes.

The specialty intermediate described above described above is being produced commercially by the <50 ppm PCBs process at an incremental cost penalty of 10-15% and at a reduced capacity penalty of 50% as compared with the preferred process. Moreover, although the less than 50 ppm process produces fewer pounds of PCBs, it does produce a larger quantity of total waste material for disposal which results in an additional penalty of 20% in waste disposal costs. The less than 50 ppm process offers no benefit to health or the environment since the PCB by-product from either process are separated for disposal in accordance with EPA regulations.

It is believed that a responsible foreign competitor could operate the 2000 ppm process, without threat to health or the environment, and in compliance with local regulations, at an economic advantage. At capacity, the U. S. process would operate at an estimated penalty in excess of two million dollars per year (1981 dollars).

In summary, this project has resulted in an expenditure of $750,000 (should this be $800,000) with extensive associated manpower resources expended to develop a process which complies with current regulations but which affords no additional benefit to health or the environment. Further, additional ongoing multimillion dollar per year operating penalties will be incurred, again without environmental benefit.

D. Reducing PCB Concentration After Generation

Methods for removing PCBs or reducing their concentration after they have been incidentally generated are known. These are more likely to succeed at minimum loss of capacity than efforts

o reduce PCB generation. The following brief discussiona is
neant to be only illuetrative of approaches to remove PCBs and
not to be a comprehensive treatise on chemical unit operations
capable of such removal.

. Standard Separation Processes

(a) Distillation

The separation of trace contaminants by distillation
enerally requires one or more of the following:

(a) Widely differing boiling points between desired output and trace contaminants;

(b) Very high reflux ratio (recylce with attendant high energy cost penalty;

(c) Reduction in yield of desired output with a corresponding increase in waste for disposal.

In addition to the operating cost penalties inherent in (b) nd (c), capacity reduction caused by high recycle and/or reduced ield require substantially greater investment to achieve the ame output results.

(b) Extraction

Extraction processes depend on partition coefficients or easures of lack of affinity of solvent for product but with ignificant affinity of solvent for solute. In the case of PCBs, he most successfull extractions proceed in the wrong direction, .e., from contaminated water or raw material inputs to process treams. Thus, process waters contaminated at the part per illion level may end up in the organic chemical processes oncentrated to part par million levels.

There are no known successful extraction processes for removing trace levels of PCBs from all chemical process streams.

(c) Adsorption

Adsorption processes rely on the surface characteristics of solids to preferentially retain the contaminant while allowing product to pass unaffected. Complicated procedures are usually needed to limit yield loss. Adsorbants are usually regenerated in place by removal of concentrated contaminants for subsequent disposal.

Substantial capital investment is usually required, and such processes are sometimes successful in reducing trace contaminants to low levels.

(d) Absorption

Absorption processes are most often applied to the preferential removal of certain gases or vapors. Absorption has no known applications to the reduction of trace PCB contamination in chemical materials. Absorption of PCBs from trace contaminated mineral oil transformer fluid oil has been reported using a polymerized absorbant._/(ref. needed) This completely non-polar mineral oil transformer fluid has a significantly different partition coefficient relative to PCBs than do process streams and therefore the efficiency of separation is lost.

2. <u>Special Processes</u>

Chemical processes for the reduction of PCB concentration in transformer oils have recently be announced. These porcesses appear to be very effective in reducing PDB concentrations in transformer oils; however, they will have few applications in operations. Because transformer coolant oils are essentially inert saturated hydrocarbon oligomers, very powerfull reactants such as metallic sodium or organo sodium compounds can be used to strip the chlorine from PCBs while forming essentially harmless salts and phenylene polymers both of which can be filtered from the oil.

Only a limited number of commercial chemical processes would find use for such treatments to decontaminate their products. In most cases, the use of powerful reducing agents such as sodium would result in reactions destroying or significantly altering desired producte.

(a) EXAMPLES OF COMPANY EFFORTS TO REMOVE PCBs AFTER INCIDENTAL GENERATION

CASE ONE

Identifying the Problem of Incidental Chlorobiphenyl Generation.

1. DISCOVERY

In the case described below, the existence of mono and dichlorinated biphenyls as impurities resulting from th reaction process was known from theoretical considerations, by physical separation, and identification of PCBs during the earliest days of process development. One of the key material inputs is a chlorinated aromatic.

The process described was developed during the late 1930's and early 1940's. The fact that mono and dichlorinated biphenyls are unavoidably produced as incidental by products in this process was published in the literature in the 1940's.

2. THE NEED FOR ACTION

Action to reduce the concentration of these chlorobiphenyls in the intermediate manufactured in thi process was initiated because of early state legislation requiring that any product sold in that those state containing 100 or more ppm chlorobiphenyls be labeled.

B. Analytical Development

1. EXISTING CAPABILITY

When the time came for action to reduce the chlorobiphenyl concentration in the intermediate manufactured in this process, analytical capability was limited to identification of three of the fifteen possible mono and dichlorinated biphenyl isomers. Quantification was not sufficiently developed to meaaur less than 0.1% PCB by weight (1000 ppm).

2. DEVELOPMENT OF NEW ANALYTICAL TECHNIQUES

In order to reduce the known PCB concentration, several sophisticated analytical procedures were developed to analyse intermediates, products and waste streams containing mono and dichlorinated biphenyl isomers formed in this process. Procedures were developed to identify PCB isomers at trace levels in river and process waters.

The total effort to develop and implement these procedures as protocols required 2.4 person-years of professional (PhD level) time and 2.6 person-years of technician time.

C. Development of Removal Process

1. REDUCTION VS REMOVAL

The scientific assessment of this situation led to the conclusion that removal of the PCBs was the only feasible way to reduce the PCB concentration level to a low concentration. A simple experiment demonstrated that at essentially zero yield of useful output, the process still generated mono and dichlorinated biphenyl at concentrations in the 1000 ppm range. This result was also theoretically consistent.

2. RESOURCES REQUIRED

a. PHASE I: State Regulation - 100ppm cutoff

In order to comply with the early state law requirement, the company's initial goal was to reduce the chlorobiphenyl concentration in the intermediate to below 100 ppm. This was necessary to assure that PCBs in concentrations greater than 100ppm would no be achieved in any product manufactured from this

68

intermediate. This initial phase required the following completions and resources:

a) Analytical Development

1.) 2.4 professional (PhD) person-years

2.) 2.6 Technical person-years

b) Development of a removal Process (Design/installation/startup of pilot system)

1.) 5 professional (Engineer/Scientist) person-year

2.) 6 technician person-years

b. PHASE II: TSCA Regulation-50ppm

Based on federal (EPA) proposed regulations lowerin the cutoff to 50 ppm, the full scale process was designed to routinely meet an analytically measured concentration of less than 41 ppm. The "less than 41 ppm" goal was necessary to insure compliance due to analytical uncertainty.

The additional resources needed were as follows:

a) process development

1 professional person-years

1 technician person-years

b) design/installation/ startup of system

2 professional person-years

3 technician person-years

D. <u>Costs</u>

1. Personnel Costs-Development.

Professional

Analytical	1.32* X 2.4 years X $55,000 = $174,000	
Phase I	1.32 X 5.0 years X 35,000 = 231,000	
Phase II	1.32 X 3.0 years X 35,000 = 139,000	
Total		$544,000

Technician

Analytical	1.32 X 2.6 years X $22,000 = $ 76,000	
Phase I	1.32 X 6.0 years X 20,000 = 158,000	
Phase II	1.32 X 4.0 years X 20,000 = 106,000	
Total		$340,000
Development Expense		$884,000

* This represents direct and overhead expenses.

2. INVESTMENT

(a)	Pilot system	$1,000,000
(b)	Full Scale System	2,500,000
(c)	Analytical Equipment	350,000
(d)	System Modifications Vent changes Additional storage Tank dikes Sewer segregation	800,000
(e)	Incinerator Based on 10% use for chlorobiphenyls Waste disposal (Total cost $10,000)	1,000,000
	Total Investment	$5,650,000

3. OPERATING COSTS INCREASE

Basis: Total cost at capacity in 1981 dollars

(a)	Labor, material, IME	360,000
	IME=Indirect Mfg. Expense	
(b)	QC	120,000
(c)	Incinerator fuel	100,000
(d)	all other	100,000
	Total	680,000

When the total investment cost of $5,650,000 is amortized on a ten year straight line basis and allocated per pound of useful output, the total increase in cost per pound is 60%.

CASE TWO

PCB levels of 20ppm were measured in the reactor efference of a chlorinated organic process. Through several distillations, the PCBs remained in the bottom streams and w eventually contained in the plant tars for latter incinerati However, several streams contained PCBs at concentrations gr than 50ppm.

In order to comply with PCB regulations on in-process streams, the manufacturer invested in $200,000 of equipment to concentrate the PCBs in one step following the reactor. In addition, an operating expense of $50,000 per year is necessary to keep all non-waste process bottom streams below the 50ppm regulatory cut off.

61

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VI. WASTE DISPOSAL COST

One important consideration of lowering the regulatory cut-off of PCBs would be the increased disposal cost. Current disposal costs are significantly greater than the $.08/pound for incineration that EPA's consultant Versar predicted. The current incineration price is $.60/pound for PCB contaminated oils. (What about (Freightcost) as compared to $.014-0.18 per pound for non-PCB containing chlorinated chemical waste. At a concentration of 50 ppm, the incineration cost per pound of PCB is $12,000. When the level of PCB contamination is reduced, the cost per poun of PCB increases as shown in the following table:

Level of Contamination	Cost/lb. of PCB Incinerated
50 ppm PCB	$12,000
25 ppm PCB	$24,000
10 ppm PCB	$60,000

By lowering the regulatory cutoff from 50, the required amount of contaminated material to be disposed of would be multiplied by a large factor. This would overwhelm the waste disposal capacity for PCBs.

IX Impact of the Exemption Procedure on Industry and EPA

[THE ASSUMPTIONS AND CALCULATIONS IN THIS SECTION NEED TO BE CLARIFIED]

A. Overview

Congress authorized EPA to grant, on a case by case, rule by rule, year by year basis, exemptions from the Act's limitations on the manufacture, process or distribution of PCBs ( ). An exemption may be granted if the Administrator of EPA finds that:

(i) an unreasonable risk of injury to health or the environment would not result, and

(ii)good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl. (   )

As is explained more fully in our legal and legislative analysis (infra at ___________), it is clear that Congress focused its attention on the deliberate use, manufacture and distribution of PCBs. It was not aware that some manufacturers produce PCBs as incidental by-products of their manufacturing processes. There is simply no indication whatsoever that Congress intended to subject industry or EPA to a filings and rulemaking procedure on the great number of industrial processes which CMA's data indicate generate PCBs and are, therefore, candidates for exemption petitions.

Beyond the fact that reliance on the exemption petition procedure as the only means of relief from the overbroad language of the statute would impose significant administrative burdens on EPA, the economic consequences for an industry of such reliance could well be severe.

In general, the petition procedure:

1. would inject considerable uncertainty into the business planning of manufacturers, as well as their customers and suppliers, thus adversely impacting production, innovation and growth, with impacts in both domestic and international markets.

2. would very likely force the abandonment of products, and new investment and expansion plans simply because the profit margins for the output of small firms or for low volume products could not support the scientific, technological, resource and dollar commitments necessary to successfully clear the exemption petition process.

B. General Scope of the Potential Economic Impact on Industry

The economic impact of EPA's reliance on the exemption procedure could be substantial. First of all, processes in which PCBs are incidentally generated are basic and widely used in the chemical industry (see _____) as well as other segments of the economy.

Many of the adverse economic impacts would occur principally because of the way in which firms make investment decisions. Industrial chemical firms, like their counterparts in other major capital intensive sectors, make long-range planning forecasts of projected returns on investment (ROI), and then compare those forecasts with their target investments. Those projects expected to meet or exceed target levels of profitability are commenced. Those below profitability targets are rejected.

It is important for EPA to recognize that these profitability projections are normally made on an individual product line basis. Small firms <u>and</u> the low volume product lines of large firms are <u>both</u> in the category of commercial activities whose profit margines may be significantly impacted by even small cost increases [Consider citation to CMA's submission on the economic impacts of EPA's PMN rules on innovation.]

Reliance on the exemption procedure would almost certainly impose cost burdens, uncertainties and delays on firms along the economic chain of suppliers through manufacturers to customers. There could be a significant reduction in replacement or expansion capital for existing processes, as well as in innovative new processes designed to offer cost-reducing process alternatives for existing products or serve new product manufacturing needs. The impacts could also translate into losses for the economy as a whole in the form of employment and foreign trade losses, as well as into inflation-feeding losses in productivity and efficiency.

Of particular relevance is the fact that many chemicals that come out of the complex reactions where PCBs can occur are highly engineered for unique properties or for highly critical specialty applications. Substitution or replacement of these materials is often impossible, or at best requires long-term, expensive development programs which could be expected to result in significant inflationary cost increases for entire categories of affected products.

For example, PCBs are generated in the production of phenyl-containing silicone products, which are typically used in highly critical applications such as military and commercial aircraft, military equipment, space vehicles, and nuclear reactors. In many applications, specifications require a phenyl-containing silicone product. In those cases, even if lower performance materials could be substituted, such substitution would require development programs estimated to range between one to ten years in duration._/ More critical applications would require longer development and evaluation times.*

As another example, PCBs are generated in the production of benzene phosphorus dichloride, an intermediate in the production of a catalyst for nylon in carpets. No substitute has been found for this intermediate material and without it, carpet quality nylon cannot be manufactured.** Withdrawal of that intermediate from the marketplace would require the producer of nylon for carpets to shut down a large process line, in order to

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* Cite to Hearing Transcript, July 10, 1979, pp. 83, 96, etc. Testimony of NASA, pp. 65-93; and Naval Air Command, pp. 93-107.

** Cite

reestablish production, embark on a substantial expensive research program for a substitute catalyst or a substitute for carpet nylon. The carpet manufacturer would have to find a substitute fiber or go out of business. The consumer in turn would be faced with reduced choice in carpet selection.

Costs of the Exemption Procedure

The direct financial cost of complying with an annual exemption requirement is an important factor exerting substantial negative economic impact on firm's investment and production plans.

Initially, this would consist of the cost of preparing, assembling, and coordinating the firm's presentation of its rationale for an exemption. This would include the cost of analytical testing, developing of other supporting materials, (use of experts and consultants,) as well as the costs involved in interacting with EPA and other officials. Included within these costs are incremental analytical testing costs the firm might feel necessary to gain exemption petition approval, over and above those which would normally be incurred. After initial approval, there would be additional annual costs of assembling and filing any supplemental materials needed by the agency, as well as additional annual costs of any necessary communication with the agency.

Again, the significance of these costs should be evaluated in terms of their impact upon particular product lines. In addition, they may require, especially for small firms, a significant commitment of the firms administrative, technical and regulatory resources. The CMA incidental generation survey report indicates there may be a large number of small firms that generata some finite amount of PCBs at less than 50 ppm. With sole relience upon the exemption procedure, the aggregate burden of the reporting requirement on these small firms could be of a large magnitude. Furthermore, for those processes which may have been operating naturally at some concentration below 50 ppm, elimination of a regulatory cutoff may mean, as to them, a first time inquiry into complicated and costly analytical issues. The analysis of incidentally generated PCB is difficult, both because of the low concentrations involved, and the technical limitations of the available analytical tools. The published technical scientific literature does not contain one paper which deals with the issue of analysis of process streams for PCBs. Hence, firms must independently develop their own analytical procedures at great expense. It is important to note that detailed procedures for such analysis many never be published in the scientific literature because:

- The process-specific aspects of the problems involved severely limit the general interest in such papers and thus inhibits their publication;
- The process aspects inherent in a useful discussion of such analytical problems increases problems of the potential disclosure or industrial secrets.

Based on information provided in the CMA's analytical report and the survey of incidental manufacture, it is possible to make some order of magnitude projections of the analytical costs involved if EPA choose to rely solely upon the exemption procedure rather than a regulatory cut off. The following assumptions are utilized as a basis for projecting anticipated analytical costs:

- The number of processes involved would be substantially larger than the number of processes reported in the CMA survey as generating PCBs as suggested by the [cite to Pittaway Report]. We will assume that 700 processes would be the subject of an exemption petition.
- The nature of the exemption petition process is such that monitoring or sampling of the process will be employed as a conservative and prudent approach to obtaining relevant process information. If a process is stable, less sampling may be warrented. Furthermore, while the CMA survey indicated that almost all of the reporting processes operated between eleven and twelve months per year, many small manufacturers may have processes which operate for much shorter periods, such as a few weeks a year. Estimates of the total number of samples to the analyzed must take these factors into account.
- CMA's estimates of the costs associated with needed equipment, procedure development and monitoring costs are real world approximations.

Given these assumptions, the cost for analytical work in support of exemption petition could be roughly estimated as described below:

The analysis of PCBs in process streams requires the development of an analytical protocol. The development of a protocol for analysis of <u>clean</u> product streams is much less expensive than the development of a protocol for analysis of all process output streams (e.g. product and waste streams), because of, among other things, complex matrix problems associated with waste streams. The CMA analytical report has estimated the cost of full protocol development at $120,000. If one assumes that only the products of a process streams would be analyzed then a protocol might be developed for one-tenth the cost, or $12,000. The number of such protocols to be developed is dependent on the number of different firms involved with the estimated 700 different processes, <u>and</u> the number of different chemical substances produced by those processes. Since it is assumed that most of these processes are operated by small manufacturers, it is arbitrarily assumed that the number would be on the order of 350. On this basis, the protocol development cost could be: 350 x 12,000 = $4,200,000. [Can we provide additional clarification of the basis of our assumptions]

Once a protocol has been developed, the cost of running an analysis is a function of the number of processes, the length of time a process is in operation, the rate of sampling required to assure process stability, and the cost of single sample analysis. For purposes of developing order of magnitude cost estimates, the following assumptions are made, since no objective data are available to provide better estimates. It is assumed:

- o 10 percent (70) of the processes operate 12 months a year and require weekly samples, i. e. 1 x 52 x 70 = 3640 samples.
- o 40 percent (280) of the processes operate 3 months a year and require three samples per week, i. e. 3 x 12 x 280 = 10,080 samples.
- o 50 percent (350) of the processes operate 1 month a year and require daily samples, i. e. 1 x 30 x 350 = 10,500 samples

Based on data supplied in the analytical paper on the cost of a PCB analysis, it is estimated that the occasional weekly sample would cost $200 each, that the more frequent analysis of 3 per week would cost $125 each, and that a daily analysis would cost about $75 each. Therefore, the cost of analytical work could be on the order of:

(3640 x $200) + (10,080 x $125) + (10,500 x $75) = $2,775,500

Equipments cost are separate from and in addition to the above analysis costs, and can be estimated from the number of samples to be analysed, and the amortized equipment and maintenance costs. From CMA's analytical report it is known that a PCB analysis requires two to four hours of instrument time, including the running of standard samples and other instrument calibration procedures. At an equipment cost of $250,000 amortised over five years (i. e. $50,000 per year) plus an equipment maintenance cost of $12,000 per year, the investment cost is approximately $62,000 per year. Assuming that the equipment can be used eight hours per day five days per week, 52

31

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weeks per year, the equipment and maintenance cost is approximately $30 per hour. Assuming that a PCB analysis requires two hours of instrument time, the cost per sample is therefore about $60. The estimated total number of samples is 3640 + 10,080 + 10,500 or 24,220. The $24,220 X $60 = $1,453,200.

In summary, the rough estimate of the analytical costs involved would be on the order of $8,430,000 for the first year, and $4,229,000 in subsequent year annual operating costs. If no processes were to be excluded from regulation, then the estimated number of processes affected could more than double; these estimated costs would also at least double, if for no other reason than the increased cost of analytical protocol development for waste stream analysis.

It will be noted from CMA's analytical report that firms have had little experience with trace analysis for PCB, and that the analytical requirements press the capacity of the available instrument methods. It can be expected that this situtation would improve over time under the impetus of exemption petitions. In the short run (i.e., 2 years) this would increase the analytical expense considerably over the figures given above, as more money was spent in protocol development and improved instrument techniques. In the long run (i.e., 5 years) costs could fall as methods became more routine and automated, but better methods would probably lead to the discovery of more instances of insignificantly low levels of PCBs. This would

82

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result in additional processes requiring montoring, thus maintaining the overall level of cost burden to industry, in order to control essentially the same amount of PCB.

The principal issue to keep in mind in evaluating these costs is that their total magnitude for the industry is not nearly as important as the impact on a single product line. For the manufacturer of a low volume product to be faced with spending $12,000 to develop an analytical protocol, and $4,000 more for analysis of samples on a process operated 30 days per year, plus the cost and personnel time required to file the exemption petition itself, means that production may well be abandoned. The profit margin would not justify such costs. Significant dislocations on the availability and costs of many small volume chemicals would result.

It is worth noting that while many processes have the potential to produce incidentally generated PCB, only analytical analysis can determine if in fact a process does produce PCB. The scale of manufacture and the equipment materials of construction are both determining factors in incidental generation. [need clarification] Consequently, a small manufacturer may not be able to determine in advance if an exemption is required until the analytical work is completed. Manufacturers will tend to avoid processes with the potential for PCB generation in the face of an exemption requirement, thus stifling innovation in the development of new and improved chemical products.

(2) Effect of Uncertainty

When a firm files an exemption petition, it faces two major kinds of uncertainty, both of which would have severe adverse impact on their economic decision.

The first type is inherent in the regulatory exemptions process itself. Becaue exemptions are issued for only one year at a time, uncertainty would exist: (a) for manufacturers who from year-to-year would not know whether the process would be allowed to continue; (b) for customers, who would not know whether the product would continue to be available; and (c) for suppliers, who would not know whether their markets would continue to exist. The year-to-year petition process would in effect become a sword of Damocles over the head of manufacturers and their suppliers and customers, creating and re-creating annually a new element of risk to be factored into each year's investment projection, without any corresponding benefit to the public. Firms would be put at the mercy of year-to-year contingencies, potential changes in enforcement priorities, state-of-the-art changes in EPA testing requirements--factors which simply cannot be taken account of in the long investment planning cycle which characterises this capital-intensive segment of the economy. Such levels of risk will inevitably choke off investment.

The second type of uncertainty arises from the requirement of Section 6(e)(3)(B) that firms make a "good faith" effort to develop a substitute process under a general exemptions requirement that: (a) does not present an unreasonable risk of injury to health or the environment; and (b) may be substituted for the process which incidentally generates PCBs. It is not certain, of course, how the interpretation of "good faith" might change over time. Second, the requirement creates a particularly acute investment dilemma for many firms. Incidentally generated PCBs are frequently not easily controlled. The natural laws of chemistry are such that they do not allow an absolute 100 percent reaction to form a given product. Thus some processes will <u>always</u> generate PCBs as an incidental by-product. For firms with such processes, a "good faith" effort to find a replacement for the processes would ultimately have to be directed at finding substitutes <u>for products which themselves are not PCB-containing materials</u>. Firms in such a situation could be faced with a <u>de facto</u> ban on a whole class of materials generated from major classes of process reactions which are basic to the chemical industry. This was surely not intended by Congress.

Firms faced with one or both of these types of uncertainty are likely to do one or more of several things depending on the nature and specialisation of their processes, the level of economic risk they face in making investment decisions, and the specific nature of their own particular incidental generation process situtation. For existing processes, firms are likely to take one of three steps: [are these the only options?] (a) limit investment to minimum maintenance of replacement levels, with no improvement or expansion; (b) gradually phase-out their relevant processes by not replacing existing equipment as it wears out;

and (c) look for ways to develop modifications to disperse PCBs. A commitment of scarce investment resources to this last course is as unproductive as the deliberate capital diminution program associated with the first two courses of action. Several industrial chemical manufacturers indicated that they have already begun an investment retrenchment program for processes affected by a potential expansion of the exemption requirement. [True? or was this because of the current exemption requirement?]

The impact is also likely to be significant for investment in new processes. New process innovation investments ere of two types: (a) investment in more efficient, cost-reducing alternative to existing processes; and (b) investment in completely new processes to serve new product needs. Both of these types of innovation investment are likely to be severely discouraged. Firms faced with the uncertainty of the exemption process would be unlikely to be interested in making the large capital investment necessary for innovation of a process characterized by a completely certain annual regulatory requirement. In most cases, the risk would almost certainly outweigh the project return.

3. Effects of Delay

The process of obtaining initial approval under an exemption petition would also impose cost burdens by delaying a firm's ability to realize its investment objectives.

Delay costs involved in obtaining an approved exemption petition can add untold millions to plant costs, currently at the rate of 15-20% (7) per year. Thus, even a few months delay can add enormous sums to the cost of these projects.

The impact of this delay on innovation will come in two forms. In some cases it is not been possible to determine whether a process generates incidental PCBs until a full scale plant is placed in operation. This is true for several reasons. First of all, the level of operation at bench scale and pilot plant may operate at auch low levels that the PCBs are below the limit of detection of available analytical tools. Second, in the changes between pilot plant scale and full scale, such items as materials of construction, mixing velocity in the reactor, etc., can lead to PCB generation in full acale not present in pilot plant scale. Third, there are inatances where two full scale production processes which are believed to be identical are observed in one case to produce PCBs and in the other not to produce PCBs. For these reasons, a firm may erect a full scale plant with a multimillion dollar investment, only to find that an exemption is required for operation. At this point, delay in approval is the cost of the investment at today's cost of money plus the lose in product on the material to be produced. In addition, product is sold in advance of production and delay can cause a chain reaction of similar costa to customers. Firms will be reluctant to chance this kind of event for all chemical processing situations where PCBs have been observed to occur.

A second type of innovation impact will fall most heavily on small manufacturing operations, whether by larger or small firms. These firms will have to file an exemption petition for operation of very small and/or one-time manufacture of chemical substances. These petitions will have to be filed in advance, knowing that the process has the potential for generation of PCBs. Thus manufacturers of such items as specialty organic chemicals will have to tell customers that the material requested cannot be produced until EPA approves an exemption petition for the production. Such a situation would have a far more devastating impact on innovation than the Premanufacture Notification Rule (PMN) of TSCA Section 5, because the prohibition is not limited to 90 days, and the filing costs could be at least as great as those of PMN rule. [Cite to CMA's comments to EPA on the economic impact of EPA's proposal PMN program.]

In summary, delays associated with such compliance procedures can be substantial, and can spell the difference between proceeding with a significant process investment and cancelling it. Such delays involve potentially large dollar amounts in terms of the increased cost of both facilities and equipment (due to inflation impact), high interest and finance cost, ultimately lost sales, loss of competitive advantage, and can involve as well, lost opportunity costs when the firm has alternative developmental choices which were foregone.

International Trade Impact

Reluctance of U.S. businesses to produce products covered by the exemptions process would open the door to foreign competition, giving foreign firms an undue competitive advantage.

For example, in Canada, incidental generation of PCBe is not limited <u>per se</u>. Limits are placed on releasee to the environment and in concentrations of PCBs in the product. Thus, a process which would require an annual exemption in the United States bears no restriction in Canada. American industry could lose its competitive position with respect to certain materials to those foreign producers who are free to develop, produce, and export to the U.S., and elsewhere, products derived from processes which generate PCBs as an unwanted by-product.

Several examples of this have already occurred. One CMA member company reported that they were unable to manufacture a valuable new industrial product because the PCB concentration in the manufacture process streams would be greater than 50 ppm. The new product was a 50:50 mixture of components A and B. Manufacturing component B would be relatively easy and contains PCBs in concentrations much lower than 50 ppm. However, its manufacturing process would contain between 70 and 100 ppm PCB. It was therefore necessary to purchase component B from a Japanese chemical company. This will potentially result in an annual purchase cost of $2,000,000 versus an estimated manufacturing cost in the U.S. of $1,500,000. Moreover U.S. jobs have been lost to Japan. The situation may also arise where manufacturing industries which use PCB contaminated product would have to relocated outside the United States.

Though it was beyond the scope of this effort to estimate the precise economic significance of processes affected by incidental generation, indications are that these basic and widely used processes employ substantial numbers of workers whose jobs could be significantly reduced or eliminated by the threat of curtailing investments resulting from exemptions requirement. In addition, loss or disruption of customer markets by feedstock suppliers, and loss, reduction, or higher cost of products resulting from curtailed or eliminated processes for which off-setting substitutes are not found, would make their own significant adverse incremental contribution to unemployment.

Productivity and Efficiency

Loss of innovation of cost-saving or new production processes because of a incidental generation exemptions petitions process, could result in substantial adverse impacts on efficiency and productivity. These effects might go well beyond the lost opportunities for cost reduction or innovation product development for the individual firm by extending to the economy as a whole.

Such an impact would occur because the benefits from a particular innovation are not confined solely to cost savings or new revenues for the originating firm, but rather, may be passed along to competing firms who may achieve new efficiencies or manufacture new products by imitating the innovating process, or using it as a basis for improvement. An innovation may be passed along to customers and suppliers, to whom it may become the market stimulus for their own innovative activity, and/or the basis of lower-priced outputs. One study, based on a limited number of chemical industry innovations, showed that the social rate of return on an innovation (counting the added benefits to customers and competitors) amounted to more than twice the private rate of return for the individual firms.*

Workload Impact on EPA Staff

Though not a specific burden on firms, there is yet another significant administrative cost associated with a uniform exemption provision that merits discussion here. This is the burden on the compliance and enforcement resources of the government. As indicated above, EPA received over 70 applications for exemption at the end of 1978. Each applicant for an exemption is entitled to a hearing and an opportunity for cross-examination on disputed issues of fact. (TSCA Section 6(e)(3)(b); 6(c)(2),(3).) Even before the EDF decision, two years had passed without EPA's having taken final action on the exemption petitions. Under an exemption petitions process, such a petition would have to be renewed annually, with potentially a new hearing each year. Given the potentially hundreds of processes which would be potential candidates for exemption proceedings, this process would constitute a significant burden for an agency already under substantial budgetary and resource constraints, and with many more significant enforcement responsibilities in areas posing much greater potential for unreasonable risk. Any unnecessary regulation that results in exemption applications should be avoided. Without the exclusion of unintended PCB by-products in controlled systems, the

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* Mansfield, Edwin, et. al. The Production and Application of New Industrial Technology pp. 144-158.

administrative burden would be great, particularly if the 50 ppm cutoff were lowered. For example, for 1000 exemptions, EPA would have to hold five public hearings per day, each working day of the year, just to allow public comment.

X. THE EFFECT OF A REGULATORY CUTOFF ON THE LEVEL OF AMBIENT PCBs

[TECHNICAL PORTIONS OF THIS SECTION WILL BE CLARIFIED AND SUMMARIZED IN LAY LANGUAGE]

The Agency asks the question (46 F.R. 27621)

> Could a regulatory cutoff be established such that uncontrolled PCBs below that cutoff would not significantly increase ambient PCB concentrations? What cutoff would be appropriate and why?

It can be shown that (1) the ambient PCB concentration will decrease regardless of the regulatory cutoff and (2) that the rate of decrease will not have much relation to incidental manufacture. The National Research Council[1] has calculated that as of 1975, there were 68 million Kilograms of PCBs that were free in the environment. Of this quantity, the NRC estimated that 38% of the total quantity was comprised by the lower chlorinated biphenyla. There is ample evidence in the Support Document of the May 31, 1979 rule and in recent literature[2] to show that the lower chlorinated biphenyls degrade with a half life of five years. Hence, 36.8% of the 38% lower chlorinated biphenyls would degrade between 1975 and 2000. This represents over 55,000,000 pounds of degradation in spite of

(1) Beaton, A. M., et. al. (1979) Polychlorinated Biphenyls, National Academy of Sciences, Washington, D.C.
(2) (2) Tabak, H. H., Quave, S. A., Maskin, C. I. and Barth, E. F., Journal of WPCF, Vol. 53, No. 10. p. 1503 (October, 1981)

ignoring the slower, but significant, degradation of the higher chlorobiphenyls and using a degradation half life that is probably overly conservative by a factor of 5-10. The Agency, in the preamble to the May 31, 1979 rule, estimated that 100,000 to 500,000 pounds of PCB's were generated by incidental manufacture. Exemption petitions have been filed for incidental manufacture in concentrations greater than 50 ppm as required by the rule. The Agency can revise the estimate based on that data and the Agency can estimate the percentage of such PCBs that will reach the mobile environment. In addition, CMA presents with this submission data relative to incremental manufacture of PCBs and the fate of such PCBs for processes not regulated in the May 31, 1979 rule. These data indicate very low generation of such PCB's and of those almost all are diverted to controlled disposal site.

The total quantity of chlorinated material incidentally generated between today and the year 2000, as represented in the CMA survey, would be less than 0.5% of the quantity degraded as defined above. This quantity is infintesimal in relation to the amount of PCBs which will still be mobile in the environment.

It may be useful to examine a purely theoretical calculation in order to appreciate the degree of impact on the ambient environment from PCBs incidentally manufactured.

Theoretical Calculation

Assumption #1: 10,000 lbs. of incidental PCB's <u>released</u> per year.

Assumption #2: Such PCB's degrade with a five-year half life.

$$A = \frac{k_o}{k}(1-e^{-kt})$$

A = New PCB's, 1980-2000
k_o = Rate of addition = 10,000 lbs./year
k = Rate constant for dissipation

A = 67,000 pounds
A = 0.12% of the above calculated degradation.
A = 0.07% of the undegraded PCB's from above calculations.

This vastly over-simplified calculation ignores many factors but puts in perspective the impact of incidental PCB's relative to the amount of PCB's now mobile in the environment.

Biodegradation

Degradation rates have been measured on some chlorianted biphenyls. Environmental measurements, although preliminary, appear to confirm a decrease in ambient concentrations already occurring.[a,b] It is impossible to get an exact half life for each isomer since each homolog will vary as will the air, wate and sediment degradation rates. Order-of-magnitude estimates can be made and degradation put into perspective.

Furukawa et al [c] investigated the effect of chlorine substitution on the biodegradability of polychlorinated biphenyls. They used two pure strains: Alcaligens Y42 and Acinetobacter P6. They came to the following conclusions:

A. Degradation decreased as chlorine substitution increased.

B. PCBs containing two chlorines on either the ortho position of a single ring, i.e. 2,6 or on both rings, i.e., 22' showed poor degradability.

C. PCBs containing all chlorine atoms on only a single ring were generally degraded faster than when the same number of chlorines were substituted on both rings.

D. Ring fission of the molecular occurred preferentially with nonchlorinated or lesser chlorinated rings.

Since these authors indicated the microbial cell count in cells/mL, it is possible ot convert their data to a second order rate constant and subsequently estimate the lifetime of the chemicals in a typical lake or river. For this purpose, the data summarized in Table I for the Acinetobacter strains will be used.

(a) National Academy of Science. p. 21.
(b) Great Lakes Fish - Ck. Craddock
(c) Furukawa, K. Tonomura, K. and Kamebayashi, A. (1978). "Effects of Chlorine Substitution on the Biodegradability of PCBs", Appl. Environ. Microbial. 35:223-227.

In order to convert this rate data into a half-life, a knowledge of the concentration of microorganisms is required for representative water bodies. Baugham and Lassiter[a] gave such concentrations and these are shown in Table II. They also assumed that only 10% of the natural population of organisms would be active in any degradation. Accepting this assumption, the half-life for a lake and the bottom sediments are shown in Table III. These data are in order of magnitude agreement with specific degradation experiments and with observed decreases in environmental concentrations. One such degradation experiment is reported by Tabak et al.

Photodegradation

Using the correlation analysis of Hendry and Kenley[b] a rate constant for photodegration in the atmosphere can be estmated for the various chlorinated biphenyls. The correlation is based on the Hammet sigma constants for the chlorinated phenyl species. Assuming that all the chlorinated phenyls have a sigma similar to phenyl, an estimate was made of the rate constant for gas phase photodegradation and atmospheric half-life for chlorinated biphenyl and the results are shown in Table IV. Due to this assumption all half-lives reported in Table IV for the higher biphenyls are probably too short. However, it does

[a] Baughman, G. L. and Lassiter, R.R. (1978). "Prediction of Environmental Pollution Concentration Estimating the Hasard of Chemical Substances to Aquatic Life", ASTM STP 657, John Cairns, Jr., K. L. Dickson and W. Maki, Eds. ASTM p. 35-54.
[b] Hendry, P.G. and Kenley, R.A. (1979). "Atmospheric Reaction Products of Organic Compounds", EPA-560/12-79-001.

indicate that chlorinated biphenyls are photoreactive. Hence this becomes an important cleansing reaction for removing PCB from the environment.

Conclusion

The data clearly indicate the complexity of calculating environmental degredation rate for a real world situation. However, it is obvious that degradation does occur at its possible to illustrate the impact of mobile PCBs from incidental manufacture using order of magnitude estimate. Such order of magnitude estimates are clearly simplistic but serve to show the major points: PCBs in the ambient environment will decrease and the rate of decrease will not be influenced by release of PCBs from incidental manufacture. One can find many issues to debate relative to any specific calculation but the overall result will be the same. Arguments could fill pages but the facts remain that well over 100,000,000 lbs. of PCBs are in the environment, that incidental PCB generation would require centuries to develop quantities of comparable magnitude and that degradation, even slow degradation, of the material currently in the environment will result in a net decrease.

EPA'S PROPOSED EXCLUSION FOR
CLOSED MANUFACTURING PROCESSES/
CONTROLLED WASTE PROCESSES

In its May 20, 1981 ANPR, EPA describes and asks for comments on a proposed exclusion from regulation for "closed" manufacturing processes or processes from which all wastes are "controlled" (46 Fed. Reg. 27617, May 20, 1981). That proposal, in part, is a product of discussions between CMA and EPA.

During CMA's negotiation with EPA on the nature of the data collection effort the Association could undertake, CMA indicated believed that there were a significant number of chemical industry processes containing PCBs which had one or both of two characteristics - the PCBs were either destroyed by chemical or other reactions within the process or were essentially enclosed within the process. CMA commented that, while some number of <u>molecules</u> of PCBs might at some point escape from the process, for all <u>practical</u> purposes there would be no significant exposure to those PCBs from outside the process system <u>regardless of the concentration of PCBs within the system</u>.

CMA and EPA agreed that if what CMA believed to be the case proved true, a separate category of exclusions from PCB regulations might be justified. CMA agreed to collect data from its members regarding the existence and prevalence of these systems and asked EPA to propose such an exclusion in an advanced notice of proposed rulemaking. EPA agreed.

Unfortunately, in two respects, EPA's proposed version of this exclusion does not comport with the details of the exclusion which CMA urged EPA to propose. First of all, it made no sense at all to propose such an exclusion for only those processess which had a PCB concentration of 50ppm or less. Such an exclusion would add nothing which a repromulgated general regulatory cut-off of 50 ppm would not achieve. EPA staff assured CMA that consideration would be given to excluding qualified processes regardless of their PCB concentration. The ANPR does not by its words propose that option. However, we assume that EPA will evaluate the merits of its final proposal on the basis of that same logic it previously shared with CMA.

Secondly, CMA resisted the EPA's use of the term "closed system". In the course of negotiations both CMA and EPA staff understood that as a technical matter it was probably impossible to prevent at least some number of PCB molecules or some niniscule concentration of PCB from escaping a given process.

100

At that time CMA favored use of the term "essentially enclosed" with a request for views and data as to how that term might be defined. The majority of the EPA staff involved favored use of the term "closed system" with a request for views and data on how it might be defined.

CMA's membership survey provides evidence of only 4 processes out of the total of 135 reporting an incidental generation of PCBs which the respondents defined as "closed". There is some question as to whether even these 4 processes are in fact completely closed. However, based on CMA's report to EPA on the uncertainties involved in the analysis of process streams for low concentrations of PCBs, it is possible that this data merely reflects a limitation of available analytical tools.

As CMA has consistently maintained, there exists no chemical process which incidentally generates PCBs or which uses as an input PCB contaminated material from which some miniscule amount of PCB will escape.

101

EPA's proposed exclusion would operate only if EPA were assured that no PCBs entered the product. However, such a requirement is obviously impractical. More importantly, we believe that the Agency should focus its attention on the nature of PCBs and the potential for exposure to them rather than on what might constitute a technical definition of a closed chemical process.

Accordingly, insofar as the data collected by CMA to date is concerned, there does not appear to be a basis for developing an exclusion for regulations of the type proposed in the Agency's ANPR... However, it does appear that substantial evidence exists to support an exclusion from regulation of certain types of processes which, on the one hand, contain various concentrations of PCBs, including concentrations above 50ppm, but where virtually all PCBs exiting the process are directly controlled or are in a state which demonstrably do not pose an unreasonable risk to health or the environment.

To illustrate what type of an exclusion might be utilised, assume first that a particular chemical process contains any concentration levels of PCBs. As to any discharge from that process which are to navigable water, or publicly owned treatment works, the stringent discharge prohibitions of the Clean Water Act are applicable. Othe wastes or discharges from the process would have to be disposed of or handled according to applicable EPA PCB disposal regulations. [See discussion of those regulators infra at _____ .]

As to employee exposure within the workplace, several important sets of restrictions would apply. First of all, OSHA has established a PCB workplace threshold limit value for PCBs is designed to assure a safe workplace (supra pp.____ to ___). Furthmore, threshold limit values applicable to primary chemicals in a process which incidentally contains PCBs result in PCB exposure orders of magnitude below the OSHA TLV for PCBs. (supra pp. _ to ___).

A partial examination of EPA's files containing pending industry petitions for exemption from the Agency's PCB rules reveals a number of process streams incidentally generated PCBs which also primary chemical which are subject to various EPA and OSHA regulations (see infra at ____).

Workplace exposures are theoretically of three types--inhalation, ingestion and dermal. The potential for inhalation exposures from PCBs contained in chemicals which have accidentally spilled or leaked is infinitesimal. As the PCB vapor pressure calculations set forth at pp___ to ___ above illustrate, the possibility of exposure by inhalation can be dismissed for all practical purposes.

There are two important points to observe with respect to the potential for workplace exposure to PCBs by dermal routes and by ingestion routes as a result of dermal exposure. First of all, the worker protections are especially effective in view of the recent health effects information concerning the low toxicity of PCBs exposure (see supra pp__). Secondly, worker exposures which might occur as a result of accidental spills or leaks would be minimized or eliminated by routine instituted worker protection and good management practices. These potential exposures are miniscule compared with the potential exposures in the authorized non-enclosed uses of PCBs which have already been sustained by the D.C. Circuit Court of Appeals. See discussion infra _____.

On connection with those authorized uses, the Administrator found that proper protective clothing and good management practices should reduce PCB exposure to very low levels the regulations permit routine servicing of PCB transformers and electromagnets". Furthermore, insofar as spills or leaks of PCBs in concentrations above 50ppm occur in plants, the existing PCB disposal regulations would again be applicable.

Finally, as explained above, CMA believes that PCB concentrations below 50ppm in products do not pose an unreasonable risk to human health or environment (supra pp___to___).

Accordingly, CMA believes substantial evidence exists to support an exclusion from regulation for:

Any chemical process containing any concentration of PCBs where:

1. all wastes or discharges are handled or disposed of in accordance with applicable EPA or OSHA PCB regulations;
2. The PCB concentration in products of such process do not exceed 50ppm (or such higher level as EPA may establish by rule).

104

XII AN ANALYSIS OF THE LEGAL, PROCEDURAL AND POLICY ISSUES IN EPA'S REVIEW OF THE RECORD IN THIS PROCEEDING

A. Introduction and Summary

The purpose of this section of CMA's submission to EPA is to:

1. review the legislative and regulatory history of PCBs under the Toxic Substances Control Act;

2. review the decision in Environmental Defense Fund v Environmental Protection Agency, 636 F.2d 1267, (D.C. Circuit 1980) in setting aside certain of EPA's PCB regulations;

3. detail the purpose, nature and scope of CMA's voluntary agreement to assist EPA in collecting information relating to PCBs;

4. summarize other significant regulatory controls of PCBs ;

5. suggest the legal, policy and procedural issues which EPA should take into consideration in reviewing the record in this proceeding.

Summ done

B. THE LEGISLATIVE AND REGULATORY HISTORY OF PCBS UNDER THE TOXIC SUBSTANCES CONTROL ACT

When Congress enacted Section 6(e) of TSCA in the fall of 1976, it used the term 'polychlorinated biphenyls' to mean material which was produced with the intention that the product consist of polychlorinated biphenyls, such as Aroclor, Askarel, etc. EPA interprets the Section which is ... to assume that the prohibition on the production of polychlorinated biphenyls (intended) subparagraphs 6(e)(2) and (3) of TSCA) prohibits the production of any amount of PCB, however small, which is manufactured as an unintended ... along with some other product.

In general, Congress established in Section 6(e) of TSCA a detailed, phased scheme for the disposal of PCB's and the limitation of its manufacture, processing, distribution, and use. Section 6(e) directs the Agency (by January of 1977) to have prescribed PCB disposal methods and to require that PCB containers to be marked with appropriate warnings. By July of 1977, PCB's were to be manufactured, processed, distributed and used only in a "totally enclosed" manner. By July of 1978 all manufacture of PCB's was to cease. Six months later, all processing and distribution of PCB's in commerce was to be prohibited.

The Act contains two narrow exceptions to its regulatory scheme for PCBs. First, by rule the Administrator may authorize the continued use of PCB's in a non-totally enclosed manner if he finds that such activity "will not present an unreasonable risk of injury to health or the environment." [] Second, the Administrator may grant case-by-case, year-by-year exemptions to the prohibitions on manufacture, processing and distribution, on such conditions as he may set, and on the basis of his finding that "an unreasonable risk of injury to health or environment would not result, and ...good faith efforts have been made to develop a chemical [substitute] which does not present an unreasonable risk of injury to health or the environment."[ ]

On February 17, 1978, EPA promulgated a PCB Disposal and Marking Rule pursuant to Section 6(e)(1) of TSCA [43 Fed. Reg. 7150]. That rule was subsequently clarified by amendment [43 Fed. Reg. 33918, August 2, 1978] and slightly modified in the publication of the ban rule challenged in EDF v. EPA.

On June 17, 1978 EPA proposed (43 Fed Reg. 24802) and on May 31, 1979 finalized (44 Fed. Reg. 1514) its so called Ban Regulations which were the subject of litigation in EDF v EPA.

The most significant aspects of the Ban Regulations for present purposes were the Agency's:

1. exclusion from regulation of any materials containing less than 50 ppm of PCBs;

2. definition of statutorily exempted "totally enclosed uses" (in general, nonrailroad electrical transformers, capacitors and electromagnets) as uses which were "intact and nonleaking"; 3. determination to allow the continued use

of eleven non-totally enclosed uses: servicing of non-railroad transformers; use and servicing of railroad transformers; use and servicing of mining equipment; use in heat transfer systems; use in hydraulic systems; use in existing stacks of carbonless copy paper; use in pigments; servicing of electromagnets; use in natural gas pipeline compressors; use in small quantities for research and development; and use as a microscopy mounting medium. (See 44 Fed. Reg. at 31549-51 (1979), to be codified in 40 CFR §761.31.)

The first two regulations - the 50 ppm regulatory cut off and the definition of "totally enclosed uses", were set aside by the D.C. Circuit; the third set of regulations were substained by the Court.

Unfortunately, where Congress enacted Section 6(e) of TSCA neither Congress, industry or other interests concerned about PCBs knew that in addition to PCBs purposely manufactured for various commercial uses there also were low levels of PCBs unintentionally generated or concentrated as by-products in a wide range of chemical processes. They certainly knew nothing of the risks of human or environmental exposures for these PCBs and they did not know that these PCBs varied <u>significantly</u> in chemical, physical and toxicological characteristics from purposely manufactured PCBs.

Section 6(e) was added to the Senate and House TSCA bills as a floor amendment in both the Senate and House debates. (*See* House Committee on Interstate and Foreign Commerce, Legislative History of the Toxic Substances Control Act, 94th Cong., 2d Sess. at 233, 580 (Comm. Print. 1976) [hereinafter cited as "TSCA Legis. Hist."]. Thus, it was not the subject of the thorough and complete committee analysis which other TSCA matters were accorded. However, that the focus of Congress' concern was on intentionally manufactured PCBs of the so-called Arochlor type, which were produced, when TSCA was passed, only by Monsanto, is clear from a reading of various studies and reports referred in the legislative history.

Agree

For instance, a report prepared by the Legislative Research Service of the Library of Congress (TSCA Legis. History at 235) refers to Monsanto as "the sole United States producer of PCBs" and that the company "limited PCB sale to a few companies for use in electrical closed systems." The Council on Environmental Quality reported that PCBs are "also known as "Aroclors" (TSCA Legis. Hist. at 776).

Senator Tunney, further evidencing the focus of Congress' concern on highly concentrated mixtures of PCBs of the type included in electrical equipment stated:

> Despite assurances from the sole domestic manufacturer of PCB's, they are still escaping into the environment in awesome quantities, in fact some 10 million pounds per year. Although an agreement several years ago by the Monsanto Co. supposedly restricted PCB's use to closed systems, Monsanto obviously has no control over those to whom it sells PCB's nor does Monsanto have any control over those who import PCB's. Id. at 240.

Even more vivid evidence that Congress was targeting Arochlor type PCBs is the statement by Congressman Dingell, the House sponsor of the Section 6(e) amendment, that the restrictions it contained would have no economic impact because it was consistent with Monsanto's plans to phase out its production of PCBs. The Congressman stated:

agree

> I spoke, on the way over here, to a representative of one of the major manufacturers of PCB's, and he advised me his company does not object to this amendment. His company felt that it is a good one and it would help his company to be citizens. The

> amendment does not call, I want my colleagues to know, for immediate prohibition but, rather, a gradual phase out, to assure action within a reasonable period of time. TSCA Legis. Hist. at 582.

c

Environmental Defense Fund v. Environmental Protection Agency: the 50 ppm Regulatory Cutoff

As part of its regulatory scheme for PCBs, EPA limited application of its disposal and Ban Regulations to articles and materials containing concentrations of at least 50 ppm of PCBs. In almost all cases, materials with lower concentrations remained unregulated. EDF contended that this limitation contravened the statutory command in Section 6(e)(2)(A) and Section 6(e)(3)(A) to regulate "any polychlorinated byphenyl." While the Court did not adopt all of EDF's reasoning, it held that, under the applicable standard for judicial review, there was a lack of substantive evidence in the record to support the Administrator's decision to establish a regulatory cut-off at 50 ppm.

In the proposed Ban Regulations, EPA had listed four reasons for setting the regulatory cut-off at 50 ppm limit would "exclude from the rule municipal sludges and other mixtures containing low, (less than 50 ppm) levels of PCB's whose presence is due to ambient levels of PCB presnt in the air or water." 43 Fed. Reg. at 24804. Second, EPA believed that some industrial chemical processes inevitably produce traces of PCBs, and that careful control could reduce the concentration of PCBs only to 50 ppm. Third, EPA felt that it was impractical to regulate the "diffuse and extremely numerous PCB sources" with concentrations below 50 ppm. Id. EPA believed that the proposed cut-off would ensure maximum effectiveness of the regulation by focusing agency attention under TSCA upon the most significant and controllable sources of PCB exposure." Id. Fourth, the Agency believed that other statutes were available to regulate low concentrations of PCBs, particularly in municipal sledges and dredge soils.

The Court agreed with EPA that the legislative intention was not to require regulation of ambient concentrations of PCBs. However, it determined that, while some cut-off might be appropriate, EPA had not explained why the regulation could not be designed expressly to exclude ambient sources, thus directly fulfilling the congressional intent, rather than achieving that goal indirectly with a cut-off of 50 ppm.

Nor did the Court find persuasive EPA's justification for the regulatory cut-off on the basis of the serious impact a lower court would have on industries that inadvertantly produce PCBs during the manufacturing process. The Court emphasized that, as the Agency itself had conceded, inadvertent commercial production of PCBs was intended to be regulated under Section 6(e). By providing a blanket exemption for concentrations below 50 ppm, the Court found tha the Administrator had circumvented the authorisations and exemptions requirements provided in the statute. The Agency had made no finding that the cut-off posed no unreasonable risk to health or the environment, which is the finding required by Section 6(e). Consequently, the Court held the burdens faced by industries could not be the sole basis for the 50 ppm cut-off.

The Court also rejected the argument that the 50 ppm cut-off was justified on the basis of an Agency's inherent authority to create exemptions to a statute based on administrative necessity, or upon an inherent authority to exempt de minimis concerns from regulations. EDF v. EPA, supra, slip op. at pp. 25-38

It should be emphasized that the Court did not independently determine that incidentally generated PCBs were covered by Section 6(e) of TSCA, and EDF v. EPA cannot be read as representing a final determination on this issue. the question of Congressional intent was not before the Court. A careful and fair reading of footnote 37 discloses that the Court recognized that Congress did not even know about such PCBs. However, it thus proceeded to adopt as "reasonable" EPA's conclusion that incidentally generated PCBs were covered by PCBs and that

> ...Congress's express concern with widespread contamination and worker exposure, the chemical's toxicity at extremely low levels and the statutory language of "any polychlorinated biphenyl in any manner lead us to conclude that Congress intended to include all commercial sources within the EPA regulations...(emphasis added.)

But CMA's data demonstrate that the concern which the Court supplied to Congress was misplaced: there is no widespread worker exposure to these PCBs, they are not toxic at extremely low levels, and there are chemical, physical and toxicological differences between the two categories of PCBs.

In addition, as will be explained below, CMA's submission contains substantial evidence to support a regulatory cutoff of not less than 50 ppm by demonstrating that such a cutoff does nto pose unreasonable risks to human health or the environment, is necessary in order to avoid imposing unreasonable administrative burdens on EPA; regulations more stringent will achieve benefits of de minimis or trivial value.

C. CMA'S AGREEMENT TO CONDUCT AN INTENSIVE, EXPEDITED INFORMATION GATHERING EFFORT

CMA was not a party to EDF v. EPA. Nevertheless, it voluntarily entered the negotiations among the parties in the wake of that decision which had as its goal the structuring of an expedited data collection effort to assist the Agency in developing a new regulatory program for PCBs.

All of the participants recognised that if the Court's opinion setting aside the 50 ppm regulatory cutoff went into effect, the regulation of PCBs would be governed by the literal language of the Act. No PCBs could then be manufactured, distributed or used without the grant of a specific exemption by EPA. There was by this time a recognition that low concentrations of PCBs might well exist in a great many industrial processes. Accordingly, the prospects were that EPA and industry would be unreasonably burdened by an extensive petitions process.

The participants also recognized that a large segment of industry utilizing transformers, capacitors and electromagnets would be out of compliance by virtue of the

Court having set aside the Agency's definition of what constitutes statutorily exempted "totally - enclosed" uses of PCBs.

Agreement was reached that if the details of how industry and EPA might cooperate in a data collection effort could be agreed upon the parties would file joint motions with the court seeking a stay of the mandate of the Courts opinion during that data collection effort.

CMA was one of three trade association which agreed to undertake specific data collection efforts._/ The Agency asked CMA to collect, on an expedited basis, "scoping" data,

_/ The Edison Electric Institute and Dry Color Manufacturers Association, parties to the litigation, also agreed to assist the Agency.

information on hand, reasonable estimates or narrative dissertations, which would help the Agency go "back to the drawing boards" and plan its reconsideration of the regulation of low concentration PCB's.

CMA agreed to provide all three types of data on certain conditions: (1) because rapid production of complex, competitively sensitive data was required, the confidentiality of company data sources had to be maintained; (2) only aggregate, non-confidential data would be provided to the Agency although CMA's consultant would describe to EPA the procedures utilized in collecting and analysing data which had not been agreed to in advance; (3) the Association would have to be given adequate time to collect the data; (4) de novo data collection would not be required given the expedited schedule the Agency proposed: (5) based on CMA's belief that most of the incidentally generated PCB poundage exists in essentially closed processing systems with controlled waste, the EPA would propose an exclusion from its regulations such PCB's in its ANPR on the 50 ppm issue from its regulations; and (6) because of the many "unknowns" connected with the 50 ppm issue, agreement on all substantive details was necessary before the joint motion on this issue was filed with the Court including agreement on CMA's survey questionnaire, survey instructions and protocols for the analysis of the data.

CMA also presented the curricula vita for its consultants to the litigants. After an intense schedule of cordial but detailed negotiations between CMA, EPA and EDF, the following program was agreed to:

1. CMA's entire submission would be given to EPA within 210 days of Court approval of the request for a stay on the 50 ppm issue;

2. PCB data would be collected and reported to EPA in terms of its relationship to certain manufacture or process situations (chlorination; chlorinated intermediates; chlorinated solvent; contaminated input; and other) and, as to each of those situations, in terms of its relationship to certain structural classifications (alkanes, alkenes, alkynes, cyclo, aromatics).

The manufacture or process situations identified were selected because they were recurrent factors in industry petitions to EPA for exemptions for streams with PCB concentrations above 50 ppm. Logic dictated that they might also be the situs of low concentration PCB's.

3. PCB data for any concentrations below 50 ppm for each of the general process/structure categories would, in general, relate to:

(a) PCB poundage per year;

(b) the general fate of the PCB's;

(c) the general exposure characteristics associated with the PCB's;

(d) whether PCB controls had been applied to the streams, and

(e) general use characteristics of the product.

4. Narrative dissertations would be provided on the following topics:

(a) the problems and costs associated with the analysis of complex chemical streams for the identification of the presence and concentration of PCB's.*

(b) problems and costs associated with the reduction of PCB concentrations in complex chemical streams.

(c) recent information on the toxicity of PCB's.*

5. Attempts will be made to relate the data collected to a larger segment of industry.

Additional detaila of CMA's undertaking are aet forth in the report on oour incidental generation aurvey.

In addition to responding to EPA's request for data on incidentally generated PCBs CMA also indicated that it would conduct a survey of its members on the so-called "totally enclosed uses". That information is being submitted separately, on December 7, 1981, in response to the Agency's advanced notice of proposed rulemaking on that issue._/

_/ Cite

MONS 013549

D.

LEGAL, PROCEDURAL AND POLICY ISSUES IN EPA'S DEVELOPMENT OF A REGULATORY PROGRAM FOR INCIDENTALLY GENERATED PCBs

The major tasks which EPA faces in determining what its regulatory program for incidentally generated PCBs should be are:

1. To utilize its discretion and expertise in implementing TSCA in light of the latest information available to the Agency and to support its conclusions with substantial evidence.

3 ~~2~~. To determine, on the basis of the latest scientific information, the nature of the health or environmental risks posed by PCBs.

2 ~~3~~. To implement the Act's individual provisions while at the same time giving effect to the intent of Congress that the Act be implemented in a reasonable and prudent manner, and that consideration be given to environmental, economic and social impacts of Agency actions.

4. To propose regulations which are efficiently coordinated with the Agency's other statutory responsibilities and the responsibilities of other agencies.

5. To review the costs and benefits of any proposed regulatory program and alternatives to that program on the basis of Executive Order 12291.

I. The General Nature of EPA's Authority and Discretion to Fashion A Regulatory Program for Incidentally Generated PCBs.

In delegating authority to an agency, Congress is often forced to leave to the agency the power to identify problems issues and solutions. This policy simply recognizes that Congress and its staff work under demanding time constraints, and may lack an agency's scientific and technical expertise. Sunshine Anthracite Coal Co. v Adkins, 310 U.S. 381, 398, (1940).

An agency is often the better vehicle by which to assure that government regulatory activities are economically, practically, scientifically, and administratively feasible.

Consequently, an administrative agency is often entrusted with wide latitude in interpreting its governing statute, especially when extremely complex economic, scientific, or technical judgments are essential to administer a particular law.

In such situations, courts usually permit an agency's interpretation of its authorizing statute to be controlling, Weyerhaeuser Co. v. Costle, 590 F.2d 1011, 1025 (D.C. Cir. 1978); Lubrizol Corp. v. E.P.A., 562 F.2d 807, 816 fn. 23 (D.C. Cir. 1977); E.I. du Pont de Nemours & Co. v Collins, 432 U.S. 46, 54-55 (1977). This is especially applied to the initial, contemporaneous construction of a statute which requires an agency to act "under the gun" or under a tight statutorily mandated schedule. Norwegian Nitrogen Co. v. U.S., 288 U.S. 294, (1977); Udall v. Tallman, 380 U.S. 1, 16 (1968), and especially when scientific matters are concerned, Hercules, Inc. v. E.P.A., 598 F.2d 109, 116,117 (D.C. Cir. 1978).

When Congress provides an administrative agency with a specific directive, however, the agency cannot redefine or broaden the scope of its delegated powers by going beyond an unambiguous Congressional mandate. Alabama Power Co. v. Costle, 636 F.2d 323 (D.C. Cir. 1979); Asarco, Inc. v E.P.A., 578 F.2d 319 (D.C. Cir. 1978); Association of American Railroads v Costle, 562 F.2d 1310, 1315, 1318 (1977). Under no circumstances can an agency exceed authority which Congress has delegated to it, Trenton Chemical v U.S., 201 F.2d 776 (6th Cir. 1953), cert. denied, 345 U.S. 994, (1953), or act at variance with the statutory language, Miller v Laird, 349 F. Supp. 1034 (D.O.C. 1972). While an administrative agency may select the best means of implementing regulatory actions when they are not detailed in the governing legislation, Public Service Commission of the State of New York v F.P.C., 327 F.2d 893, 897 (D.C. Cir. 1964), agency discretion is available only upon the agency's showing that Congress has allotted that discretion to the agency. Citizens to Preserve Overton Park v Volpe, 401 U.S. 402, 416 (1971).

It is clear that these principles apply equally to the E.P.A. Ethyl Corp. v E.P.A., 541 F.2d 1 (D.C. Cir. 1974), cert. denied, 426 U.S. 941 (1976). The courts have accorded the EPA flexibility in interpreting its statutory obligations, so long as the agency exercises its regulatory and enforcement powers to achieve the best protection of human health and the environment. Ethyl Corp. v E.P.A., 541 F.2d at 24.

In view of the fact that EPA new has data which was clearly not available to Congress ~~wh~~ when it enacted Section 6(e) of TSCA, EPA should utilize its expertise and discretion and implement regulatory controls ~~and~~ on incidentally generated PCBs in a fashion which comports with all relevant scientific, economic and administrative facts.

123

2 Sole Reliance On ~~The~~ ~~Exemption Petitions Process Will Impose~~ Unreasonable Administrative Burdens ~~Which~~ On EPA ~~May Not Be Able to Meet~~.

Sole reliance upon the exemption petitions' process as a mean of affording industry relief from inappropriate regulation of PCBs. will impose unreasonable administrative burdens on EPA. Approximately 460 manufacturing, processing, distribution in com merce and use exemption petitions*/ have been filed with EPA. None have been acted on. If these petitions undergo the longer administrative procedure of a full rulemaking, that procedure will take an inordinate amount of time, and require greater personnel needs at the agency. As noted in our incidental generation survey, over 1300 exemption petitions could be filed with the Agency.

Under the proposed rulemaking procedures for each exemption petition, each applicant for an exemption would be entitled to a hearing and the opportunity for cross-examination on disputed issues of fact. TSCA Section 6(e)(3)(b);6(c)(2),(3). Each petition would have to be renewed annually, with potentially hundreds of processes which would be potential candidates for exemption proceedings. This process would constitute a significant burden for The Agency. For example, if 1,000 exemption petitions were filed, CMA has calculated that EPA would be required to hold five (5) hearings per day, each working day of the year, to allow a full hearing of public comments.

As the court recognized in E.D.F v E.P.A., citing Alabama Power Co. v Costle, 636 F. 2d 323 (D.C. Cir. 1979),

MONS 013554

> ...an agency may depart from the requirement of a regulatory statute. See id. at 357-360 (opinion for the court by Leventhal, J.). While the court in Alabama Power emphasized that "[c]ategorical exemptions from the clear commands of a regulatory statute, though sometimes permitted, are not favored," id. at 358, it also noted thawt there is "substantive authority [for an agency] to take appropriate action to cope with the administrative impossibility of applying the commands of the substantive statute." Id. at 358-359. However, "[t]he agency's burden of justification in such a case is especially heavy." Id. at 359.
>
> Considerations such as the availability of enforcement resources are relevant to the administrative necessity exemption.

The theory of administrative convenience is not new. It is in fact a longstanding rule that an Administrative "agency confronted with a complex task may rationally turn to simplicity in ground rules, and administrative convenience, at least where no fundamental injustice is wrought." Gulf Oil Corp. v. Hickel, 435 F. 2d 440, 446, (D.C. Cir. 1970), citing Carmichael v Southern Coal Co., 301 U.S. 495, 511, (1937) See also, Permian Basin Area Rate Cases, 390 U.S. 747 , 777 (1968). If regulatory action results in an undue burden on an administrative agency, courts have allowed the agency to simplify its procedures. The court in Alabama Power Co. v. Costle applied the theory of administrative convenience to the EPA, once the agency demonstrates the infeasibility or impossibility of meeting the administrative demands involved:

> Courts frequently uphold streamlined Agency approaches or procedures where the conventional course, typical case by case determinations, would as a practival matter, prevent the agency from carrying out the mission assigned to it by Congress. 636 F. 2d at 358.

EPA cannot be expected to perform impossible tasks N.R.D.C. v. Train, 510 F. 2d 692 (D.C. Cir. 1975). The exemption petitions process as contemplated by the agency in its ANPR would constitute or approach such an impossible task. Nothing in TSCA requires the agency to embark upon such a rigorous and administratively infeasible for incidentally generated PCBs in closed manufacturing processes.

3 Regulation of PCBs Below 50 ppm Would Yield Trivial or de Minimus Benefits

The principle of de minimis non curat lex also applies in this proceeding. The PCB regulatory proceedings are particulary suited to the de minimis exception to statuatory commands. The court in E.D.F. v E.P.A., supra, addressed the applicability of this theory to the agency's regulatory cutoff level of 50 ppm:

> ...In Alabama Power, this court found that an agency has the power, "inherent in most statuatory schemes, to overlook circumstances that in context may fairly be considered de minimis." Id. at 360. That power "is not ability to depart from the statute, but rather a tool to be used in implementing the legislative design." Id. at 360. As the Alabama Power court emphasized, de minimis authority may be available "when the burdens of regulatory yield a gain of trivial or no value." Id. It is not

> sufficient that the agency may believe that the costs outweigh the benefits, for Congress has already made the judgement that the benefits of regulation are sufficient. 636 F. 2d at 1283.

As further explained by the Alabama Power v Costle Court,

> [T]he "de minimis" doctrine that was developed to prevent trivial items for draing the time of the courts has room for sould application to adminsitration by the Government of its regulatory programs.... The ability ... to exempt de minimis situtations from a statuatory command is not an ability to depart from the statute, but rather a tool to be used in implementing the legislative design. Determination of when matters are truly de minimis naturally will turn on the assessment of particular circumstances, and the agency will bear the burden of making the required showing. But we think most regulatory statutes...permit such agency showing in appropriate cases. 636 F. 2d at 360

The court in E.D.F. v E.P.A. did not permit the Agency to avail itself of the de minimis exception because the record was devoid of any indication that the Administrator relied on this principle.

As indicated by the results of CMA's survey, amounts of incidentally generated PCBs below the 50 ppm regulatory cutoff level are clearly de minimis amounts. Because Section 6(e) does not address incidental generation specifically, and because of the de minimis standard to closed manufacturing processes and to maintain a cutoff level of 50 ppm, at a minimum.

See. Volkswagen v. F.M.C., 390 U.S. 261, 276-277 (1968); Marine Space Enclosures, Inc. v. F.M.C., 420 F. 2d 577 (D.C. Cir. 1969); District of Columbia v. Orleans, 406 F. 2d 957 (D.C. Cir. 1968.

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127

EPA MUST INTERPRET SECTION 6(e) TOGETHER

WITH OTHER PROVISIONS OF THE ACT

The U.S. Court of Appeals for the D.C. Circuit has ruled that an agency must, when undertaking a regulatory action or investigation pursuant to an Act of Congress, construe that statute in the context of the entire regulatory scheme. An agency must interpret each provision of a statute in light of the entire statute, rather than looking only to one specific provision as the basis for its action, F.T.C. v Manager, Retail Credit Company, Miami Branch Office, 515 F.2d 988, (D.C. Cir. 1975); See also, Weinberger v Hynson, Westcott and Dunning, Inc., 412 U.S. 609, (1973). In Section 6(e) of TSCA, Congress designated one specific chemical, PCBs, as the target for regulatory action. In devising any regulatory scheme with regard to PCBs, however, EPA must also comply with the intent of Congress as expressed in Section 2(c) of the Act which provides:

> (c) Intent of Congress. - It is the intent of Congress that the Administrator shall carry out this Act in a reasonable and prudent manner, and that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this Act.

As the Court in EPA v EDF noted this section of the Act anticipates that the Agency will consider a range of benefits and costs of proposed regulations._/

MONS 013558

128

The information in CMA's submission addresses all of the factors involved in Section 2(c), and more.

V. EPA's Assessment of the Benefits of Regulating Incidentially Generated PCBs: The Health Effects of PCBs; Risks To Be Addressed In Proposed Regulations

Accurate estimates of the benefits to be derived from proposed regulations are essential. Such evaluations are especially necessary for environmental health and safety regulations in general, which confront agencies with a potentially intimidating array of scientific and technical evidence.

Perhaps the most important task facing EPA in this entire proceeding is the need to adequately address the information on the health risks posed by PCBs, and whether any risks posed are unreasonable. These analyses will permit the Agency to identify any benefits which will be acheived by regulating incidentially generated PCBs.

In conducting this analysis EPA of course, will want to analyse the record in this proceeding in light of the unreasonable risk criteria set forth in Section 6(c)(1) of the Act:

> (A) the effects of such substance or mixture on health and the magnitude of the exposure of human beings to such substance or mixture,
> (B) the effects of such substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture,

(C) the benefits of such substance or mixture for various uses and the availability of substitutes for such uses, and
(D) the reasonably ascertainable economic consequences of the rule, after consideration of the effect on the national economy, small business, technological innovation, the environment, and public health.

One of the pivotal aspects of the litigation over EPA's PCB regulations was EPA's finding that no level of exposure to PCBs can be considered safe._/ While the Court in EDF v EPA resisted EDF's attempt to equate a risk of exposure to an unreasonable risk, EPA's policy position combined with its failure to present an assessment of the risks involved was clearly a fatal flaw in the Agency's defense of its regulations.

In view of the Congressional, government and public misunderstanding of the risks which PCBs pose we urge EPA to give careful consideration to utilizing scientific expertise outside the agency to supplement its staff scientists in obtaining the best judgments available on the health effects of PCBs.

The National academy of Sciences, the General Accounting Office and other groups have stressed the value of independent review in ensuring that agencies draw accurate conclusions from scientific data.[58] A number of agencies are making increased use of outside scientific review. EPA, itself, of course, plans to make increase the use of the Science Advisory Board.[59]

We applaud these efforts and urge EPA, at an early date, to establish procedures which will provide the Agency, on an expeditious basis, with the scientific judgments it needs to conduct a thorough analysis of the health risks of PCBs.

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[58] See, e.g., General Accounting Office, Improving the Scientific and Technical Information Available to the Environmental Protection Agency in Its Decisionmaking Process 20 (September 21, 1979); National Academy of Sciences, Decisionmaking in the Environmental Protection Agency 46-51 (1977); Clean Air Scientific Advisory Committee, Setting Ambient Air Quality Standards: Improving the Process 1-4 (September 1981); Conference Report, Environmental Protection Agency Research Authorization for Appropriations for Fiscal Year 1978, H.R. Rep. No 722, 95th Cong., 1st Sess. 16-17 (1977); Senate Comm. on Environment and Public Works, Environmental Research and Development Authorization Act of 1977, S. Rep. No. 188, 95th Cong., 1st Sess. 1-4 (1977).

[59] See Memorandum from Deputy Administrator John Hernandez, "Improving the Scientific Adequacy of Agency Regulations and Standards" (July 20, 1981), reported in Inside EPA 11-12 (August 28, 1981).

(lower tier)

6. ~~THE~~ EPA'S OBLIGATION TO CONSIDER THE EFFECTS OF OTHER REGULATORY CONTROLS OF PCBS

Certain provisions of TSCA require that the Administrator of EPA consider the totality of the regulatory controls of chemical substances. It was Congress' general purpose to avoid overlapping and duplicative regulations._/

For instance, Section 9(b) of TSCA specifically requires the Administrator to coordinate its actions under TSCA with actions taken under other laws administered by the Agency. Legislative history of this section of the Act makes clear that the Administrator, in determining to utilize TSCA is to publish a review of other authorities in the Agency's jurisdiction and publish that review at the time the Administrator takes actions under TSCA.[cite]

Furthermore, Section 9(d) of TSCA requires the Administrator of EPA to "consult and coordinate" with other agencies for the purpose of acahieving maximum enforcement of TSCA while imposing the least burdens of duplicative requirements on persons subject to the Act, and for other purposes.

The following is a review of other regulatory authorities relevant to the control of PCBs.

1. ~~EPA may regulate PCBs under t~~The Resource Conservation and Recovery Act of 1976.

In its PCBs ban regulations issued on May 31, 1979, EPA noted that it would integrate its PCB rules with the regulations issued pursuant to the Resource Conservation and Recovery Act of 1976, 42 U.S.C. 3251 <u>et seq</u>. (RCRA). (<u>See</u>, 44 Fed. Reg. at 31539.) The same notation was made in EPA's RCRA Regulations. (<u>See</u>, 45 Fed. Reg. at 33118.) To date, the agency has not so integrated these regulations. In the RCRA regulations, PCBs are listed as "Hazardous Constituents" (<u>See</u>, Appendix VIII to 49 CFR Part 261, 45 Fed. Reg. 33084, 33133, May 19, 1980), but are not regulated <u>per se</u> under the RCRA regulations. Hazardous constituents are those chemicals which caused the EPA to list a waste as a EP toxic waste or toxic waste in Sections 261.31 and 261.32, as stated in 49 CFR Section 261.30(b), 45 Fed. Reg. at 33122.

One court has ruled that PCBs are not currently regulated under RCRA, <u>U.S. v Burns</u>, 15 E.R.C. 2120 (W.D. Pa. 1981). The <u>Burns</u> court specifically determined (1) that the federal government cannot bring an action concerning PCBs under RCRA, since PCBs are regulated under TSCA, and (2) that the federal government cannot recover its clean-up costs under TSCA, but may recover such costs under Section 311 of the Clean Water Act. However, CMA believes that as a practical effect, RCRA does regulate many [redacted] hazardous waste mixtures which contain incidentally generated PCBs in concentrations at less than 50 ppm.[1]

The CMA survey indicates, for example, that the majority of incidentally generated PCBs are associated with process involving the chlorination of hydrocarbons or the use of chlorinated solvents. At least 17 wastes are listed as "hazardous" under 40 CFR 261.31 and 261.32 can reasonably be expected to contain some level of incidentally generated PCBs because they are generated from the types of processes noted above.[2] Finally, the CMA survey demonstrates that over sixty percent (60%) of these wastes are incinerated.

2. ~~EPA Directly Regulates PCBs Under~~ the Clean Water Act

Polychlorinated biphenyls are directly regulated in two ways under the Clean Water Act, 33 U.S.C. 466 et seq.: (1) point source discharges from manufacturers are regulated by effluent standards pursuant to Section 402; and (2) discharges from any facility are regulated under Sections 311 and 501. Other materials which may be reasonably expected to have low-level PCB contamination, e.g., dredge spoila, are directly regulated under the Act thereby, in effect, regulating the introduction of PCBs into the environment.

The effluent standards of §307 of the Act currently require that no detectable PCbs be "in any discharge from any PCB manufacturer." 40 CFR 129.105. The standard is directly enforceable against any manufacturer of PCBs through the provisions of Paragraph 309(a)(3) of the Act. Further, the standard sets a water quality criteria of 0.001 microgram/liter for PCBs in navigable waters (see, 40 CFR §129.105). When implemented by the states, these requirements regulate PCBs which may be discharged at very low concentration levels.

Section 311 of the Act is general in its applicablility and regulates the discharge of PCBs into navigable water from any source. Regulations promulgated under this section provide for the designation of PCBs as a hazardous substance, the establishment of the maximum quantity of ten (10) pounds which may be discharged without complying with the reporting requirements or the becoming subject to penalties for failure to report such discharges. (see, 40 CFR 116 and 117).

2. ~~EPA further regulates PCBs under~~ other Provisions of TSCA
3. ~~other than Section 6(e)~~.

EPA should recognize that TSCA regulations already place established adequate control of PCBs generated as a process waste.

Detailed recordkeeping and monitoring activities are currently required under the PCB Ban Rule, 40. C.F.R. §761.45; Fed. Reg. at 31527. The regulation applies to process wastes or contaminated primary chemicals containing PCBs in concentrations of 50 ppm or greater. In general, the current requirements included the maintenance of inventories of PCBs and PCB equipment as well as the monitoring of incineration process and chemical waste landfill facilities. In addition, whenever an uncontrolled release of PCBs or a PCB mixture into the environment poses a substantial risk to human health or to the requirement, notification of EPA would be required within the parameters of Section 8(e) of TSCA 15 U.S.C. 2607 (3). (See, 43 Fed. Reg. 11110.1111-11112 (March 16, 1978), EPA Statement of Interpretation and Enforcement Policy.)

– Food [illegible] controls

c) The United States Department of Agriculture ~~has Demonstrated its Authority to Control Incidental PCB~~ Contamination in Food Establishments.

The United STates Department of Agriculture (U.S.D.A.) under its proceedng entitled Prohibition of PCB-Containing Equipment in Machinery, and Liquid PCBs in Federally Inspected Meat Establishments, Poultry Product Establishments and Egg Product Plants proposed an amendment to the Federal meat inspection regulations, and the Federal poultry products inspection regulations governing the inspection of eggs and egg products prohibiting the use of PCB-containing electrical equipment in concentrations exceeding 50 ppm PCB. 45 Fed. Reg. 30980 (May 9, 1980). The purpose of these proposed amendments were to reduce the potential of accidental PCB contamination of food products. Id. However, in response to the court's decision in E.D.F. v E.P.A., supra, the U.S.D.A. issued a notice of abeyance of the ruled proposal in 46 Fed. Reg. 15512 (March 6, 1981). The Department noted "the desirability of further FSQS [Food Safety and Quality Service] consideration of relevant technical data" and "[i]n the meantime,...encourage the submission of additional comments by anyone who has information that would assist U.S.D.A in making its decision." 46 Fed. Reg. 15512.

5 ~~Il~~ The Food and Drug Administration ~~has Demonstrated its Authority to Control Incidental PCB Contamination in Foods and Drugs.~~ — Food and Drug Controls

136

The Food and Drug Administration (FDA) has previously acted to control accidental PCB contamination of food, feeds and food packaging materials. 38 Fed. Reg. 18096 (July 6, 1973). In addition, the FDA has proposed further amendments to its earlier PCB regulation in its proceeding entitled Current Food Manufacturing Practice Relating to Poisons and Deleterious Substances in Food, Feed, and Food Packaging Material Plants, Docket No. 80N-0128, 45 Fed. Reg. 30984 (May 9, 1980). However, this proposal is also being held in abeyance pending the outcome of this instance regulatory action, 46 Fed. Reg. 15518 (March 6, 1981).

In FDA Docket No. 77N-0080, entitled Polychlorinated Biphenyls (PCBs in Fish and Shellfish; Reduction of Tolerances (Notice of Proposed Rulemaking, 42 Fed. Reg. 17487 (April 1, 1977), a final rule was issued reducing toleranace for unavoidable residues of the PCBs in certain foods (44 Fed. 57389 (October 5, 1979), and stayed its rule regarding fish and shellfish. On May 1, 1981, 46 Fed. Reg. 24551, FDA announced that it would hold a formal avidentiary rulemaking hearing on the tolerance of PCBs in fish and shellfish to admit into the record toxicity data and information previously unavailable on the issue:

> is the magnitude of the human food loss (in terms of dollars, poundage, percentage of catch, etc.) that would result from lowering the tolerance of PCBs in fish from 5 ppm to 2 ppm?

Hearing are now in progress before an Administrative Law Judge.

e) The Occupational Safety and Health Administration ~~[illegible]~~ ~~[illegible]~~ Exposure Limits for PCBs.

EPA may be permitted, under Section 9(c) of TSCA, to prescribe and enforce standards or regulations affecting occupational safety and health, so long as EPA coordinates its regulatory program with Occupational Safety and Health Administration (OSHA), as required by Section 9(d) of TSCA.

Existing OSHA regulation (29 C.F.R. Part 1910.1000) establish stringent exposure limits for PCBs upon degree of chlorination, and assign a lower exposure limit (expressed as an 8-hr. time-weighted averate (TWA) to the more hightly chlorinated category, as follows:

	8 hour TWA
Chlorodiphenyl, 42% chlorine (skin)	1 mg/M^3
Chlorodiphenyl, 54% Chlorine (skin)	0.5 mg/M^3

The skin notation indicates that skin contact is the most probable route of entry into the body, but provision is also made for entry via inhalation. The OSHA regulations provide that if respiratory protection is deemed necessary, respirators must be selected and used in compliance with provision of 29 C.F.R. 1910.134.

EPA should recognize the degree of protection that the cited OSHA regulations provide to chemical plant personnel, especially in the matters of incidental generation of PCBs in various chemical processes, and refrain from promulgating additional, unneeded regulations in this area.

Agency Proceedings Held

7 4) ~~Several Federal Agencies Are Holding Their Proceedings~~ in Abeyance ~~Pending Collection Of Good Scientific Evidence~~

The U.S.D.A., F.D.A., and, as will be explained later, the EPA, are currently holding their PCB-related proceedings in abeyance for the specific purposes of (1) collecting additional scientific data for support their respective regulations, and (2) allowing EPA to gather data pursuant to its advanced notices of proposed rulemakings in the "regulatory cutoff," "closed manufacturing processes" and "totally enclosed" PCB proceeding. These actions are in keeping with the Administration's policy to employ good scientific data to substantiate regulatory action.

In conclusion, any regulation of incidentally regulated PCBs should be based upon a thorough assessment of the extent to which existing federal regulations already address health and environmental protections against incidentally generated PCBs.

H. <u>EPA Should Review Any Proposed Regulation Of Incidentally Generated PCBs In Accordance With Executive Order 12291</u>

On February 17, 1981, President Ronald Reagan issued Executive Order No. 12291, entitled "Federal Regulation." ~~With~~ The ~~stated purposes~~ goals of the order are: increased agency accountability for regulatory actions, minimizing duplicative and conflicting regulations, and insuring well-reasoned regulations, the President issued the following mandate:

> Sec. 2. <u>General Requirements</u>. In promulgating new regulations, reviewing existing regulations, and developing legislative proposals concerning regulation, all agencies, to the extent permitted by lew, shall adhere to the following requirements:
>
> (a) Administtrative decisions shall be based on adequate information concerning the need for an consequences of proposed government action;
>
> (b) Regulatory action shall not be undertaken unless the potential benefits to society from the regulation

outweigh the potential coats to society;

(c) Regulatory objectives sahll be chosen to maximise the net benefits to society;

(d) Among alternative approaches to any given regulatory objective, the alternative involving the least net cost to society shall be chosen; and

(e) Agencies shall set regulatory priorities with the aim of maximizing the aggregate net benefits to society, taking into account the condition of the particular industries affected by regulations, the condition of the national economy, and other regulatory actions contemplated for the future.

Sec. 3. Regulatory Impact Analysis an Review

(a) In order to implement Section 2 of this Order, each agency shall, in connection with every major rule, prepare, and to the extent permitted by law consider, a Regulatory Impact Analysis. Such Analyses may be combined with any Regulatory Flexibility Analyses performed under 5 U.S.C. 603 and 604.

Although Section 8(a)(2) of the Executive Order (EO) exempts from the requirement of Section 3(a) the preparation of

Regulatory Impact Analysis in any regulations subject to deadlines imposed by a judicial order, such as the regulations at issue, the President required that

> any such regulation shall be reported to the Director of the Office of Management and Budget together with a brief explanation of the conflict, the agency shall publish in the Federal Register a statement of the reasons why it si impracticable for the agency to follow the procedures of this Order with respect to such a rule, and the agency, in consultation with the Director, shall adhere to the requirements of this Order to the extent permitted by...judicial deadlines (Section 8(a)(2).

CMA does not believe that it will be impracticable for the agency to prepare a Regulatory Impact Analysis as part of its decisionmaking process in this matter.

The Agency has data relating to:

1. The benefits and costs of regulating incidentally generated PCBs.
2. Alternative approaches to consider, e.g., the regulatory cutoff, the exemptions procedure alone.
3. Information on the benefits of regulatory PCBs based upon the latest information on the health affects of PCBs and the economic consequences of regulation.

142

Again, CMA strongly urges EPA to solicit the views of known experts outside the Agency in the fields of toxicology and analytical chemistry to add to the views of its staff scientists or questions relating to the health effects of PCBs and currently available analytical capability for the identification and measurement of low concentration PCBs in complex streams. These views can be obtained expeditiously and perhaps at minimal costs by tapping resources in the academic and research communities.

CONCLUSIONS

Based upon the information and legal analysis being submitted to the Agency, CMA concludes:

1. Congress did not intend to ban incidentally generated PCBs under Section 6(e) of TSCA. Such PCBs were not even known to Congress when it passed the Act. Congress' assumption concerning the economic impact of its actions and concerning the few hardships which the provisions of Secton 6(e) might impose simply do not address the nature, scope and prevalence of incidentally generated PCBs.

[redacted]

[redacted]:

3 [redacted] There is no basis for concluding that such regulations should apply to materials containing less than 50 ppm of PCBs; evidence may exist to demonstrate that a higher level would be appropriate; and,

MONS 013574

147

b. Substantial evidence exists to support an additional exclusion from regulation of chemical processes generating any concentration of PCBs where:

- o the PCB concentration in its product does not exceed 50 ppm [or such higher level as EPA may establish by rule];

- ~~o the wastes are controlled according to EPA's~~ PCB regulation; and,

  PCB wastes and all PCB

- o all discharges comply with any applicable EPA or OSHA regulations.

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105

Appendix________

Perspective of PCB Exposure Associated with Primary Chemicals Containing Incidental Quantities of PCBs

The higher homologs of PCBs, trichlorobiphenyl to decachlorobiphenyl, which CMA believes are the compounds of concern for potential exposure, are high molecular weight (MW) compounds with low vapor pressures (VP).* See Table I. This fact and the low concentrations of incidentally generated PCBs dictate that PCBs cannot be present in the atmosphere at other than very low concentrations when the exposure is due to chemicals with incidental PCBs. The calculations below demonstrate this and indicates why CMA believes that control of the primary chemical inherently controls potential exposure to incidentally generated PCB contaminants.

The calculations are based on Raoult's Law, a basic principle in the properties of solutions. Raoult's Law states that the vapor pressure of a component of a solution (in this case, PCBs are a component of the solution consisting of the primary chemical and the PCBs) is equal to the vapor pressure of that component in its pure form multiplied by the mole fraction (i.e., concentration) of that component in the solution.

Mathematically,

$$VP_{A(sol)} = VP_A \times MF$$

Where,

$VP_{A(sol)}$ = Vapor pressure of component A in atmosphere above solution (sol).

VP_A = Vapor pressure of component A in its pure form.

MF = Mole fraction of component A in the solution.

Once this vapor pressure of PCBs above the solution has been calculated, the atmospheric concentration of PCBs can be calculated using the partial pressure law, a basic principle in the properties of gases, which states that the volumeric concentration of a gaseous

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* Vapor pressure can be viewed as the tendency of a liquid or solid to escape into the gas phase. A low vapor pressure indicates a low tendency to vaporise.

component is directly proportional to the ratio of that components partial pressure to the total pressure of the system. In this case, we will be dealing with the partial pressure $[VP_{A(sol)}]$ of PCBs and atmospheric pressure.

Using the above principles, calculations can be made to demonstrate the levels of potential PCB exposure in the work place. For example, if the PCB concentration in the primary chemical is 1000 ppm and the primary chemical has a molecular weight of ≈ 1/2 that of the PCB (the case if the primary chemical is trichlorobenzene and the PCB is hexachlorobiphenyl), then the mole fraction is calculated:

$$MF = \frac{\text{Moles PCB}}{\text{Moles total solution}}$$

$$MF = \frac{\dfrac{1000\text{ (parts PCB)}}{361.0\text{ (MW PCB)}}}{\dfrac{999{,}000\text{ (parts trichlorobenzene)}}{181.5\text{ (MW trichlorobenzene)}} + \dfrac{1000\text{ (parts PCB)}}{361.0\text{ (MW PCB)}}}$$

$$= 5.03 \times 10^{-4}$$

Repeating these calculations for various assumptions of concentrations and molecular weight ratios allows us to construct Graph I, which illustrates the range of mole fractions for the most common situation -- PCB concentration below 1000 ppm and PCB: primary chemical molecular weight ratio (MWR) between 1:1 and 2:1. As can be calculated, the mole fraction varies between $5x10^{-7}$ (at 1ppm) and 1×10^{-3} (at 1000ppm). These are obviously small numbers. Applying Raoult's Law and noting the low vapor pressures (Table I) of PCBs, it is easily seen that the vapor pressures of PCBs $[VP_{A(sol)}]$ are extremely low since we are multiplying two small numbers.

To illustrate the practical effect of these calculations on atmospheric concentrations of PCBs, we give the example below of 50 ppm of trichlorobiphenyl (the most volatile of the PCBs which CMA believes should be considered in the rulemaking) in monochlorobenzene, a typical primary chemical with which PCBs may be associated.

The vapor pressure of trichlorobiphenyl (TCB) is about 0.001 mm at 25°C. Therefore, assuming 50 ppm of TCB in chlorobenzene:

$$(1) \quad MF = \frac{50/257.5}{999{,}950/112.5 + 50/257.5} = 2.2 \times 10^{-5}$$

$$(2) \quad VP \text{ at equilibrium} = 0.001 \text{ mm} \times 2.2 \times 10^{-5} = 2.2 \times 10^{-8}$$

and the atmospheric concentration at equilibrium and 25°C is:

$$\frac{2.2 \times 10^{-8} \text{ mm}}{760 \text{ mm}} \times 257.5 \text{ g/mole} \times \frac{1000 \text{ l/m}^3}{24.45 \text{ l/mole}} \times 1000 \text{ mg/g} = 3.1 \times 10^{-4} \text{ mg/m}^3$$

Therefore, the maximum PCB vapor inhalation exposure (25°C) that can occur from exposure to chlorobenzene containing 50 ppm of trichlorobiphenyl is 0.03% of the OSHA TLV (1.0 mg/m^3) for lower chlorinated biphenyls.

This is a specific example. The range of molecular weight ratios between chemicals involved in these processes is generally within the range of 1:1 to 2:1. Table II shows the results of assuming various concentrations of trichlorobiphenyl in the primary chemical for these assumed ratios.

Table II also shows the calculated atmospheric concentrations as a percentage of the OSHA TLV for lower chlorinated biphenyls.

Conversely, control of the primary chemical to meet OSHA limits for that chemical will result in control of potential exposure to PCBs. Continuing our example above, the OSHA TLV for monochlorobenzene is 350 mg/m^3. The vapor pressure @ 25°C of monochlorobenzene is 12.8 mmHg. We calculated above that the partial pressure of PCBs above a solution of 50 ppm TCB in monochlorobenzene is 2.2×10^{-8} mmHg. Therefore, the mole fraction of PCB in the vapor is:

$$MF_v = \frac{2.2 \times 10^{-8}}{12.8} = 1.7 \times 10^{-9}$$

Therefore, using the same principles above, the equivalent concentration of PCBs in the vapor if monochlorobenzene is controlled below the OSHA TLV is calculated:

$$\text{Concentration} = \frac{350 \text{ mg MCB}}{M3} \times 1.7 \times 10^{-9} \times \frac{257.5 \text{ (MW TCB)}}{112.5 \text{ (MW MCB)}}$$

$$\text{Concentration} = 1.4 \times 10^{-6} \frac{\text{Mg TCB}}{\text{M}^3}$$

Thus, controlling monochlorobenzene at the OSHA limit resulte in a PCB atmospheric concentration that is 0.0002% of the OSHA limit for PCBs and, even more importantly, is so low as to be not measurable. - Thus, the potential exposure to PCBs represents far less risk than exposure to the primary chemical of which the PCB is a contaminant. The same principle would apply to skin contact where exposure to the primary chemical is 1000 to 1,000,000 times greater (1000 to 1 ppm PCBs) than the exposure to PCBs.

The above calculations show:

(1) Vapor exposure components of a solution is dependent on concentration.

(2) Low concentrations must result in low exposure.

(3) If volatility (vapor pressure) of the component is low, and the concentration is low, the exposure must be very low.

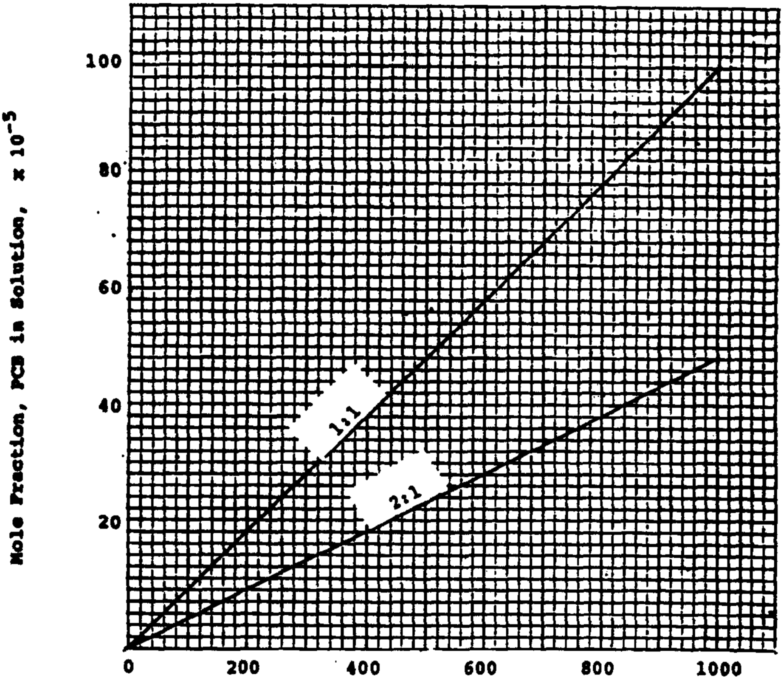
(4) 50 ppm represents a weight ratio of 1/20,000. If the MW of the components is equal, the mole fraction at 50 ppm is 1/20,000. If the PCB MW is twice as high as the primary chemical, the mole fraction is 1/40,000.

(5) Vapor pressures for pure PCBs are very low and when multiplied by 1/20,000 to 1/40,000 weight ratios shown above, the vapor is not a significant exposure problem.

149

Graph I

Mole Fractions of PCB in Solution as a Function of PCB concentration w/ molecular weight ratio (PCB: Primary Chemical) as a Parameter



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