

Environmental Protection Agency
Office of Toxic Substances
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**COMMENTS ON EPA'S ADVANCED
NOTICE OF PROPOSED RULEMAKING ON
DISPOSAL OF POLYCHLORINATED BIPHENYLS**

Submitted Jointly by

Polychlorinated Biphenyl Panel
of the
Chemical Manufacturers Association

National Electrical Manufacturers Association
and

Utility Solid Waste Activities Group of the
Edison Electric Institute

Chemical Manufacturers Association

Gordon D. Strickland
Vice President Technical Services

Elizabeth Festa Gormley
Manager
Polychlorinated Biphenyl Panel

David F. Zoll
Vice President and
General Counsel

Of Counsel:

Timothy S. Hardy
Patricia A. Franco

Kirkland & Ellis

NATURAL
**Interstate Natural Gas
Association of America**

Theodore L. Kinne
Vice President,
Safety, Environment and
Operations

**National Electrical Manufacturers
Association**

Douglas Bannerman, Ph.D.

Of Counsel:

Steven S. Rosenthal
Morrison & Foerster

**Utility Solid Waste Activities
Group**

John F. McKenzie
Pacific Gas and Electric Company
Chairman, USWAG PCB Committee

Of Counsel:

Toni K. Allen
Robert M. Sadler

Piper & Marbury

*FYI
This is expected to
be finalized as the
official submission
of the Commerce Group
this afternoon.
This presents us an
excellent opportunity
to work with EPA to
harmonize PCB standards
for old & new spills
as well as work with
authorities such as RCRA
Superfund etc. There
is indication EPA
will work in harmony
with us to achieve this
goal and they are reformu-
lating our help in and
the "New Spill" Chemistry
7/1/91*

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EXECUTIVE SUMMARY

The Polychlorinated Biphenyl Panel of the Chemical Manufacturers Association, the National Electrical Manufacturers Association, the Utility Solid Waste Activities Group and the Interstate Natural Gas Association of America (collectively, the Consensus Group) have worked for over a decade with federal and state environmental agencies and environmental groups to develop rules that provide objective standards and practical guidance for the proper disposal of PCBs. We thus fully support EPA's efforts in this rulemaking to reassess EPA disposal rules given the changes over the past decade in disposal technology and the new evidence on PCB toxicity and persistence.

The Consensus Group urges EPA to modify the PCB rules to reflect the best available information on toxicity, persistence and the need for a flexible disposal policy. The scientific evidence now available indicates that PCBs are neither as toxic nor as persistent as EPA assumed in prior rulemakings. This new scientific understanding provides a sound basis for the Agency to reconsider and adjust some of its earlier policies and approaches. The epidemiological studies, animal research, and reproductive toxicity data all show a lack of harmful health effects at any likely human exposures and support regulatory changes that will accurately reflect low risk.

Finally, the Consensus Group responds to EPA's request for comments in a number of specific areas.¹ In particular, we urge the Agency to harmonize its regulations with overlapping requirements of other agencies, to establish PCB rules that will not thwart technological development of new disposal methods, and to promulgate rules that are not overly burdensome with de minimis public health benefit. The Consensus Group makes suggestions that will make compliance with EPA PCB rules uniformly feasible and rational, while more than adequately protecting the public.

¹ The Consensus Group intends to supplement these comments by addressing other issues in the near future.

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LIST OF ATTACHMENTS

1. Abelson, Philip, Editorial, Excessive Fear of PCBs, 253 Science, 361 (July 26, 1991).
2. Brown, John F., Bedard, Donna L., Brennan, M.J., Carahan, James C., Feng, Helen, Wagner, Robert E., Polychlorinated Biphenyl Dechlorination in Aquatic Sediments, 236 Science 709 (May 8, 1987).
3. DesRosiers, J.P.E. and Haley, Jennifer (EPA), Remedy Selection at Superfund Sites Contaminated with Polychlorinated Biphenyls (EPRI PCB Conference) (June 11-12, 1990).
4. General Electric Company, Research and Development Program for the Destruction of PCBs, Ninth Progress Report (Aug. 1990).
5. Harbison, Raymond D., James, Robert C., Roberts, Stephen M., Biological Data Relevant to the Evaluation of Carcinogenic Risk to Humans (Aug. 1987).
6. Institute for Evaluating Health Risks, Reassessment of Liver Findings in Five PCB Studies in Rats (July 1, 1991).
7. James, Robert C., Roberts, Stephen M., Kerger, Brent D., Clevenger, M. Ann, Millner, Glenn C. of TERRA, Inc., A Critical Evaluation of the Human and Animal Evidence Concerning the Reproductive Toxicity of Polychlorinated Biphenyls (PCBs) (Nov. 1988).
8. James, Robert C., Roberts, Stephen M., Kerger, Brent D. of TERRA, Inc., A Review of the Carcinogenic Risk of Polychlorinated Biphenyl Mixtures of Approximately 54% Chlorine Content (Apr. 1989).
9. Quensen, John F., Tiedje, James M., Boyd, Stephen A., Reductive Dechlorination of Polychlorinated Biphenyls by Anaerobic Microorganisms from Sediments, 242 Science 752 (Nov. 4, 1988).

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INTRODUCTION

The Polychlorinated Biphenyl Panel (PCB Panel) of the Chemical Manufacturers Association (CMA), the National Electrical Manufacturers Association (NEMA), the Utility Solid Waste Activities Group (USWAG) and the Interstate Natural Gas Association of America (INGAA) (collectively, the Consensus Group) have for many years worked with the Environmental Protection Agency (EPA) to develop objective standards and practical guidance for the proper management and disposal of polychlorinated biphenyls (PCBs). We support EPA's efforts in this rulemaking to reexamine the parameters of its PCB disposal methods in light of new information on disposal technology and the latest evidence on PCB toxicity and persistence.¹

I. THE CONSENSUS GROUP'S INTEREST IN THIS RULEMAKING.

CMA's PCB Panel, NEMA, USWAG and INGAA have for more than a decade worked with federal and state agencies, often through regulatory negotiations along with other groups including the Association of American Railroads, the Environmental Defense Fund, and the Natural Resources Defense Council to establish rational, scientifically-based standards. We first worked with EPA to implement its initial set of Toxic Substances Control Act (TSCA) Section 6(e) regulations on PCBs in the early 1980s.² We

¹ See EPA, Disposal of Polychlorinated Biphenyls, Advance Notice of Proposed Rulemaking, 56 Fed. Reg. 26738 (June 10, 1991) (hereinafter, ANPRM).

² 15 U.S.C. § 2605; 40 C.F.R. Part 761 (1990).

have provided considerable data and, often, proposed regulatory language for the electrical equipment rule (1982); the closed and controlled rule (1982); the inadvertent generation rule (1984); the Spill Cleanup Policy (1987); and the manifest, storage and disposal rule (1989).

The Consensus Group continues to work with the Agency and other interested parties to formulate PCB rules that provide appropriate public health protection while being reasonable and cost-effective. In all these proceedings, we have discovered that by working with the agencies (often in close consultation with environmental groups) that it is possible to develop rules that both effectively and efficiently control PCB risks. We approach this new rulemaking with the hope that close cooperation can again lead to improved PCB rules.

Given the short comment period provided for this ANPRM, the Consensus Group focuses in these comments on broad, overview issues. We also submit at this time some of the relevant underlying evidence upon which the rulemaking should be based. Consistent with EPA's indication to us in denying our request for an extension of the ANPRM comment period that it will continue to review any additional comments or information submitted in the next few months, we will be supplementing these comments.

II. EPA SHOULD AMEND OVERLY TECHNICAL AND STRINGENT
PCB RULES THAT ARE NOT NECESSARY TO PROTECT PUBLIC
HEALTH

This rulemaking is a significant opportunity to update rules based on past perceptions, to eliminate unfounded rigidities, and to incorporate flexibility. EPA correctly identifies the purpose of this rulemaking, namely "to allow for maximum flexibility in controlling PCBs or PCB Items based on their risk to human health and the environment."³ The Agency's "experience gained over the past 12 years in dealing with PCBs"⁴ should indeed provide a more than adequate basis upon which to depart from the overly restrictive rules that often impeded expeditious cleanup and disposal in that period.

Amendment of the overly technical and stringent rules that have often been applied uniquely to PCBs is particularly merited in light of the fact that PCB concentrations in the environment appear to be a declining public health problem. A study examining the trend of PCB concentrations in various media throughout the country has been commissioned by the Consensus Group. Preliminary results already demonstrate clearly, as the Agency is no doubt aware, that PCB concentrations have decreased significantly. Upon completion, we will submit this study to the Agency.

Principally, this rulemaking should address -- and revoke -- the anti-dilution rule as the basis upon which disposal

³ 56 Fed. Reg. at 26738.

⁴ Id.

alternatives are to be chosen. Whatever may have been the initial rationale for the Agency's arguments that accidental spills are dilution (which thus require disposal as if the contaminated materials were still at the PCB concentration of the spilled material), the result has been unwarranted disposal requirements having an effect opposite to the rule's stated intention of protecting public health. The Agency's Superfund office has decried, indeed termed "punitive," the irrationality of the TSCA anti-dilution approach:⁵

This [TSCA anti-dilution] interpretation of the regulations could pose severe impacts on Superfund remedial actions where PCBs were disposed after 1978. For example, soil contaminated by a PCB-oil containing greater than 500 ppm PCBs would have to be incinerated or treated by an "equivalent method" even where the PCB concentration in the soil is relatively low, i.e., less than 50 ppm. Large volumes of soil could be subject to this type of evaluation with disposal costs running as high as \$500 per cubic yard.

Compliance with this applicable requirement goes beyond the scope of Superfund since protection can usually be achieved without incinerating low concentration material. The requirement is basically punitive in nature. A strict interpretation of how this requirement applies to Superfund response actions would prevent Superfund from addressing contaminated media in a manner consistent with the requirements of the National Contingency Plan.

As the Superfund Office concluded, "[t]he more appropriate interpretation of the TSCA requirement is that Superfund

⁵ J.P.E. desRosiers and Haley, Jennifer (EPA), Remedy Selection at Superfund Sites Contaminated with Polychlorinated Biphenyls (EPRI PCB Conference) June 11-12, 1990 (appended as Attachment 3) (emphasis added).

response actions should treat contaminated media based on the form and concentration that exist in the environment." That interpretation should be explicit in the TSCA rules and should apply to all -- not just Superfund -- cleanups. The EPA authors indicated last year that the Agency was "scrutinizing the TSCA regulations to identify where changes may be appropriate."⁶ Now is the time to implement that scrutiny.

The Agency should also clarify its rules to reverse In re Rollins Environmental Services,⁷ which held that the anti-dilution rule required rinsate with concentrations below 50 ppm to be disposed of as if it were at the PCB concentration in the liquid that had been in container being rinsed. As the Court of Appeals recently noted in reviewing that decision, the EPA provision was not a model of clarity and EPA's present interpretation of the regulation is "strained."⁸ EPA should make a rational determination of when such rinsate does not pose a

⁶ EPA also indicated it was committed to "considering the issue of proper disposal of PCBs found at Superfund sites" in its June 8, 1990, response to a TSCA Section 21 petition filed in connection with the New Jersey BROS Superfund site; see Letter from L. Fisher, Office of Pesticides and Toxic Substances, USEPA to W. Walsh and W. Hyatt, at 2 (June 8, 1990) (EPA Dkt. OPTS-66009, Ex. E1-003).

⁷ TSCA Appeal No. 90-2, Docket No. II-TSCA-PCB-88-0116.

⁸ See, Rollins Environmental Service (NJ) Inc., v. EPA, No. 90-1508 (D.C. Cir. July 5, 1991) (LEXIS, Genfed Library, U.S. App. File), affirming the Agency's interpretation because, although it "would not exactly leap out at even the most astute reader," the Court felt it must give substantial deference to an Agency's choice. 1991 U.S. App. LEXIS 13866. The Court ordered, however, that no penalty be assessed, because imposing such a penalty given the ambiguity of the regulation was without justification.

public health problem and should establish disposal rules premised on level of risk of the rinsate -- not the concentration of liquid that had been drained from the container. There is no risk justification for treating all rinsate like the predecessor liquid.⁹

Finally, EPA should take the opportunity afforded by this rulemaking to reverse the unfortunate decision in Standard Scrap that the mere presence of PCB-contaminated materials can be the basis for an enforcement decision that unauthorized disposal has occurred.¹⁰ The decision, in effect, turns the TSCA prohibition on unauthorized disposal into a PCB Superfund scheme -- a scheme never contemplated by Congress or the authors of the TSCA rules. In addition, it allows an enforcement action for pre-TSCA activity -- a clear impermissible, retroactive application of TSCA jurisdiction. As part of this rulemaking, the Agency should clarify that the prohibition on unauthorized disposal does not, as Standard Scrap implies it does, require cleanup of all PCB-contaminated material, or apply to pre-TSCA disposals. Such a clarification would carry forward the original interpretation made by EPA in a memorandum written August 3, 1979, by John W. Lyon, then of the EPA General Counsel's office, to Sanford W.

⁹ Cf., New York State Department of Environmental Conservation (NYDEC) from Richard Baker, dated Dec. 1, 1988 (Memorandum on disposal of PCB contaminated soils from spills states that EPA's anti-dilution policy may "drastically alter" NYDEC waste disposal approvals).

¹⁰ In re Standard Scrap Metal Company, TSCA Appeal No. 87-4, Docket No. TSCA-V-C-288.

Harvey, Jr., then Director of EPA's Enforcement Division, Region IV.

In sum, this rulemaking provides the Agency a unique opportunity to develop some new approaches to various aspects of PCB regulation. The Consensus Group urges EPA to view its opportunities broadly in addressing these issues.

III. PCBs ARE NEITHER AS TOXIC NOR AS PERSISTENT AS EPA ASSUMED IN PRIOR RULEMAKINGS.

Because PCBs are neither as toxic as originally assumed nor as persistent in the environment as once estimated, the "problem" of PCB contamination is less than originally forecast and is, moreover, rapidly declining. EPA's regulations for PCB disposal and other activities should set standards in light of these new facts and provide health protection commensurate with the real-world likelihood of harm.

A. The Latest Health Effects Information.

The most up-to-date information on the health effects of PCBs indicate that prior assessments, on which EPA rulemakings were based in the past, overestimated PCB toxicity. The human and animal evidence of PCBs' association with cancer is weak. Comprehensive review of the available evidence -- epidemiologic studies, carcinogenicity studies, and reproductive toxicity studies -- all indicate that PCBs rarely are found in sufficient concentrations to present a significant risk to humans or the environment.

1. Epidemiologic Studies.

There have been numerous studies of PCB exposed workers and non-occupationally exposed populations.¹¹ The results of these studies agree on one important point: there have been no clinical illnesses associated with PCB exposure other than dermatitis. Studies of non-occupationally exposed populations have found neither dermatitis nor other clinical evidence of exposure-related effects, with the exception of a single study that suggests that diastolic blood pressure may be related to blood level of PCBs.

Mortality studies concerned primarily with cancer present problems of interpretation due to the small sample size of some of the studies, and to the confounding effect of other exposures. However, the pattern common to the studies as a whole is that none of the studies agree on the cancer sites at which an excess mortality was found, and even these excesses are, in general, not statistically significant.¹² As each individual researcher concludes, the findings of the mortality studies reflect a sporadic pattern of excess mortality at different sites that is not consistent with a carcinogenic effect of PCBs. In addition, where an examination of duration and latency of exposure was possible, no association with these variables was found. In short, none of the studies support a conclusion that PCB

¹¹ Harbison, Raymond D., James, Robert C., Roberts, Stephen M., Biological Data Relevant to the Evaluation of Carcinogenic Risk to Humans (Aug. 1987) (appended to this submission at Attachment 5).

¹² See, id. at 15, 18.

exposure resulted in an increase in cancer.¹³ EPA itself has not considered the evidence of human carcinogenicity convincing. EPA should state that finding clearly in this rulemaking.

Two studies, one by Nicholson¹⁴ and one by Sinks,¹⁵ merit particular mention. Nicholson performed a "meta" analysis, combining several studies into a single cohort, and claimed to find significant excess for a combination of liver, gall bladder and biliary cancers. Nicholson's analysis, however, notably omitted two later studies (by Sinks and Taylor) with large cohorts showing no excess of these types of cancers. Nicholson's finding is negated when these other large studies are incorporated into his analysis. Although Sink's study does report excess cancer for malignant melanoma, the excess is not related to PCB exposure levels, thus rendering this alleged excess difficult to interpret.

Occupational exposure to PCBs at high levels has been associated with chloracne,¹⁶ but the relationship is not straightforward, suggesting that the actual risk of chloracne is also a function of individual susceptibility and personal work habits, as well as possible exposure to other contaminants.

¹³ Id. at 29.

¹⁴ Industrial Disease Standards Panel (Ontario Ministry of Labor), Report to the Workers' Compensation Board on Occupational Exposure to PCBs and Various Cancers (Dec. 1987) (Dr. Nicholson was the Panel's chair).

¹⁵ NIOSH Health Hazard Evaluation Report, Westinghouse Electric Corporation, Bloomington, Indiana (Jan., 1991) (HETA 89-116-2094) (Dr. Sinks was the chief NIOSH investigator).

¹⁶ See Harbison, supra n.11 at 21-22.

Dermatologic problems other than chloracne have been associated with occupational exposure, but they are likely related only to exposure to highly chlorinated PCBs. Alterations of liver function and fat metabolism associated with PCB exposure have been observed in several studies, but are characterized by investigators as mild and of no clinical significance.¹⁷

The existing mortality studies of occupational exposure do not show the agreement that would lead one to infer an excess risk of cancer.¹⁸ Much of the conflicting findings can be attributed to the possible effect of confounding exposures, and to the "noise level" or sporadic excesses which would be expected in the absence of any occupational hazard.

Taken as a whole, the epidemiologic studies find that high occupational exposures to PCBs may cause dermatitis of various kinds, but no other clinically observable effects. Thus, EPA should base its new rule on this most up-to-date health evidence.

2. Animal Studies.

Several experts have reviewed and summarized the PCB animal studies and their relationship to assessing human risk. They find that the animal studies neither support extrapolation to human risk assessment nor generally characterize all PCBs as equally carcinogenic.¹⁹

¹⁷ Id. at 21.

¹⁸ Id. at 16.

¹⁹ Id. at iv.

First, the evidence from animal studies does not justify regarding all PCBs as carcinogenic to humans. PCB-treated rats, including those with liver tumors, lived significantly longer than control rats. Similarly, PCB-treated rats had an overall lower cancer risk than controls.²⁰ Finally, the liver cancers found did not metastasize to other organs. In short, as in the epidemiologic studies, investigators have found that the PCB carcinogenic mechanism, if any, is not typical and thus animal data are not useful in determining human risk.²¹

Second, at most the data indicate only that the "higher chlorinated" PCBs, e.g., 60% chlorine and higher, may be classified as suspect animal carcinogens. This fact led the state of California initially to list only PCBs with greater than 60% chlorine on its Proposition 65 hazardous substance list.²² With respect specifically to commercial mixtures of PCBs containing approximately 54% chlorine, detailed re-evaluation of the published literature found that the weight of evidence is insuf-

²⁰ Id. at iii.

²¹ Id. at iv.

²² Official Cal. Code of Regs. Tit. 26 § 22-12000 (1991). Based on the data, California originally listed only PCBs containing more than 60% chlorine by molecular weight. In late 1989, however, California was required to expand its listing to include all PCBs in order to comport with Proposition 65's requirement that a substance be listed even if only one identified environmental agency has designated the chemical as a carcinogen, whether or not the Scientific Advisory Panel finds such a designation justified. See AFL-CIO v. George Deukmejian, 212 Cal. App. 3d 425, 260 Cal. Rptr. 479 (July 20, 1989).

ficient to classify 54% chlorine PCBs as carcinogenic.²³ Specifically,

- Extensive testing demonstrated PCBs mixtures of 54% chlorine content are not genotoxic.
- On the whole, the results of the animal studies provide insufficient evidence that PCBs are carcinogenic in animals. The rat data is negative. The positive data in mice is both sex- and dose-dependent and is seen only at hepatotoxic doses. As such, it suggests PCBs mixtures of 54% chlorine may promote the growth of spontaneously occurring liver tumors in mice secondary to recurrent liver injury. Mouse liver tumor induction under these conditions represents weak and insufficient evidence of carcinogenicity, especially when tests in other species prove negative.
- There are no epidemiologic data from populations exposed exclusively or primarily to 54% chlorine PCB mixtures. However, the weight of evidence from numerous epidemiological studies of populations exposed environmentally or occupationally to all forms of PCBs has failed to show any causal effect relationship between PCBs and carcinogenicity (or any other chronic human health effect).

In addition, the animal data on liver effects have recently undergone review due to the recent changes in criteria and nomenclature for such lesions.²⁴ A group of six expert pathologists working with the Institute for Evaluating Health Risks (IEHR) have re-read the slides of the five most important PCB animal studies using the National Toxicology Program (NTP) current procedures. The pathologists' report found: (1) no

²³ James, Robert C., Roberts, Stephen M., Kerger, Brent D. of TERRA, Inc., A Review of the Carcinogenic Risk of Polychlorinated Biphenyl Mixtures of Approximately 54% Chlorine Content, (Apr. 1989) (appended to this submission as Attachment 8).

²⁴ Institute for Evaluating Health Risks, Reassessment of Liver Findings in Five PCB Studies in Rats (July 1, 1991) (appended to this submission as Attachment 6).

statistically significant increase in benign and malignant liver tumors with exposure to a 54% chlorinated PCB formulation; and (2) tumor increases only with chronic dietary exposures in formulations of at least 60% chlorinated PCBs. IEHR recommended that EPA revise its present policy that all PCB formulations are probable human carcinogens and that all PCBs formulations are equally potent.

In short, the cancer studies bolster the position that regulatory flexibility is necessary given the weak link between PCBs and cancer.

3. Reproductive Toxicity Studies.

PCBs have not been found to be a human reproductive toxin. An expert technical review of studies of the potential effects of PCBs on human and animal reproduction and development concluded that PCBs do not exhibit reproductively toxic mechanisms.²⁵ Pertinent animal studies were reviewed carefully according to guidelines proposed by California Proposition 65 Scientific Advisory Panel and the EPA 1986 Guidelines For Health Assessment of Suspect Developmental Toxicity. The consultants concluded:

- No studies demonstrate an adverse effect of PCBs on human reproduction or fetal or neonatal health. Critical examination of currently available studies shows insufficient evidence to suggest that

²⁵ James, Robert C., Roberts, Stephen M., Kerger, Brent D., Clevenger, M. Ann, Millner, Glenn C. of TERRA, Inc., A Critical Evaluation of the Human and Animal Evidence Concerning the Reproductive Toxicity of Polychlorinated Biphenyls (PCBs), (Nov. 1988) (appended to this submission as Attachment 7).

exposure to PCBs from a job site or the environment represents a human reproductive hazard.

- No animal studies of PCB mixtures clearly demonstrate adverse effects on spermatogenesis, sperm characteristics, genetic characteristics of sperm, or the formation of significant lesions of the reproductive organs.
- No animal studies of PCB mixtures clearly demonstrate adverse effects on oogenesis, ovulation, genetic characteristic of oocyte, or the formation of significant lesions of the reproductive organs.
- No animal studies of PCB mixtures clearly demonstrate reproductive dysfunction in male or female animals at doses below those causing other systemic toxicities. To the contrary, those reports of reproductive problems were generally observed only in conjunction with severe systemic toxicity or mortality in the adult animal.
- No animal studies of PCB mixtures clearly demonstrate an increased incidence of teratogenic effects (physical deformities or neurological dysfunction) at dose levels that do not also cause severe maternal mortality.
- No animal studies of PCB mixtures clearly demonstrate increased incidences of any adverse developmental effects as dose levels below the no observable effect level (NOEL) for organ toxicity in one or both parent animals.²⁶

* * *

In sum, the available epidemiology and toxicology demonstrate that EPA should recognize the dearth of scientific evidence attributing health effects to PCBs and should regulate accordingly. Such a regulatory decision would comport with the

²⁶ Despite the data, the California Scientific Advisory Panel ultimately listed PCBs as a reproductive toxicant. However, it did so with little opportunity for public scrutiny or input to the Panel's rationale for its action. In any event, a listing under Proposition 65 places no restriction on a chemical's use or disposal. See also supra n.22.

conclusions of many noted scientists who have independently reviewed the evidence:

In conclusion, various toxic effects of PBBs and PCBs have been described in laboratory animals. In humans, acute poisons outbreaks have only occurred following exposure to a combination of PCBs and PCDFs. When humans were exposed only to PCBs or PBBs, the only observed acute effects have generally been minor. So far, no significant chronic health effects have been causally associated with exposure to PCBs or PBBs. (Kimbrough, 1987).

Since industrial exposure to high levels of PCBs elicits only mild to moderate toxic symptoms which are reversible, it is unlikely that environmental uptake of PCBs results in significant adverse human health effects. (Safe, 1987).

Thus, despite positive laboratory animal data and except for chloracne, exposure to PCBs has led to no convincing, clinically demonstrable, chronic health effects in humans. (Kimbrough, 1988).

B. Numerous Studies Have Shown PCBs to Degrade in the Environment.

EPA's previous PCB rules were based on the premise that PCBs are generally resistant to biodegradation and thus would never dissipate. As the attached studies show, PCBs have been shown to degrade in the environment to a greater extent than previously believed.²⁷

²⁷ Brown, John F., Bedard, Donna L., Brennan, M.J., Carahan, James C., Feng, Helen, Wagner, Robert E., Polychlorinated Biphenyl Dechlorination in Aquatic Sediments, 236 Science 709 (May 8, 1987) (appended to this submission as Attachment 2); General Electric Company, Research and Development Program for the Destruction of PCBs, Ninth Progress Report (Aug. 1990) (appended to this submission as Attachment 4); Quensen, John F., Tiedje, James M., Boyd, Stephen A., Reductive Dechlorination of Polychlorinated Biphenyls by Anaerobic Microorganisms from

(continued...)

Research in this area continues to show the potential for complete biodegradation of even the most chlorinated PCB formulations by both aerobic and anaerobic methods.²⁸ It appears that the rate at which PCBs degrade in the environment is dependent upon chlorine content. Highly chlorinated PCBs are more difficult to biodegrade under aerobic conditions, although partial dechlorination may occur anaerobically, allowing for later aerobic biodegradation.²⁹ Researchers are developing PCB biodegradation technology for field application that will provide an alternative to the present limited PCB disposal methods.

The Consensus Group is in the process of collecting and reviewing the many studies on the different methods of PCB biodegradation in different media. Upon completion of this review, we will submit to EPA these studies and a summary on available technologies.

EPA should promulgate a rule that supports the development of this new technology. Such a rule would provide sufficient flexibility for biodegradation methods to be used as an alternative disposal method. General regulatory flexibility in disposal methods is also warranted because the evidence on

²⁷ (...continued)
Sediments, 242 Science 752 (Nov. 4, 1988) (appended to this submission as Attachment 9).

²⁸ See General Electric Company, supra n.27 (Attachment 4).

²⁹ See Abelson, Philip, Editorial, Excessive Fear of PCBs, 253 Science 361 (July 26, 1991) (appended to this submission as Attachment 1).

biodegradation shows that PCBs will naturally biodegrade and thus any contaminants left in any medium will eventually dissipate.

IV. EPA SHOULD INTERPRET ITS DISPOSAL RULES TO
DEAL FLEXIBLY AND RATIONALLY WITH PCB ISSUES.

We support EPA's efforts to "allow for maximum flexibility in controlling PCBs or PCB items based on their risk to human health and to the environment."³⁰ To further that end, we urge EPA to adopt the following suggestions:

A. EPA Should Allow Any Approved DOT Containers
for Movement and Storage of PCB Waste.

EPA has suggested that it defer to the Department of Transportation (DOT) on issues of packaging PCB waste for transportation and storage.³¹ We support EPA's effort to avoid duplicative and possibly contradictory requirements for such packaging. EPA should allow PCBs to be stored and transported in any DOT-approved containers.

EPA also seeks comments on whether, in light of the recently finalized DOT rule, EPA should rewrite § 761.60(b) (2)(vi) (requiring that prior to disposal in a chemical waste landfill, all large and small PCB Capacitors described in § (b)(2)(iv) be placed in a DOT container described in § 761.65(c)(6)).³² The Consensus Group supports this revision

³⁰ 56 Fed. Reg. at 26738.

³¹ 56 Fed. Reg. at 26740-26741.

³² 56 Fed. Reg. at 26741.

so as to harmonize EPA regulations with DOT regulations regarding containment, shipment or storage of PCB waste.

B. New Restrictions on Drained PCB-Contaminated Transformers Are Unnecessary.

EPA suggests a need to impose controls on disposal of drained PCB-contaminated transformers.³³ Their disposal currently is explicitly not regulated.³⁴ The admittedly "anecdotal information" upon which EPA's suggestion is made does not justify any new rules.

A substantial unwarranted burden would be imposed on disposal of the thousands of PCB-contaminated transformers that contain low levels of PCBs (liquid concentrations of 50-499 ppm) due to past practices that allowed small quantities of PCBs inadvertently to enter such equipment. Such equipment today contains only very small amounts of PCBs; the possibility that these PCBs are distributed to the environment in any meaningful quantity due to inappropriate uses upon disposal (e.g., the Agency suggests it has heard that used transformers have been employed as "bar-b-que grills") is minute. Such units are exceedingly unlikely to be put to such uses, and given the existing requirement that "all free flowing liquid" be drained, would be unlikely to contain any meaningful quantity of PCBs. Moreover, such "bar-b-que" activities are already illegal -- as they would constitute unauthorized use.

³³ Id. at Part IID.

³⁴ 40 C.F.R. § 761.60(b)(5)(ii).

In short, there is no significant likelihood of harm from drained PCB-contaminated transformers; EPA already has appropriate enforcement authority for any such activities, and, thus, the Agency should not initiate regulation of drained PCB-contaminated transformers.

C. Movement of PCBs to Storage for Disposal
 Is Authorized Distribution in Commerce
 That Should Not Be Considered Storage.

EPA raises for comment a disposal/storage scenario involving filling of drums and their loading on trucks for shipment to storage and suggests that this activity should not be considered authorized distribution in commerce for purposes of disposal.³⁵ The Agency indicates no reason for concern about this scenario, but suggests that the described filling and loading period might be characterized as storage, thus subject to the requirements of 40 C.F.R. § 761.65(c). We fail to understand why the Agency is suggesting any change in a long-understood interpretation of its rules.

The foundation of the timing requirement in the PCB disposal rules is the requirement that the material be removed from storage and disposed "within one year from the date when it was first placed into storage" (emphasis added).³⁶ Although the phrase "placed into storage" is not defined, it has always been understood that placement in storage means putting the PCB materials into a storage area. Collecting the PCBs, first into

³⁵ 56 Fed. Reg. at 26741, Part IIE.

³⁶ 40 C.F.R. § 761.65(a).

drums, then into trucks or other vehicles, and moving the PCBs to a storage area, has always been understood as distribution in commerce for purposes of disposal -- an authorized activity (40 C.F.R. § 761.30(c)(2)) -- that precedes placing the materials in storage, whether it be 30-day temporary, or permanent storage. We find no rationale for changing this understanding.

It is, of course, true that disposers could attempt to avoid the requirements for storage by unwarranted delays in moving collected PCBs to the storage area. On a case-by-case basis, therefore, violations of the rule could be found if undue delay indicated that the disposer had in fact left (i.e., placed) the material in a location in a manner that could be considered storage. If, however, the disposer is reasonably loading drums, filling trucks, and moving the material to a storage area -- as suggested in the Agency's scenario -- all such activities should be considered to precede storage for disposal and thus already be fully authorized as activities inherent in distribution in commerce for purposes of disposal.

If, perchance, the Agency does not read its current regulations to recognize the necessary activities that always occur before wastes are placed into storage, then this rulemaking presents a good opportunity to revise its thinking. No purpose is served by placing undue restrictions on such necessary waste movements.

D. Existing Authorizations Already Allow Distribution in Commerce of Analytic Standards and Round Robin Samples.

EPA discusses two issues related to analyses of PCB samples: (1) whether authorizations are needed to participate in round-robin analytical exercises and (2) whether standards and audit samples can be distributed in commerce.³⁷ With respect to both, the Agency is certainly correct that such activities should be authorized. But, given the reality that the entire PCB disposal program is premised on such activities occurring on a routine basis, it is difficult to perceive why the Agency expresses any doubt that such activities are not already so authorized.

Small quantities of PCBs may be used for research and development indefinitely.³⁸ As the Agency wrote in 1984:

Small quantities of PCBs are used . . . in analytical testing by industry, the public and governmental agencies. Analytically pure samples of PCBs are probably used everyday in laboratories throughout the country . . . [and] . . . will be needed for the foreseeable future. Thus, EPA is issuing an indefinite use authorization.

49 Fed. Reg. 28193, 28198 (July 10, 1984). Such authorized activities could not occur unless the analytical standards and quality assurance (round-robin) trials inherent to such activities were also authorized.

Beyond authorizing research and development (R&D) use, EPA further issued a class exemption in 1986 to all persons

³⁷ 56 Fed. Reg. at 26743, Parts II (I) & (J).

³⁸ 40 C.F.R. § 761.30(j) (1990).

processing and distributing PCBs in commerce for research and development purposes.³⁹ Finally, manufacture or import of PCBs for research purposes requires exemption petition approval, but EPA automatically approves annual renewals of such approvals.⁴⁰

The Agency has not identified what problems, if any, occur with existing authorizations so as to warrant additional authorizations. Under existing rules, analytical standards and samples can be distributed in commerce by any person involved in small quantity research and development. Samples are already exempt from PCB manifesting requirements. EPA's suggestion that only the government does not need an exemption to distribute analytic standards and samples is contrary to the rules; any party should be able to take advantage of the 1986 class exemption.

We thus urge the Agency to recognize the scope of the already existing R&D authorizations. If the Agency believes there is ambiguity, it should issue a clarification.

E. Small-Scale Treatability Studies And Research on PCB Disposal Should be Allowed Without a Need for a Specific Permit.

EPA encourages the use of alternative disposal methods to ensure proper PCB waste management.⁴¹ Yet, EPA also suggests that all parties, except for EPA or other federal entities (and their contractors acting as agents), could be required to

³⁹ 51 Fed. Reg. 28556 (Aug. 8, 1986).

⁴⁰ 53 Fed. Reg. 32326, 32336 (Aug. 24, 1988).

⁴¹ 55 Fed. Reg. at 26738.

obtain authorization or exemption to use small samples for analytical purposes.⁴² EPA should ensure that it does not inadvertently thwart development of new disposal methods by promulgating such overly prescriptive rules.

To encourage research and development of improved disposal methods, small-scale treatability studies and PCB disposal research should be allowed without a permit. If the Agency deems it necessary, either notification to EPA of such disposal research/small-scale studies or a similar "permit by rule" provision (incorporating both Agency notification and compliance with basic regulations on conducting treatment and alternative disposal studies) would be all that is warranted to protect the public while not preventing needed research.

Such a scheme would comport with RCRA's regulatory exemption for treatability study samples⁴³ and would have the added benefit of regulatory uniformity. It will also encourage development of new disposal technologies. As EPA knows well, many developments have occurred in disposal methods in the last few years. Requiring exemption or authorization to use PCB samples to develop new disposal methods will impede the availability of technical developments that would actually make PCB disposal more efficient than presently available methods. EPA should carefully draft its rule so that it allows state-of-the-art advances in disposal methods.

⁴² 56 Fed. Reg. at 26743.

⁴³ 40 C.F.R. § 261.4 (1990).

F. Disposal Flexibility for Large Volume,
Non-Liquid PCBs Is Necessary.

EPA seeks comment on incorporating within its rules specific disposal methods concerning large volume, non-liquid PCBs for which a party now must obtain an approval as an alternative disposal method.⁴⁴ EPA suggests that those disposal methods might include thermal extraction, in-situ vitrification, bioremediation, or even more conventional approaches not now applicable to certain high volume items. These items could include shredded automobiles, white goods, industrial scrap, certain classes of soils, sediments and sludges.

The Consensus Group supports EPA's position of granting increased flexibility and greater ease of disposing of or managing such PCB items. For example, we believe EPA should issue guidance to encourage the states to recognize that the disposal of wastes contaminated with low levels of PCBs need not be restricted to chemical waste landfills. Use of such landfills is inappropriate when the wastes could easily be disposed of in ordinary sanitary landfills, or by other alternative means. Further, as will be addressed in supplemental comments, we believe that a distinction must be drawn between disposal and reuse of certain high volume items.

⁴⁴ 56 Fed. Reg. at 26739.

G. Transport Vehicle Marking Regulations Should Be Harmonized.

EPA seeks comment on how best to address what appears to be a duplication in the regulations governing the marking of transport vehicles.⁴⁵ EPA suggests that it could delete either one of the sections or delete both and rewrite the provision.

We note that DOT already has regulations requiring the truck or other means of transportation to be marked, even though the placard would only have a number and not the word "PCB." Accordingly, we suggest that the PCB label under TSCA be eliminated in favor of DOT marking and labeling.

If, however, EPA retains a specific marking provision in the PCB rules, we believe that the provision in 40 C.F.R. § 761.40(e) should be deleted and that the provision in 40 C.F.R. § 761.40(b) be retained, as the latter applied one year prior to the provision in subsection (e) and the substance of subsection (e) appears to be subsumed within subsection (b).

⁴⁵ 40 C.F.R. §§ 761.40(b) and (e); see 56 Fed. Reg. at 26740.