UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
BEFORE THE ADMINISTRATOR

In the Matter of:

PROPOSED TOXIC POLLUTANT EFFLUENT STANDARDS FOR POLYCHLORINATED BIPHENYLS (PCBs)	)	FWPCA (307) Docket No. 4

OPENING BRIEF OF THE ELECTRONIC INDUSTRIES ASSOCIATION'S AD HOC PCB COMMITTEE

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CONTENTS

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The issue presented in this proceeding is whether the Administrator should adopt proposed effluent standards for discharges of polychlorinated biphenyl (PCB or PCBs) into navigable waterways. The pertinent statute is Section 307(a) of the Federal Water Pollution Control Act, as amended by the Federal Water Pollution Control Act Amendments of 1972 (Pub.L. 92-500, 86 Stat. 816, 33 U.S.C. §1251 _et seq_.)

In its Notice of Proposed Rulemaking, 41 Fed. Reg. 30468 (July 23, 1976), the Agency proposed a 1 part per billion (ppb) discharge limitation on all "manufacturers of transformers and capacitors who use PCBs and who discharge directly into the navigable waters." (41 Fed. Reg. 30468) The Electronic Industries Association's Ad Hoc PCB Committee filed objections to this proposed standard, and participated as a party in the rulemaking proceeding. The Ad Hoc Committee is composed of the nine capacitor manufacturers who use Aroclor 1016, one of the many different varieties of the family of chemical compounds known generally as PCBs. Five of these companies*/ would be directly and adversely affected by the proposed discharge limitation.

Although the Agency has proposed PCB discharge regulations and has undertaken to prove that treatment technology exists which can reduce PCB effluent levels to 1 ppb as proposed, the practical effect of the Agency's proposed PCB discharge regulations is to ban the use of Aroclor 1016 in capacitors and transformers. The evidence is undisputed that no capacitor or transformer manufacturer will invest the very substantial sums required by the proposed discharge limitation to install and maintain effluent treatment facilities. (see Tr. 2116; 2310-2312; EIA Exh. A at 2; EIA Exh. C at 7) The reasons can be traced to two developments which occurred after the Agency's issuance of its July 23, 1976 Notice of Proposed Rulemaking.

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*/ Aerovox Industries, Inc., Cornell-Dubilier Electronics, Inc., Jard Company, Sangamo Electric Company, Sprague Electric Company, and Universal Manufacturing Corporation discharge into navigable waters and their effluent arguably contains Aroclor 1016.

First, the Toxic Substances Control Act, Pub.L. 94-469, 90 Stat. 2003, 15 U.S.C. §2601 et seq., passed by Congress this last session and signed into law by President Ford on October 11, 1976, will ban the use of PCBs in the manufacture of capacitors and transformers after January 1, 1979. See 15 U.S.C. §2605(e)(3)(A). Thus, irrespective of the effluent standards adopted by the Agency, no manufacturer of capacitors will be permitted to use Aroclor 1016 after 1978, unless exemptions are granted by the Administrator pursuant to the TSCA.

Second, the only U.S. manufacturer of Aroclor 1016, the Monsanto Chemical Co., recently announced that it will terminate all production of PCB, including production of Aroclor 1016, by August 31, 1977 and that it will terminate all shipments of PCB by October 31, 1977. It is estimated that with maximum use of stockpiles, capacitor manufacturers will cease all PCB use by the third quarter of 1978 because PCBs will not be imported to substitute for the Monsanto-produced Aroclor 1016 material. (EIA Exh. B at 9-10 [Hutzler]; EIA Exh. C at 10-11 [Clark]; Tr. 2086-2087)

The Agency should be aware that in undertaking to regulate PCB discharges, it is effectively banning the use of Aroclor 1016 prior to the PCB ban mandated by Congress in the TSCA. Indeed, the Agency's economic impact assessment was expressly predicated on the assumption that all direct dischargers of PCB will end their use of the material by the effective date of the proposed discharge regulation rather than expend the several hundreds of thousands of dollars required for the treatment technology recommended by the Agency. (Tr. 67 of the Hearing on November 30, 1976; EPA Exh. 16 at vii-viii)

The imposition of a ban on the use of Aroclor 1016 in capacitors poses serious risks. A ban on Aroclor 1016 will create the substantial risk of fire by forcing the industry to use highly flammable substitutes. (EIA Exh. B at 5-6) Such a ban also will result in a 20-30 percent increase in the costs of capacitors using the less desirable substitute materials. (EPA Exh. 16 at xi; see also Exhibit B to EIA Exh. B)

In this brief, we will review the nature and use of Aroclor 1016 in capacitors and will then argue two alternative propositions. First, it is our position that no national standards should be established setting discharge limits on Aroclor 1016. The Toxic Substances Control Act preempts totally this area of regulation and establishes a Congressional scheme of PCB regulation leading to a ban on PCB use in capacitors after 1978. No further regulation under the FWPCA is warranted or sanctioned under TSCA. Further, national effluent standards are unwise in the circumstances here presented and an abuse of the Administrator's discretion under the FWPCA. Only on-site regulation can properly evaluate local ecological conditions and set appropriate discharge limits to correspond to varying local conditions.

In the event the Administrator determines that a national effluent discharge limitation should be established, we will urge that the proposed 1 ppb limit at the pipe for PCBs generally be modified substantially respecting Aroclor 1016. The record establishes substantial and important differences between the type of PCB used by the capacitor industry, Aroclor 1016, and all other PCBs. There is no basis for a uniform national standard for all PCB discharges. The maximum limitation justified by the record in this proceeding for Aroclor 1016, which at the same time provides the requisite ample margin of safety, is 100 ppb. The lower limit proposed by the Agency is inappropriate for Aroclor 1016 in light of all the evidence of record. Further, the imposition of a 1 ppb standard on Aroclor 1016 would create a system of regulation which could not be fairly administered. The 1 ppb limit cannot be accurately measured in industrial effluent and cannot be the basis for regulation save with allowable variations of 100 to 400 percent. Moreover, by providing only for an aggregate discharge limit, the Agency has failed to allow for the possibly substantial levels of PCB extant in each company's <u>in</u>fluent water.

Such an aggregate limit on PCB would serve only to penalize the capacitor and transformer companies, requiring them to attempt to treat water containing PCB discharged both in the past and currently by non-regulated companies.

FACTUAL BACKGROUND

A. The Chemistry of Polychlorinated Biphenyls

The Agency has undertaken to regulate all "PCB" discharges, claiming that "PCBs have been conclusively demonstrated to produce lethal and sublethal toxic effects . . . ." 41 Fed. Reg. 30468. The Agency has sought to validate this sweeping indictment of "PCBs" by lumping the more than "209 separate compounds, or isomers, of the chlorinated biphenyl family," (*Id.*) under the umbrella label "PCB." There is no scientific basis for this failure to acknowledge the important chemical differences between different types of PCBs. As the Agency defined the term "PCB" in its Notice of Proposed Rulemaking:

> "PCBs are a class of organic compounds manufactured by the chlorination of biphenyl with anhydrous chlorine using iron filings or ferric chloride as a catalyst. The biphenyl molecule has a total of ten carbon-hydrogen bonds at which chlorine substitution can be accommodated. In the manufacture of PCBs, anywhere from one to ten chlorine atoms may be located on the biphenyl molecule. Depending upon

the location of these substitutions, theoretically as many as 209 separate compounds, or isomers, of the chlorinated biphenyl family can be manufactured." (emphasis added) (Id.)

Some varieties of PCBs have been shown to be resistant to degradation in the environment, and have thus proved to be highly persistent. As these PCBs persist and accumulate in aquatic organisms, they move up the food chain--by fish-eating mammals ultimately to humans. It has been established that the degree of persistence is directly related to the degree of chlorination of the compound: the more highly chlorinated the PCB, the more likely it is to persist and pose a possible hazard to the environment.

This fact became understood less than ten years ago. By that time PCBs had become a ubiquitous chemical, used in many thousands of industrial and business applications. The Agency has estimated that 1.4 billion pounds of different PCBs were produced in the United States over the past 45 years--of which 1.25 billion pounds were used in this country. (See 41 Fed. Reg. 30469; see also EIA Exh. 17 at p. 111 for more complete Monsanto-production data) The only remaining users of PCB are the capacitor and transformer manufacturers. Their annual discharges of PCB do not exceed 10,000 pounds; PCB is now used only in "closed-systems" which do not expose the vast bulk of the material to the environment. (Id.) Aroclor 1016 is the only type of PCB used by the capacitor industry. (EIA Exh. B at 2 [Hutzler]; EIA Exh. C at [Clark])

B. The Chemisty of Aroclor 1016

Aroclor 1016 bears little resemblance to the types of PCBs used previously. It is these earlier, now-abandoned types of PCB which presented the problems of persistence the Agency is belatedly undertaking to ameliorate, and which for the most part form the basis for the Agency's present "case" against Aroclor 1016.*/

The many different PCB compounds vary substantially in their molecular composition, which affects directly their differing environmental characteristics. The number of chlorine atoms in each molecule affects directly the ability of organisms to metabolize the material. Molecules with only a few chlorine atoms (e.g., -mono, di- and trichlorobiphenyl, also referred to as mono- and di- and tri-BP) have been found to be metabolized rapidly, with the rate of metabolism a function of the chlorine content of the molecule. (EIA Exh. G at p. 4 [Mueller]) The following table, taken from the Criteria Document, gives the molecular composition of some of the Aroclor mixtures produced by Monsanto, as reported variously in three different studies. It reflects the very substantial differences between Aroclor 1016 and such highly chlorinated Aroclors such as A.1254 and

*/ See Appendix One to this brief, which outlines the evidence presented by the Agency. This demonstrates that the vast bulk of the scientific evidence pertaining to PCBs is wholly irrelevant to Aroclor 1016.

A.1260, which are composed almost entirely of penta-, hexa- and hepta-BP molecules that are metabolized so slowly as to pose problems of persistence.

Approximate Molecular Composition of Several Aroclors

lorobiphenyl	1221		1232	1016	1242			1248	1254			1260
	[1]	[2]	[2]	[1]	[1]	[2]	[3]	[2]	[1]	[2]	[3]	[2]
$C_{12}H_{10}$	11	7	6	Tr	Tr	-	-	-	Tr	-	-	-
$C_{12}H_9Cl_1$	51	51	26	1	1	1	Tr	-	Tr	-	-	-
$C_{12}H_8Cl_2$	32	38	29	20	16	17	4	1	0.5	-	-	-
$C_{12}H_7Cl_3$	4	3	24	57	49	40	39	23	1	-	0.5	-
$C_{12}H_6Cl_4$	2	-	15	21	25	32	42	50	21	16	36	-
$C_{12}H_5Cl_5$	0.5	-	0.5	1	8	10	14	20	48	60	45	12
$C_{12}H_4Cl_6$	-	-	-	Tr	1	0.5	-	1	23	23	18	46
$C_{12}H_3Cl_7$	-	-	-	-	Tr	-	-	-	6	1	1	35
$C_{12}H_2Cl_8$	-	-	-	-	-	-	-	-	-	-	-	6
$C_{12}H_1Cl_9$	-	-	-	-	-	-	-	-	-	-	-	-
$C_{12}Cl_{10}$	-	-	-	-	-	-	-	-	-	-	-	-

Tr - Trace (less than 0.1 percent)

[1] Data from Criteria Document Ref. 13

[2] Data from Criteria Document Ref. 14

[3] Data from Criteria Document Ref. 15

Source: EPA Criteria Document Table II.3.1

Aroclor 1016 contains so few of the highly chlorinated molecules that the other materials have in high degree that its biological implications are entirely different from those of the materials which are no longer used--but from which the Agency has attempted to analogize to establish a basis for regulation of Aroclor 1016.*/ Aroclor 1016 contains only 1 percent pentachloro BP and a trace of hexachloro-BP; 99 percent of Aroclor 1016 consists of mono-, di-, tri- and tetrachloro-BP, which have been found to be rapidly metabolized and show little accumulation tendencies. (EIA Exh. D at 6-7 [Lauer]; EIA Exh. G at 6 [Mueller])**/

It is no accident that Aroclor 1016 is virtually the only type of PCB in use today. In 1972 the capacitor industry converted to use of Aroclor 1016 due to its environmental concern that more highly chlorinated varieties of PCB, being less biodegradable than Aroclor 1016, might pose unacceptable risks through their persistence in the environ-

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*/ Strikingly, of all the Aroclors examined, A.1016 alone has been found to contain no detectable dibenzofurans which are impurities found in other PCB mixtures and which are themselves toxic. (EIA Exh. D at p. 7 [Lauer]; See also Criteria Document at p. 37).

**/ See also EPA Criteria Document at 277 and References 2 and 332. Doctor Nisbet, the author both of the Criteria Document and the references cited above, in a 1976 oral presentation before the National Conference on Polychlorinated Biphenyls (cited as Reference 332 to the Criteria Document) stated "I think that we have had very adequate evidence here that tetrachloro isomers are indeed degraded rather rapidly, but not as rapidly as we would like." See also Criteria Document, page 305. The record establishes that mono-, di-, tri- and tetra-BPs are all degradable, at varying speeds.

ment. (Tr. 2191-2192; 2293-2294; EIA Exh. C at 4 [Clark]) Aroclor 1016 was developed by Monsanto to respond to these concerns and at the same time provide the needed quality of fire resistance required for use in capacitors. (EIA Exh. C at 4-5)

In 1973 the Agency attempted to regulate PCBs. Then, as now, it was apparent that the Agency's evidence concerning the toxic effects of Aroclors such as A.1248, A.1254 or A.1260 was irrelevant to the regulation of Aroclor 1016.*/ The Agency has commissioned several studies concerning Aroclor 1242 and a single study on Aroclor 1016 and has sought again to regulate Aroclor 1016 based on this slightly expanded data base. But now, as before, the alleged "conclusive" evidence of the toxicity of PCBs relates <u>only</u> to such highly chlorinated mixtures as A.1254 and A.1260, while the evidence concerning Aroclor 1016 is ambiguous and inconclusive.**/

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*/ In its Notice of Proposed Rulemaking, the Agency acknowledged that its earlier PCB regulatory efforts failed due to "certain gaps in the data base." (41 Fed. Reg. 30469) The Agency did not acknowledge that this "gap" turned on the critical differences betweeen Aroclor 1016 and other PCBs, differences which the Agency is again undertaking to ignore in favor of sweeping generalizations about "PCBs."

**/ The additional studies commissioned by the Agency added nothing to the data base on which to regulate Aroclor 1016. The <u>only</u> evidence pertaining to Aroclor 1016 in the record is a study by Dr. Ringer involving mink which produced no statistically significant toxic effects at low dose levels. <u>See</u> discussion <u>infra.</u>, pp. 45-47. The sole basis offered for regulating Aroclor 1016 is an analogy between it and Aroclor 1242, drawn by a single witness without any credentials in the field of organic chemistry. <u>See</u> page 43, <u>infra</u>. The record thus reflects few (if any) improvements over the data base found to be inadequate in 1974.

C. The Need for Aroclor 1016 in Capacitor Manufacturing

Polychlorinated biphenyls have been used for capacitor impregnating fluids since the 1930s. Capacitors are a type of electrical instrument used in a wide variety of industrial and consumer applications. A capacitor (speaking most generally) is composed of a metal container with a paper and foil core,*/ impregnated with an oil (called a dielectric fluid) which permits the retention of an electrical charge until needed for use. The higher the so-called dielectric constant of the fluid, the greater the charge which can be held. The industry first used mineral oil as an impregnant, which was both flammable and had a low dielectric constant thus requiring the use of relatively large capacitors to hold a suitable charge. (Tr. 2140-2141) After the introduction of PCB as an impregnant some forty years ago, the capacitor industry was able substantially to reduce the size of capacitors with a corresponding reduction in cost.**/ (Tr. 2141; EIA Exh. B at 2 [Hutzler])

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*/ Some capacitors also use a type of polypropylene film in the core--although only a few of the film-type capacitors also use an impregnant such as Aroclor 1016. (See EIA Exh. B at 8-9 [Hutzler])

**/ While PCB was much more expensive than mineral oil, that did not affect the cost of the capacitor itself, since the largest costs of capacitor construction were for the paper and foil. Thus as more efficient capacitors were developed and the size of capacitors decreased, so did their overall cost. See Tr. 2141.

Capacitors for alternating current applications are now in universal use in this country. AC capacitors include large capacitors known as power faction correction capacitors used by utilities companies efficiently to transmit electricity. Smaller types of power faction correction capacitors are also used by industry for similar purposes. AC capacitors are used in most lighting applications, ranging from mercury vapor lighting, high intensity discharge lighting and fluorescent lights. Finally, the so-called "small industrial" capacitors are used in a variety of motor-run operations--perhaps the most familiar being in the motors of home air conditioners. (EIA Exh. C at 1-3) At present, the vast majority of these AC capacitors contain PCB--and virtually all manufactured in the last four years contain Aroclor 1016. (Id. at 4)

For over thirty years the capacitor industry has conducted rigorous research and development in an attempt to locate a substitute for PCB as a dielectric fluid. (EIA Exh. B at 3) These efforts have proven unavailing. (Id.) After these many years of R & D, no known direct replacement for Aroclor 1016 exists. All suitable replacements present serious risks of flammability. (See generally EIA Exh. B at 5 and Exhibit B thereto) In use, such a flammable material can be ignited in the event of a short circuit in the capacitor, causing rupture of the case and release of the dielectric fluid. The electrical arc present will then spark the fluid and fire will result. (Tr. 2161-2164) Tests conducted by the Underwriters Laboratory establish that the non-PCB substitutes will all ignite under these conditions, presenting the risk of catastrophic fire. (See Tr. 2179-2182; 2236-2237)*/

The EPA's Notice of Proposed Rulemaking acknowleged the "unique physical and chemical properties of PCBs" which were said to include:

> low vapor pressure at ambient temperatures, resistance to combustion, remarkable chemical stability, high dielectric constant and high specific electrical resistivity . . .. 41 Fed. Reg. 30468

Unhappily, the same reasons PCB persist in the environment make them uniquely suited to serve as a dielectric fluid; the chlorine atoms provide strong chemical bonds, which are resistant to degradation (either in capacitors or in the environment), and provide stability in use in capacitors thus protecting against the dangers of fire

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*/ One observer at these tests described the "blowtorch" type fire which spurted from the ruptured capacitor case when the non-PCB material ignited. (Tr. 2237)

which are always present when utilizing electrical current. (Tr. 2139) Aroclor 1016 was developed to balance these competing concerns.

ARGUMENT

I

THE PROPOSED BAN ON PCBs UNDER THE FEDERAL WATER POLLUTION CONTROL ACT SHOULD NOT BE ADOPTED

A. The Toxic Substances Control Act Provides a Congressional Ban of PCBs Which Should Not Be By-Passed By Regulation Under the Water Pollution Control Act

The Toxic Substances Control Act, Pub.L. 94-469, 80 Stat. 2003, 15 U.S.C. §2601 et seq., signed into law on October 11, 1976, is a comprehensive statutory scheme for the regulation of virtually all chemicals (with certain enumerated exceptions). It was passed pursuant to the stated congressional policy that "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment . . . ." 15 U.S.C. §2601(b)(2). One type of chemical is singled out for individual treatment under the Act--polychlorinated biphenyls. Section 6(e) of the Act, 15 U.S.C. §2605(e), provides a detailed schedule for the phase-out of all PCB use in this country, subject only to the grant of special exemption by the Administrator.*/ The regulation of PCBs provided under TSCA is complete; it does not anticipate duplicative and ultimately inconsistent regulation in the same area by the Administrator pursuant to the authority previously granted under the Federal Water Pollution Control Act.

One year after the effective date of the Toxic Substances Control Act (by January 1, 1978), all PCB use is forbidden "other than in a totally enclosed manner." 15 U.S.C. §2605(e)(2)(A). One year later, by January 1, 1979, the Act provides "no person may manufacture any polychlorinated biphenyl." Six months later, by July 1, 1979, "no person may process or distribute in commerce any polychlorinated biphenyl," subject only to the grant of exemptions by the Administrator. 15 U.S.C. §2605(e)(3)(A).

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*/ 15 U.S.C. §2605(e)(3)(b) provides that the Administrator may grant an exemption from the requirements of the Act, if he finds "(i) an unreasonable risk of injury to health or 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."

The legislative history of TSCA reflects the unambiguous congressional intent to preempt fully the area of PCB regulation. The Toxic Substances Control Act's PCB ban was passed after the Agency's Notice of Proposed Rule-making was promulgated, and indeed was passed only after the commencement of the hearing in this proceeding. Congress was fully aware of the Agency's actions under §307(a) of the FWPCA, and chose to supplant regulation under that statute with the comprehensive scheme of regulation contained in the 1976 Act.

Despite differences between the House and Senate versions of the TSCA (which required extensive conference revisions), both bills contained virtually identical provisions banning PCBs. Senator Nelson, who introduced the amendment to the Senate bill which banned PCBs, explained his dissatisfaction with the regulatory efforts of the EPA and the need for comprehensive congressional regulation of the material--stating his view that Congress should "no longer wait to regulate and eliminate this toxic substance." 122 Cong. Rec. S 4408 (daily ed., March 26, 1976) Senator Nelson emphasized that his amendment to the bill was the most desirable method of regulating PCBs, because "[u]nder this amendment, the continued use of PCBs would be allowed if the EPA Administrator finds that 'no unreasonable risk of injury to health or the environment' exists,"*/ and further because "[t]his amendment would allow time for the phasing out of the manufacture and use of PCB's over 2-1/2 years." (Id.) Senator Tunney, one of the original sponsors of the bill, endorsed Nelson's amendment:

> "In my view, the amendment of the Senator from Wisconsin is indeed appropriate. It phases out PCB's by eliminating nonclosed system uses within 1 year and eliminating PCB's altogether within 2 years. There are mechanisms for authorizing uses of PCB's beyond these time limits should that be appropriate so that we do not create worse problems than those we solve." 122 Cong. Rec. S4410 (daily ed., March 26, 1976)

Some months later, the House adopted an amendment to its version of the TSCA banning PCBs. Strikingly, the House took this action only after promulgation of the Agency's Notice of Proposed Rulemaking under the Water Pollution Control Act. Congressional debate on the amendment reflects express intent on the part of the House to substitute its regulatory scheme banning PCBs for the program proposed by the Agency. Congressman Dingell, who introduced the amendment on August 23, 1976, emphasized

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*/ Senator Nelson noted that "[i]n making such a finding, it is implicit that consideration be given to the availability of substitutes for PCBs, presumably having less risk." (Id.)

that regulating PCBs under the Toxic Substances Control Act would fill a gap in the FWPCA and would provide the best solution to the problem:

> 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.
>
> As previously noted, the history of EPA is not one of vigorous and quick action.
>
> This amendment defines PCB's to be bad, hazardous, and dangerous, and it mandates a program for their gradual removal, beginning with those uses which are outside of enclosed containers. 122 Cong. Rec. H 8829 (daily ed., August 23, 1976)

The Congressional Record reflects vigorous debate over the merits of Congressman Dingell's proposal (which he co-sponsored with Congressman Gude). Among the criticism leveled at the proposed 2-1/2 year ban on PCBs were:

(i) "the EPA may feel that the 2-1/2 years the gentleman from Michigan (Mr. Dingell) suggests is too long and that more immediate action might be necessary;"

(ii) that "[t]he Dingell amendment could in this case actually slow down the regulatory process;"

(iii) that "there is no need for the amendment, since the EPA has indicated a willingness to proceed expeditiously in this area;"

(iv) and that "the agency may set up regulations in which the treatment of PCB's is specifically dealt with in a different way than the present pattern of control may ultimately seem the most desirable. Why carve

> out one chemical to treat in this manner? There are many other chemicals that presently pose potential danger. I think that we would be well advised to let the agency chart its own course in the same manner that we have let other agencies with like authority chart their courses, and not foist upon a preconceived manner of control before we find whether they will in due course address the question." (See 122 Cong. Rec. H 8830-31) (daily ed., Aug. 23, 1976)

Congressman Leggett responded to these criticisms:

> "The flexibility of the Dingell-Gude amendment is shown by its exemption provisions, which recognize that some uses of PCB's outweigh safety considerations . . ." Cong. Rec. H 8832 (daily ed., Aug. 23, 1976)

Congressman Leggett supported the PCB ban because in light of the importance of mandating a final solution to the problem posed by PCBs,

> "[t]he Dingell-Gude amendment will give us a program immediately, setting the mandatory deadline for a phase-out of PCB's." 122 Cong. Rec. H 8832 (daily ed., Aug. 23, 1976)

Congressman Murphy, one of the draftsmen of the bill in committee, also endorsed the amendment:

> "True, the substances are necessary at the present time for use in capacitors and transformers. We have heard the debate on what the Japanese have done and what they have been forced to do because of the effects on their environment.
>
> This amendment seems reasonable. It gives at least 2 years to the industry to come up with substances other than PCB's. I think 2-1/2 years is certainly a reasonable compromise and warning to the industry. The EPA Administrator is given the

> flexibility to extend, if necessary, that period of time . . ..
>
> Mr. Chairman, I hope we adopt this amendment." 122 Cong. Rec. H 8833 (daily ed., Aug. 23, 1976)

This review of the legislative history of the PCB ban contained in the Toxic Substances Control Act demonstrates both that Congress intentionally undertook to pass comprehensive legislation on the subject, and that after considering the reasons for a phased withdrawal of PCB use, Congress deliberately elected to establish a two and one-half year time frame in which to permit continued use of PCB in capacitors and transformers.

The debate in the House over the proposal was quite unambiguous about the relationship between the ban under consideration and the Agency's regulation of PCBs under the Water Pollution Control Act. Despite claims that a fixed schedule of regulation imposed by Congress affected the Agency's freedom to act, Congress chose to adopt a specific and comprehensive program of PCB regulation which permits no interference by the EPA--and which certainly does not permit the Agency effectively to ban the material prematurely, under the guise of regulating discharges. The Toxic Substances Control Act precludes regulation under the FWPCA--for the TSCA timetable for termination of PCB use renders discharge regulations a nullity. The very limited period of time permitted under TSCA for continued PCB use makes installation of treatment facilities economically irrational. The two statutory regimes are ultimately inconsistent. In such circumstances the carefully prescribed congressional program of PCB control preempts the Agency's discretionary authority under the Water Pollution Control Act.*/

B. National Effluent Discharge Limitations for Aroclor 1016 Represent an Abuse of Discretion under the Water Pollution Control Act

Section 307 of the Federal Water Pollution Control Act requires that the Administrator, in setting discharge standards, take into account "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any waters, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms . . . ." 33 U.S.C. §1316(a)(2). The unrebutted evidence in the record

*/ While 15 U.S.C. §2605(e)(5) provides that the TSCA's PCB ban "does not limit the authority of the Administrator, under any other provision of this Act or any other Federal law, to take action respecting any polychlorinated biphenyl," (emphasis supplied) this ambiguous provision cannot be construed to permit the Administrator to take action inconsistent with the regulatory program prescribed by the Act. At most this provision relates to the preemption standards of Section 9 of the Act, which require the Administrator to "coordinate" all regulatory actions he might take under the statutes he is charged with administering. Such "coordination" cannot be construed to permit the Administrator to frustrate TSCA's regulatory scheme.

It is noteworthy that the voluminous record in this proceeding will continue to be useful, notwithstanding the fact it may not be used to promulgate discharge regulations. The Administrator may wish to rely in part on the record in promulgating the standards required under TSCA for disposal and labeling of PCBs (see 15 U.S.C. §2605(e)(1)) and may refer to the record in determining whether exemptions should be granted pursuant to 15 U.S.C. §2605(e)(3).

in this proceeding establishes that each of these factors may only be evaluated based on varying local conditions. The effects of a pollutant in a water body depend on the specific chemical, hydrological and ecological characteristics of the water body into which the pollutant is being discharged. Dr. Gerald Lauer, an aquatic biologist with long experience both with the U.S. Public Health Service and as a private consultant, testified that no national effluent standard for a pollutant such as Aroclor 1016 can properly take into account local conditions:

> "The toxicity of toxicants such as PCBs varies from species to species and for different life stages of the same species, and depends on a host of variables including the chemical constituents and quality of the receiving water, the duration of exposure, the fate and physical-chemical state of the pollutant in the receiving water, the prior health of the exposed organisms, presence of other pollutants, previous history of exposure, etc." (EIA Exh. D at 2 [Lauer])

The need for such local regulation was also emphasized by one of the Agency's own witnesses, Dr. William Brungs, who testified that local conditions vary greatly in the dispersion effects of a pollutant in a mixing zone, and that it is thus difficult to assess the environmental implications of a given discharge by means of a national effluent standard. (See EPA Exh. U at 4 [Brungs]) It is for this reason that the National Academy of Sciences and the National Academy of Engineering, when advising EPA as to how to establish regulatory controls for the protection of aquatic ecosystems, emphasized the need to regulate based on differing "local conditions":

> "This caveat cannot be overemphasized, because variabilities are encountered in different parts of the country. Specific local recommendations can be developed now in many instances, and more will be developed as experience grows."*/

The record contains no specific information concerning the bodies of water into which the capacitor and transformer plants affected by the proposed regulation discharge. These include plants in at least seven states, and discharges into at least ten different bodies of water.**/ The Agency has failed to present any evidence concerning the "local conditions" affecting the environmental implications of these discharges. The record thus provides no basis for regulating the discharges of these plants--as

*/ Water Quality Criteria 1972, a Report of the Committee on Water Quality Criteria, 10 (1972). This EPA publication is plainly part of the Agency's body of specialized expertise, and is thus subject to notice pursuant to 40 C.F.R. §164.81(e).

**/ The EPA's economic impact assessment lists eleven capacitor and transformer plants which would be affected by the regulations. See EPA Exh. 16 at 1-3) Inexplicably, this assessment ignored Universal Manufacturing's Bridgeport plant, which is a direct discharger into the Bridgeport sewer system and ultimately into Long Island Sound (Tr. 2209) and also eliminated one other plant from consideration. (Tr. 118-119 of Hearing of November 30, 1976) the national effluent standards proposed are without adequate scientific foundation and thus improper as a matter of law.

II.

AN END-OF-PIPE LIMITATION OF 100 PPB FOR AROCLOR 1016 WILL PROVIDE AN ADEQUATE MARGIN OF SAFETY TO THE ENVIRONMENT

The Agency's proposed discharge regulations fail to distinguish among the various PCB mixtures, despite the overwhelming evidence that PCBs differ very substantially in their toxicity and persistence. See discussion pages 8-10, supra. The proposed regulations contain a single all-encompassing 1 ppb discharge standard applicable to all PCBs. (See also Tr. 1881) There is no scientific basis for this attempt to regulate all PCBs as if they were a single chemical.

Aroclor 1016 consists almost exclusively of lower-chlorinated homologs. It is far less persistent and is rapidly metabolized by predators. The record establishes conclusively that Aroclor 1016 bioaccumulates to a much lesser extent than the more-highly chlorinated mixtures. (EIA Exh. D at 6-7 [Lauer]; EIA Exh. G at 6 [Mueller]) Accordingly, an end-of-pipe limitation of 100 ppb for Aroclor 1016 was established during the course of the hearing to be completely safe to the environment.

This conclusion is based on the following five factors, each of which will be discussed in greater detail below:

1. The ambient concentration for Aroclor 1016 will be at least one thousand fold less than the end-of-pipe

concentration as a result of the dispersion and dilution of the outfall. Therefore, a 100 ppb end-of-pipe limitation for PCBs will produce an ambient concentration of 100 ppt.

2. Aroclor 1016 does not have any toxic effects on aquatic animals even at levels greatly in excess of 100 ppt. The great weight of the evidence demonstrates no adverse effects at levels approaching 100 ppb. Thus, a 100 ppb discharge limit for Aroclor 1016 would pose no threat whatever to aquatic organisms.

3. Aroclor 1016 in the ambient water will bioaccumulate in the lipid tissues of aquatic organisms by a factor not greater than 50,000. This figure is substantially lower than the bioaccumulation factor of 274,000 upon which the proposed regulations were based, which was derived for PCBs generally and which was shown to be lacking in any scientific basis.

4. Fish having a lipid concentration below 15 ppm of Aroclor 1016 will not have any adverse effects on regular consumers. A discharge limitation of 100 ppb will permit an accumulation of Aroclor 1016 in fish tissue of no more than 5 ppm and will be entirely safe for all fish consumers -- animal or human. Indeed, with regard to humans, no evidence exists that <u>any</u> level of Aroclor 1016 in the fish portion of the human diet would be injurious to human health.

5. An end-of-pipe limitation of 100 ppb for Aroclor 1016 based upon the factors just discussed will provide "an ample margin of safety" to the environment. Adoption of a lower standard for Aroclor 1016 would be unjustified.

A. Ambient Concentrations of Aroclor 1016 Will Be 1000-Fold Smaller Than The End-Of-Pipe Concentration.

It is impossible to establish meaningful ambient standards for Aroclor 1016 or any other PCB in this proceeding. The vast bulk of the PCB used in the past, which persists in the environment, will not be subject to the proposed regulation. The capacitor and transformer industries which are subject to the proposed discharge regulations account for only a relatively trivial amount of PCB discharged currently into the environment. (See 41 Fed. Reg. 30469) Recognizing that the proposed regulations will touch on only a minor fraction of the PCBs discharged currently, the Agency has focused its regulations on establishing a 1 ppb discharge limitation.

In evaluating such discharge regulations, it is necessary to take into account the substantial dispersion that occurs immediately following discharge. In determining the potential toxic effects of such a discharge, it is necessary to calculate this dispersal effect. The Agency's proposed discharge regulations are premised on the fact that "effluent disperses following discharge and becomes greatly diluted." 41 Fed. Reg. at 30474 The Agency's 1 ppb discharge regulation was thus calculated as producing an ambient standard of 1 ppt, inasmuch as dispersion and dilution "can result in a dispersion or dilution of the effluent of 1000-fold or more depending [on the discharge site]." (EPA Exh. G [Callaway] at 3.) Based on this same dispersal factor of at least 1000, a 100 ppb discharge limitation for Aroclor 1016 will produce concentrations of Aroclor 1016 in ambient waters of not less than 100 ppt. It is on this basis that the discharge level should be evaluated.

There is no dispute that the existence of a mixing zone, in which dispersion occurs and which would be the only area where levels of Aroclor 1016 would be greater than 100 ppt if a 100 ppb discharge limit is adopted, poses no risk of harm. Exposures of aquatic organisms in such a mixing zone are not of sufficient duration to cause either chronic or acute effects in aquatic organisms. 41 Fed. Reg. at 30475 This is all the more true for Aroclor 1016, which has virtually no acute toxic effects at levels below the proposed discharge limitation. (<u>See</u> pp. 31-32 <u>infra</u>.) By the same token, chronic effects for Aroclor 1016 have only been demonstrated at concentration levels slightly below the proposed discharge limitation. (<u>See</u> pp. 32-33 <u>infra</u>.)

A discharge limitation for Aroclor 1016 of 100 ppb will produce a concentration in the ambient water of 100 ppt, and any toxic effects of Aroclor 1016 must be evaluated accordingly. The record establishes that such an ambient standard poses no threat to the environment.

B. Aroclor 1016 Has Not Been Shown To Have Any Toxic Effects on Aquatic Animals Except At Levels Greatly In Excess Of The Proposed Ambient Criterion Of 100 PPT.

Considerable testimony*/ and documentary evidence has been introduced on the toxic effects of PCB mixtures generally on aquatic animals. However, there is no evidence that Aroclor 1016 produces any adverse effects, except at levels greatly in excess of the 100 ppt ambient criterion proposed by the EIA.

Virtually all of the data on the toxic effects of PCBs comes from laboratory bioassay experiments. Generally speaking, these bioassay experiments are divided into two general groups. The first group consists of acute (generally static) bioassays conducted for periods of approximately 96 hours. As the Criteria Document recognized, "PCBs do not appear very toxic in short-term static bioassasys. . . ." (EPA Exh. 2 at 114 and 119)**/ The acute bioassays conducted

*/ In the area of toxic effects on aquatic organisms the principal witness for the EIA was Dr. Gerald J. Lauer. The principal witnesses for the EPA were Drs. Allan V. Nebeker, Gilman D. Veith and David J. Hansen.

**/ Dr. Nebeker used these data as a basis for asserting that the toxicity of PCBs to fish was inversely related to chlorination. (EPA Exh. C at 8 [Nebeker]) The reliability of the data, however, are questionable because the concentrations employed for all of the Aroclors tested greatly exceeded their solubility in water. (EIA Exh. D at 10-11 [Lauer]; see also EPA Exh. 2 at 50 for the reported solubilities of the various Aroclor mixtures) Moreover, most of the recent data from chronic testing indicates a reverse pattern of increasing toxicity with increasing percentage of chlorine. (EIA Exh. D at 11 [Lauer] and attached References 3 and 6) with Aroclor 1016 produced data which showed significant short-term toxic effects only at levels some two to three orders of magnitude above the ambient criterion being proposed by the EIA. These bioassays produced 96-hour LC_{50} values,*/ for example, of from 48 to 650 ppb for blue gills, 750 ppb for channel catfish, 135 ppb for rainbow trout, 135 ppb for Atlantic salmon and 185 ppb for yellow perch. (EPA Exh. 2 at 119; see also EPA Exh. 12)

The second type of bioassay experiment, the continuous flow bioassay, is conducted for considerably longer periods. In some experiments, the exposure time exceeds the generation time of the organism. Chronic toxicity data from these experiments "indicate that most species tested tolerate low part per billion (ug/l) concentrations in the water with no apparent adverse effects on survival, growth

*/ The data produced by these studies is given in terms of LC_{50} values (the PCB level at which fifty percent mortality occurs) for a given length of time, usually 96 hours.

or reproduction."*/ (EIA Exh. D at 11 [Lauer]) Quantitatively, these experiments indicate that Aroclor 1016 ranges from slightly less toxic to one hundred times less toxic than the more highly chlorinated Aroclors such as Aroclor 1254. (Id. at 14) The chronic exposure data of Aroclor 1016 shows no adverse effects at levels below approximately 10 ppb. In fact, for most of the organisms tested, adverse effects were demonstrated only at levels substantially above 10 ppb. In a 42-day exposure study of pinfish, no significant mortality was found at a measured concentration of 7 ppb. (EPA Exh. D at attached exhibit 7, p. 367.) No effects on reproduction occurred when sheepshead minnows were exposed to Aroclor 1016 at levels of from 0.3 to 3.0 ppb. (EPA Exh. 2 at 122) Exposures of rainbow trout for seventeen days produced an LC_{50} value of 40 ppb while a 35 day exposure of bluegills produced an LC_{50} value of 43 ppb. (Id. at 120)

It is apparent therefore that Aroclor 1016 has toxic effects only at levels that are between two and three orders of magnitude above the EIA's proposed ambient criterion of 100 ppt.

*/ The Criteria Formulation chapter of the Criteria Document, on page 355, does rely upon three low-level toxic effects of PCBs as a basis, in part, for the proposed ambient criterion. Each of these effects was exhibited in studies involving the effects of Aroclor 1254. (Tr. 1861-63, EPA Exh. 2 at 102, 108, 114)

C. Aroclor 1016 Will Bioaccumulate In Aquatic Organisms By A Factor Not Greater Than 50,000

In evaluating the environmental effects of Aroclor 1016 on non-aquatic organisms, it is necessary to consider the ability of aquatic organisms to uptake the mixture from the environment and accumulate that mixture in their tissues. (EPA Exh. 2 at 283) It is in this manner that Aroclor 1016 might present risks to fish-eating mammals and other predators.*/

PCBs have a tendency to accumulate in the lipid (or fat) tissue of aquatic invertebrates and fish**/ because PCBs are much more highly soluable in lipid tissue than they are in water. (Ibid.) This tendency has been referred to variously and interchangeably in these proceedings as "bio-accumulation," "bioconcentration," and (to a lesser extent), "biomagnification." (Compare, e.g., EPA Exh. 2 at 283, EIA Exh. D at 14 [Lauer] (bioaccumulation) with EPA Exh. 2 at 296, EIA Exh. D at 13 (bioconcentration) and EPA Exh. 2 at 285, EIA Exh. D at 8 (biomagnification).) Aroclors bioaccumulate in fish tissue in direct proportion to their concentration in the ambient water. A ratio can be established

*/ No evidence was adduced during these proceedings as to the uptake, accumulation or toxic effects of PCBs by or upon plants. Our discussion, therefore, is limited to animal life.

**/ It should be noted that PCBs do not accumulate to the same degree in all tissues of an aquatic organism due to this tendency to accumulate only in specific organs. Dr. Nisbet testified, for example, that three times as much PCB accumulated in whole fish as accumulated in the edible portion of the fish. (Tr. 1754; see also EIA Exh. D at 13-14 [Lauer]) once equilibrium is reached ("the bioaccumulation factor") that relates the mixture's concentration in the organism to that of the surrounding water. That ratio will be relatively constant for a given organism and mixture over a wide range of PCB-water concentrations. (EIA Exh. D at 8 [Lauer])

A bioaccumulation factor of 50,000 for Aroclor 1016 was the highest accumulation value found in the laboratory bioassay experiments of Mr. Hansen and Dr. Veith for the Agency. Dr. Gerald Lauer, who reviewed the record in this proceeding carefully outlined these data in Exhibit E to his Affidavit (See EIA Exh. D at 9 [Lauer] and Exhibit E thereto) The laboratory bioassay results introduced into evidence support no higher bioaccumulation factor. Although the average of the bioaccumulation factors for Aroclor 1016 produced by these studies would be substantially lower than 50,000, this 50,000 figure provides the highest (and thus the most conservative) bioaccumulation ratio produced by an experiment.*/

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*/ The average of bioaccumulation factors found for Aroclor 1016 is only 14,225 (See EIA Exh. D at 13). This factor has a sound scientific basis, but for the sake of providing an "ample margin of safety," we will accept the 50,000 figure as appropriate for Aroclor 1016 for purposes of this proceeding.

The 50,000 bioaccumulation factor for Aroclor 1016 was taken from a bioassay study by Dr. Gilman Veith.*/ See EPA Exh. B at 24. In his testimony, Dr. Veith calculated the 50,000 factor based upon a ratio between the level of Aroclor 1016 found in the fish studied and the concentration of Aroclor 1016 actually injected into the water (called the "nominal water concentration"). (EPA Exh. B at attached exhibit 19)

Dr. Gerald Lauer explained in response to questions by EPA counsel, that it was mathematically possible to calculate a bioaccumulation factor using the fish tissue concentration and the actual measured concentration of Aroclor 1016 found in the water after the experiment was concluded (called the "measured water concentration"). However, Dr. Lauer did not recommend that calculating a bioaccumulation factor for Aroclor 1016, due to the unreliability of the measured water concentration data. (Tr. 2523-25, 2392, 2415-16) The studies giving measured water concentrations acknowledged only an 80 percent recovery of Aroclor 1016 in the water was obtained -- and in some cases, even lower recoveries were accomplished. (See Tr. 2416-18) Due to uncertainties over the accuracy of the measured water concentrations

*/ Veith, Gilman D. and L. Kiwus. 1975. Uptake of Aroclor 1016 by fish. I. Laboratory bioaccumulation studies with fathead minnows. Unpublished report, U.S. Environmental Protection Agency, Environmental Research Laboratory, Duluth, Minn. (cited at Reference 338 in EPA Criteria Document) at page 295.

Dr. Lauer testified he believed the nominal water concentration data should be used. (Tr. 2392)*/ This testimony stands unrebutted.

Rather than presenting bioaccumulation factors for each of the different Aroclors, the Agency chose to adopt a single bioaccumulation factor for PCBs generally -- 274,000. This figure was shown to be most unreliable in itself: it is based on a single experiment with four fathead minnows which produced patently anomalous test results of 477,000 for Aroclor 1242. Such data would normally be disregarded since they bear no relationship to any other test conducted (See EIA Exh. D at 10), and indeed were anomalous within the experiment, since the other two minnows in the experiment showed much lower accumulation. (Tr. 4162-67)

*/ Dr. Lauer also gave other reasons he rejected use of the measured concentration data: 1) measured concentrations were not given in many instances (Tr. 2418 [Lauer]) and therefore the use of measured concentrations would result in the exclusion of the numerous observations where only nominal concentrations are available; and 2) even where measured figures are given, in many cases no information is available as to analytical procedures and efficiencies of recovery and therefore no correction factor could be applied to the measured concentrations to account for differences in analytical procedures and extraction efficiencies (Tr. 2392, 2416 [Lauer]). Strikingly, the authors of most of the Agency's bioaccumulation studies used nominal concentrations which they considered a useful and valid procedure. (Tr. 2421 [Lauer])

But even if the unusually high 274,000 factor had some relevance for the Aroclor involved in that experiment, it is plain that Aroclor 1016 would be expected to have a substantially lower bioaccumulation tendency since 99 percent of Aroclor 1016 is composed of rapidly metabolized homologs. See discussion pages 8-10, supra; EPA Exh. B [Veith] at 24; EPA Exh. M [Nisbet] at 8; EIA Exh. D [Lauer] at 10; Tr. 586, see also EIA Exh. G [Mueller] at 3-4. Each Aroclor persists in direct relationship to the degree of chlorination of the mixture and the type of chlorine molecules involved; and Aroclor 1016 would have entirely different persistence characteristics than any other PCB mixture for which bioaccumulation data was presented. The record is plain that Aroclor 1242 and 1016 have quite different bioaccumulation tendencies.

Although there is some surface similarity in the overall chlorine contents of Aroclor 1016 and Aroclor 1242 (41 and 42 percent respectively, See Criteria Document, Table II.2.2, page 8), the similarity ends when the actual chemical compositions of the two mixtures are considered. Because "1242 has approximately 30 percent more tetra-CBs and 10 times more penta- and higher CBs . . ." than Aroclor 1016, "more of the Aroclor 1242 would be expected to persist and be bioaccumulated than Aroclor 1016." (EIA

Exh. D [Lauer] at 10; <u>see</u> <u>also</u> EIA Exh. G [Mueller] at 3-4.) There is no scientific basis to excuse the Agency's failure to take into account this undeniable difference between the two Aroclors in arriving at appropriate bioaccumulation factors by which to evaluate appropriate discharge criteria.

D. Aroclor 1016 has Not Been Shown To Have Any Toxic Effects on Consumers of Aquatic Organisms At A Dietary Level Below 15 ppm.

Just as there was no evidence that Aroclor 1016 could have any toxic effects on aquatic organisms at levels below 100 ppt, there is no evidence that this concentration of Aroclor 1016 would pose any hazard to fish consumers. Assuming a bioaccumulation factor of 50,000, a 100 ppb discharge limitation on Aroclor 1016 would produce maximum levels of Aroclor 1016 in fish tissues of 5 ppm. (EIA Exh. D. at 13) This level is entirely safe for all fish consumers.

The EPA's evidence concerning the alleged risks of Aroclor 1016 to predators is marked throughout by two basic flaws. The first is its failure or inability to demonstrate that the toxicological effects exhibited by other PCB mixtures may be used to assess the toxicity of Aroclor 1016. Indeed, the substantial evidence in the record establishes conclusively that Aroclor 1016, because it consists almost exclusively of lower chlorinated PCB isomers, has few if any of the toxic effects found to result from the more highly chlorinated Aroclor mixtures. Second, the EPA has failed to develop specific 1016 studies.*/ Only one study -- that conducted by Dr. Robert K. Ringer on mink -- even

*/ The absence of studies conducted on Aroclor 1016 is aptly illustrated in the Criteria Document. In the concluding chapter of the Criteria Document (page 356) there is a list of the specific adverse effects which EPA used as a basis for the proposed ambient criterion together with the levels of PCB in the diet at which these effects are exhibited. None of these effects are based upon studies that were conducted with Aroclor 1016.

arguably demonstrates adverse effects by Aroclor 1016 at levels below 15 ppm in the diet, and that study was shown to have produced wholly insignificant test results.

1. <u>The Results of Studies On More Highly Chlorinated PCB Mixtures May Not Be Applied to Aroclor 1016</u>

Almost all of the evidence allegedly demonstrating adverse effects to mammals from low level doses of PCB resulted from studies on PCB mixtures other than Aroclor 1016. The Agency has based its proposed regulation of Aroclor 1016 discharges almost entirely on the supposed analogy between Aroclor 1016 and the other PCB compounds studied. Thus, although the few studies actually conducted with Aroclor 1016 produced <u>no</u> similar adverse effects, the Agency takes the position that the same low level effects resulting from studies on other mixtures, such as Aroclors 1260, 1254 and 1242, are likely to result from exposure to Aroclor 1016.

In fact, the record provides no support whatever for this theory. Aroclor 1016 was shown to be substantially less toxic than the other PCB mixtures because it bioaccumulates in consumers of aquatic organisms to a much lesser extent than does Aroclor 1242 or any other of the more highly chlorinated PCB mixtures. Thus, mammals and birds, as well as fish and aquatic invertebrates, are able easily and rapidly to metabolize and excrete the lower chlorinated isomers of PCB and prevent their accumulation in the tissues.

Dr. Wolfgang F. Mueller summarized the available information on bioaccumulation as follows:

> "The fact that only very small amounts of di-, tri- and tetra-CB are found in living organisms, however, cannot be explained by selective enrichment alone. It must be assumed that those quantities of lower chlorinated isomers which are taken up by organisms, can be actively eliminated. It has indeed been shown in numerous studies, reviewed in Appendix E to the Criteria Document, that bacteria, invertebrates, fish, birds, and mammals are able to metabolize PCB, i.e., alter their structure to make them more water soluble and thus excretable. The ability of PCB to be metabolized decreases in all investigated organisms with increasing chlorine content: mono- and dichloro BP are generally metabolized very rapidly, trichloro BP somewhat more slowly. Although the metabolism rate for tetrachloro BP is considerably lower in all species than for mono- to trichloro BP, residue data presented by Nisbet and Sarofim indicate that it is still sufficient to prevent accumulation under environmental conditions. Biphenyls with five or more chlorine atoms, however, are metabolized so slowly that they are found to be accumulated in many species, including mammals and man. (EIA Exh. G at 3-4 [Mueller] (Footnote omitted))

The Agency made no effort to rebut Dr. Mueller's conclusions. Indeed, none of the six scientists who testified for EPA on the mammalian toxicology issues undertook to analyze the chemistry of Aroclor 1016 or, with a single exception, to make any claim that Aroclor 1016 has been proven to have toxic effects at low dose levels.*/ These EPA scientists merely assumed PCBs were a single category of

*/ Dr. Ringer related the results of his 1016 study discussed below, see pp. 45-47 supra, to the results of his 1254 study and concluded that Aroclor 1016 "does not appear to be as toxic to mink as Aroclor 1254 ...." (EPA Exh. S at 5-6 [Ringer])

chemical, no matter how different their chemical composition. The record provides no support whatever for this assumption.

The only witness for the Agency who expressly claimed that test results for other PCB compounds could be analogized to Aroclor 1016 was Dr. Ian Nisbet, the author of the Agency's Criteria Document. Dr. Nisbet broadly asserted that "there appears no convincing basis for setting different [ambient water] standards for the various isomers or Aroclor mixtures." (EPA Exh. M at 10) Dr. Nisbet made this assertion based on his understanding that the molecular composition of Aroclor 1016 and 1242 were so similar that similar toxic effects must be presumed to result. Dr. Nisbet is a physicist, with no background in biology or organic chemistry -- as author of the Criteria Document he reviewed the extensive literature on the molecular composition of different PCB compounds, but could make no claim of individual expertise in evaluating those data. (EPA Exh. M at 5) His conclusions were evaluated and rejected by Dr. Wolfgang Mueller, an organic chemist with years of experience in conducting tests on the metabolism of different PCB isomers.

Dr. Mueller reviewed the evidence contained in the Criteria Document and in the record of this proceeding, and stated flatly: "Aroclor 1016 differs in its chemical composition significantly from more highly chlorinated mixtures including 1242 in that it consists to nearly 80 percent of mono-, di-, and trichlorobiphenyls, and contains only 1 percent of pentachloro BP and a trace of hexachloro BP." As a result, Dr. Mueller concluded that "Aroclor 1016 can be metabolized relatively rapidly and much more completely than . . . 1242." (EIA Exh. G at 14) Dr. Mueller rejected the claim by Dr. Nisbet that results from 1242 studies could be extrapolated to Aroclor 1016:

> Due to the high accumulation tendency and slow metabolism of the hexa-, penta-, and to some degree also the tetrachloro-BP, these components will build up to much higher levels in the test animals upon chronic treatment with 1242 than would be expected with 1016. Consequently, prolonged intake of Aroclor 1242 will result in elevated liver concentrations of tetra-, penta- and hexachloro BP, which will eventually cause similar hepatic changes as have been found with lower levels of Aroclor 1248 and 1254. Due to its lower content of tetrachloro BP and the virtual absence of higher chlorinated isomers, 1016 will not produce these effects. (*Id.* at 6-7) (Emphasis supplied)

2. The Record Is Devoid of Credible Evidence Demonstrating That Aroclor 1016 Causes Adverse Effects at a Level Below 15 ppm in the Diet.

The lowest level at which the Criteria Document notes any purported toxic effect of Aroclor 1016 is at 15 ppm. At that level, one study demonstrates small increases in the weight of the liver (9% increase over control) and in two liver enzyme functions of rats (12% and 38% increase over control) who received a daily oral dosage for 21 days. This same study showed no significant effects at a daily dosage of either 1.5 ppm or .15 ppm. (EPA Exh. 2 at 227-30, Reference 243.)

The purported adverse effects demonstrated by this single study are of equivocal significance inasmuch as two similar studies produced no similar effect.*/ Taken for whatever limited significance this single study might have, it represents the lowest arguable adverse effect noted in the Criteria Document for Aroclor 1016.

Only one study introduced independently of the Criteria Document purports to demonstrate adverse effects by Aroclor 1016 at levels below 15 ppm. That study was one undertaken under contract with EPA by Dr. Robert K. Ringer and purports to demonstrate that Aroclor 1016 adversely affects the reproduction of mink. (EPA Exh. 5 at 5 [Ringer] and supporting Exhibit F to that affidavit.) The study consisted of feeding four groups of standard ranch mink with a basic mink diet supplemented with zero, 2, 10, and 25 ppm of Aroclor 1016. Each group consisted of three males and 12 females. Mating was begun approximately two months after the study began and whelping occurred approximately two months later. Feeding continued for approximately eight weeks post-whelping.

*/ One similar study involving six daily doses of 375 ppm of Aroclor 1016 to male rats, showed no significant effects on two liver enzyme functions, one of which was the same enzyme function noted in the above experiment. (EPA Exh. at 2 at 227 and Reference 244) The other study involved feeding female rats 100 and 500 ppm of Aroclor 1016 for six months. After one week of Aroclor 1016 at 100 ppm, none of the ten liver parameters tested was significantly different from control. Even after six months at 100 ppm, only limited effects were noted. (EPA Exh. 2 at 231, Figures III.10.7 and III.10.8 and Reference 245).

The data produced by the Ringer study is set forth in three tables. One table lists the reproduction performance of female mink fed either a control diet or one of the PCB-supplemented diets. The second table consists of the average body weight at birth and at four weeks and survival of the kits fed a control diet or one of the PCB-supplemented diets. The third table lists average body weight at four points during the experiment and hemoglobin and hematocrit values for the various female mink four weeks post-whelping.

The first point to be made is that the data presented does not demonstrate that Aroclor 1016 impairs the reproduction of mink at the 2 ppm and 10 ppm feeding levels. Looking first at Table 1, the author concedes that no tests for mathematical significance were conducted on the data presented in the table despite the fact that it was possible to conduct such tests. (Tr. 1028-29 [Ringer]) Therefore, there is no way to know whether the data were the product of chance or the result of PCB in the diet. Moreover, an examination of the data indicates no discernable effects at the 2 ppm and 10 ppm feeding level. For example, the number of live births per whelp and the average number of kits per whelp at the 10 ppm feeding level were above the comparable figures for the control group. Similarly, the number of dead births at 2 ppm were below the number of dead birth per whelp of the control. Although live births per whelp and average number of kits per female who whelped at the 2 ppm feeding level was slightly below the control group, there is no indication that such minor variations have any significance.

Turning to Table 2, the data on weight at birth, weight at four weeks and kit mortality between birth and four weeks were subject to tests for mathematical significance. (Tr. 1035-36 [Ringer]) On the basis of these tests it was determined that none of the data values at the 2 ppm, 10 ppm and 25 ppm feeding levels were significantly different from the comparable figures for control. (Tr. 1036-1040) Accordingly, there is no reason to believe that the data produced at each of the levels resulted from PCB in the diet. (Tr. 1044-1045)

The same is true for the data on Table 3. Only two figures on this chart raise any implication of statistical significance and both of these figures were produced at the 25 ppm feeding level. (Tr. 1041-1046).

The second point to be emphasized is Dr. Ringer's testimony that a prior study he had conducted on various Aroclor mixtures demonstrated that a diet of 2 ppm of either Aroclor 1016, 1221 or 1242 had no adverse effects on mink. (Tr. 1025-26) Dr. Ringer failed to attach the results of his earlier study to his affidavit and he failed to refer to it anywhere in the study of 1016 performed under contract with EPA. Thus, Dr. Ringer's study, as well as his personal bias, are subject to serious question.

E. A 100 ppb Discharge Limitation for Aroclor 1016 Provides An Ample Margin of Safety to the Environment.

We have shown that a 100 ppb discharge limitation for Aroclor 1016 presents no risks whatever to aquatic or mammalian organisms. With normal dispersion, the 100 ppb discharge immediately dilutes into concentrations no greater than 100 ppt. Laboratory studies introduced by the Agency in this proceeding conclusively established that Aroclor 1016 in this concentration has no acute or chronic toxic effects on aquatic life. Given the highest bioaccumulation factor for Aroclor 1016 which has been produced in the laboratory and which was shown to be a generally reliable datum (50,000), the 100 ppt ambient concentration will produce concentrations no greater than 5 ppm in fish consumed by predators or man. This 5 ppm level is entirely safe for all fish consumers -- it is 3 times smaller than the lowest dose level of Aroclor 1016 which produced any adverse effects in test animals, and even assuming that these rat studies can be extrapolated to man or other mammals, the 5 ppm food level for Aroclor 1016 was established as entirely safe.

The 100 ppb discharge limitation is both entirely safe to the environment and provides the requisite "ample margin of safety."

> First, it assumes only a 1000 dispersion factor while dispersion and dilution could be substantially greater. (See EPA Exh. G [Callaway] at 2.)

Second, it is based on a 50,000 bioaccumulation factor for Aroclor 1016, which is 3 times greater than the average of the bioaccumulation factors found for Aroclor 1016 in the laboratory -- and indeed, was a factor substantially higher than any other reported. Use of this highest value is the most conservative approach which can be taken.

Third, it is 3 times lower than the 15 ppm minimum feeding dosage which had any adverse effects on test animals. The 5 ppm food standard is thus substantially lower than the feeding dosage which could possibly be harmful to rats, much less to man or other mammals.

Taken together, these three safety factors establish that a 100 ppb discharge limitation recommended by the EIA should be adopted by the Administrator. Any lower standard is unreasonable as being unsupported by the substantial weight of the scientific evidence in the record.

III

A ONE PPB DISCHARGE LIMITATION FOR AROCLOR 1016 CANNOT BE FAIRLY ADMINISTERED

The record in this proceeding establishes that a 1 ppb discharge limitation for Aroclor 1016 is impossible to regulate fairly and accurately. Arbitrary enforcement must necessarily result should the Administrator elect to adopt the 1 ppb standard for two reasons. (1) It is impossible utilizing current testing methods reliably and accurately to determine PCB levels in industrial effluent to 1 ppb. If that low level is adopted, companies subject to the regulation will be unable to determine whether they are in compliance with the law. (2) PCB exists in most influent water used by capacitor manufacturers. If the discharge limitation is not modified to adjust for preexisting PCB levels, capacitor manufacturers who discharge no Aroclor 1016 into their waste water may nonetheless be subject to sanctions for failure to treat their effluent. As a matter of elementary fairness, the proposed discharge limitations should be modified to take these factors into account.

A. The Lowest Discharge Limitation for Aroclor 1016 Which Can Be Accurately Measured Is 20 ppb

There can be no dispute that the Agency may not set discharge standards which cannot be measured accurately and reliably. Discharge limits set below the point at which accurate measurements can be taken *a fortiori* expose all companies subject to the regulation to arbitrary enforcement actions, as neither the Agency nor the companies themselves can be certain whether their discharges comply with the law. The record in this proceeding establishes conclusively that it is impossible to measure PCB levels in industrial effluent accurately and reliably to 1 ppb.

Mr. James Laubscher, the director of the Woodson-Tenent Laboratory of Memphis, Tennessee, with long experience both in testing for pesticide and other pollutants in industrial effluent and other water, testified:

> I do not believe that my laboratory can produce accurate test results of PCB levels in industrial effluent water at 1 part per billion at the pipe. This level is too low for reliable testing. EIA Exh. F at 5 [Laubscher]

Mr. Laubscher explained the many obstacles to testing for PCB levels in industrial effluent. Industrial effluent may contain many different constituents, which may or may not be extracted by use of a solvent. These other constituents may create substantial confusion on instrumental and biological test systems. If clean-up procedures are used to cope with this problem, those procedures reduce the efficiency of the test procedure. PCBs adsorb onto sample containers, and pose potentially critical problems of analysis. (Id. at 2-3) For these reasons, and others, Mr. Laubscher testified that 1 ppb is an impossibly low level at which to test for PCB.

But Mr. Laubscher did not rely solely on his own experience in testing. He also relied on the results of a round-robin test conducted by Monsanto and the American Society for Testing and Materials in 1975. Twelve laboratories participated in this testing program, designed to determine whether PCB levels in river water could be accurately determined. The results of this Monsanto/ASTM round-robin are provided as Exhibit B to Mr. Laubscher's affidavit (EIA Exh. F), and reflect "substantial variations in the range of 1 ppb to 23 ppb." (EIA Exh. F at 5 [Laubscher]) After reviewing these results, Mr. Laubscher testified:

> Results which show variations of this magnitude are not reliable and establish that one laboratory's results are not readily reproducible by other laboratories using essentially identical testing techniques. (Id.)

The experience of the capacitor industry with testing for PCB levels in plant effluent reinforces this conclusion. Dr. Eunice Moore conducted a survey of nine capacitor companies which are members of the Ad Hoc PCB Committee. The detailed results of her survey are presented as Exhibit B to her affidavit. (EIA Exh. E) */ The test results contained in Dr. Moore's survey vividly demonstrate the disparity between measurements of as nearly identical samples as could be taken.**/

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*/ To preserve the confidentiality of company data, Dr. Moore did not identify the companies by name--but did identify the six independent laboratories involved in the survey, and the four EPA regional laboratories whose test results are also reported, as follows: (Tr. 2548-2551)

Laboratory 1	EPA Region I
Laboratory 2	EPA Region II
Laboratory 3	EPA Region IV
Laboratory 4	EPA Region V
Laboratory 5	Baron Consulting Laboratory
Laboratory 6	Galbraithe Laboratory
Laboratory 7	[Company's Own Laboratory]
Laboratory 8	New England Analytical Testing
Laboratory 9	Stewart Laboratories
Laboratory 10	Warf Institute
Laboratory 11	[Company's Own Laboratory]
Laboratory 12	Woodson-Tenent Laboratory

**/ In eight of the nine studies presented in Dr. Moore's survey, the EPA took duplicate samples in separate containers and left the sample with the company for comparison testing. (See Tr. 2558-2559)

The test results in the following table were also introduced into evidence by Mr. N. Ray Clark of Universal Manufacturing, who had personally conducted or supervised the sampling (producing grab samples taken simultaneously or consecutively from the same stream):

TEST RESULTS OF UNIVERSAL MANUFACTURING CORPORATION

	Woodson-Tenent	Baron Consulting
[1]	8.40 ppb	None detected (less than 1 ppb)
[2]	24.7 ppb	None detected (less than 1 ppb)
[3]	0.43 ppb	None detected (less than 1 ppb)
[4]	11.3 ppb	None detected (less than 1 ppb)
[5]	4.99 ppb	None detected (less than 1 ppb)

Source: EIA Exhs. 9-12.

* * *

The results of these different testing programs all reflect the same fact: Reputable testing laboratories, using recognized and accepted measurement techniques, "are unable in most cases to produce even approximately similar test results on PCB levels in identical samples of industrial effluent." (EIA Exh. E at 2)

Accordingly, the discharge limitation for Aroclor 1016 must be modified. Mr. Laubscher testified the allowable limits which could be tested accurately would be between 10 and 20 ppb, with a 100 to 400 percent range of reasonable variations. (EIA Exh. F at 6) This testimony is unrebutted, and requires modification in the proposed 1 ppb standard. In view of the substantial range of variations which must be expected, a 20 ppb discharge limitation is the lowest standard which could be properly enforced.

B. Any Discharge Limitation Adopted Should Be a "Net" Discharge Limitation to Adjust for Preexisting PCB In Influent Water

Over the past forty years, over one billion pounds of PCB have been used by many different industries in this country (see 41 Fed. Reg. 30469)--and to the extent that the more highly chlorinated mixtures have persisted in the environment, they can be found in many different bodies of water. Tests of influent water at capacitor plants have disclosed the presence of PCB--at times exceeding the proposed effluent limitations of 1 ppb. But the proposed regulations do not take this factor into account in regulating capacitor discharges. (EIA Exh. C at 8-10) Thus, capacitor manufacturers who discharge little (if any) Aroclor 1016 in their plant effluent and whose discharges without any pretreatment would meet the 1 ppb limitation, may be obliged to treat the water under the proposed regulations due solely to PCB for which they bear no responsibility and over which they had no control. Such a result is both unfair and improper under the Federal Water Pollution Control Act which provides only for the regulation of discharges actually made by each company subject to a discharge limitation. Accordingly, the proposed standards should be modified to adjust for preexisting PCB levels in influent water by regulating only the discharges actually made by capacitor companies.

CONCLUSION

There is no basis for the Agency's decision to regulate all "PCBs" as if the many different PCB mixtures were a single chemical, presenting identical hazards to the environment. PCBs vary substantially in their chemistry and molecular composition. As a matter of elementary organic chemistry, the persistence tendency of each compound and thus its potential for toxic effect varies directly with the number of chlorine atoms in each molecule. This is a non-controversial scientific fact. Yet the significance of this fact has been ignored by the Agency, which has undertaken to regulate "PCBs" with little attention to the differences in the materials used by the two industries subject to the discharge regulations involved in this proceeding.

The capacitor industry, represented by the Electronic Industries Association's Ad Hoc PCB Committee, has long recognized the substantial differences between Aroclor mixtures. Five years ago the industry made the decision to convert to the use of a material which was shown to be biologically safe and non-persistent. Aroclor 1016 was developed by Monsanto for the sole purpose of eliminating those highly chlorinated isomers which have been found to persist in the environment; the capacitor industry converted to its use solely out of environmental concerns. Yet despite all this, the Agency has chosen to regulate Aroclor 1016 as if it were essentially identical to such highly chlorinated PCB mixtures as Aroclor 1254 or Aroclor 1260. The record is silent when it comes to a justification for the Agency's proposal to regulate Aroclor 1016 at the same discharge level proposed for such Aroclors as 1254 and 1260.

Accordingly, the Agency's proposed 1 ppb discharge limitations for all polychlorinated biphenyls should be modified with respect to Aroclor 1016. The following arguments justify such needed modifications.

First, the Toxic Substances Control Act preempts totally this area of regulation. Inasmuch as no capacitor manufacturer will invest the substantial sums required for treatment facilities to comply with the proposed 1 ppb discharge limit, such regulation is tantamount to a premature ban on the use of Aroclor 1016 and is thus inconsistent with the 2-1/2 year gradual phase-out of PCBs mandated by TSCA. Further, the imposition of national effluent limitations is inconsistent with the requirement of the Water Pollution Control Act that the Administrator consider specifically the effects of a pollutant on the specific body of water into which it is discharged. Only local on-site regulation of discharges can fulfill this statutory requirement.

Second, if national effluent discharge limitations are to be set for Aroclor 1016, the 1 ppb limitation should be modified to 100 ppb. Such a discharge limitation would be entirely free from risk to the environment, and would provide a very substantial and "ample" margin of safety for all aquatic and non-aquatic life. Adoption of any lower standard would be inconsistent with the vast bulk of the scientific evidence introduced into the record, and would be based on a failure to recognize the characteristics of Aroclor 1016 which make it materially different in chemistry and environmental effects from all other PCBs which have been studied.

Finally, if the Administrator elects to adopt a discharge limitation for Aroclor 1016 lower than 100 ppb, the lowest criteria which can be fairly administered is 20 ppb. At any lower level, companies subject to the regulation will unavoidably be exposed to arbitrary and unfair enforcement. It is impossible accurately to measure Aroclor 1016 in industrial effluent to 1 ppb as proposed. Even at higher levels such as 10 ppb, measurements would be subject to very substantial variations. Only a 20 ppb limitation provides a reasonable basis for regulation. Further, the discharge regulation must be modified to account for the substantial levels of PCB extant in most capacitor plants' influent water--which in some cases would exceed the 1 ppb limit. Unless the discharge criteria is modified to regulate only those discharges actually made by each company, the capacitor industry will be penalized for past use of PCBs by other, non-regulated companies--a result nowhere sanctioned or authorized by the Water Pollution Control Act.

Respectfully submitted,

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APPENDIX

Outline of Scientific Evidence Presented By the Environmental Protection Agency Concerning Aroclor 1016

The following outlines the scientific evidence presented by the Agency concerning the toxicity or persistence of Aroclor 1016.

EPA Exhibit A and 24 exhibits thereto	Donald I. Mount, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibits B and 3D exhibits thereto	Gilman D. Veith, Ph.D.	Four studies presented on the bioaccumulation of Aroclor 1016.
EPA Exhibit C and 9 exhibits thereto	Alan V. Nebeker, Ph.D.	Two studies presented on the toxicity of Aroclor 1016.
EPA Exhibit D and 19 exhibits thereto	David J. Hansen	Four studies presented on the bioaccumulation of Aroclor 1016.
EPA Exhibit E and one exhibit thereto	Thomas O. Munson, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit F and two exhibits thereto	Donald Sargent	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit G	Richard J. Callaway	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit I and four exhibits thereto	Wilbur McNulty, M.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.

EPA Exhibit J and 9 exhibits thereto	Renate Kimbrough, M.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit K and seven exhibits thereto	Joseph Rizzo	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit L and 11 exhibits thereto	Delwayne Nimmo, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit M and exhibit thereto	Ian C.T. Nisbet, Ph.D.	Testimony concerning the Criteria Document.
EPA Exhibit N and four exhibits thereto	Robert Squire, D.V.M., Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit O and 10 exhibits thereto	Harry V. Gelboin, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit P and 10 exhibits thereto	David R. Young, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit Q and 9 exhibits thereto	James R. Allen, D.V.M., Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit R and one exhibit thereto	David E. Armstrong, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit S and 6 exhibits thereto	Robert Ringer, Ph.D.	One study presented on the toxicity of Aroclor 1016 in mink.

EPA Exhibit T and 4 exhibits thereto	Robert Risebrough Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit U and 4 exhibits thereto	William A. Brungs, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit V and 12 exhibits thereto	Charles E. Mauk, Ph.D.	No testimony concerning studies on the toxicity or persistence of Aroclor 1016.
EPA Exhibit W	Leonard J. Guarraia, Ph.D.	Testimony concerning the formulation of the Agency's proposed criteri