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PART VI



ENVIRONMENTAL PROTECTION AGENCY

POLYCHLORINATED BIPHENYLS (PCBs)

Toxic Pollutant Effluent Standards

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Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 678-7]

PART 129—TOXIC POLLUTANT EFFLUENT STANDARDS

Standards for Polychlorinated Biphenyls (PCBs); Final Decision

This is a rulemaking proceeding under section 307(a) of the Federal Water Pollution Control Act, as amended (the Act), 33 U.S.C. 1251 et seq.

On July 23, 1976, the Environmental Protection Agency published proposed toxic pollutant effluent standards for polychlorinated biphenyls (PCBs) in the FEDERAL REGISTER, 41 FR 30468 et seq. Pursuant to the requirements of section 307(a) of the Act, a formal rulemaking hearing was commenced on the proposed standards on August 20, 1976 and, after 21 days of hearings, was concluded on November 30, 1976.

The proposed toxic pollutant effluent standards for PCBs published in the FEDERAL REGISTER on July 23, 1976 included a prohibition on discharge of PCBs by any PCB manufacturer and stringent limitations on discharges by manufacturers of transformers and capacitors. Pursuant to section 307(a)(2) of the Act, based upon a preponderance of evidence in the record before me, I have determined that a prohibition on discharge of PCBs should be established for transformer and capacitor manufacturers as well as PCB manufacturers, in order to achieve the "ample margin of safety" required by section 307(a)(4) of the Act. The regulations establishing the prohibition are modified to provide for an adjustment of the prohibition in appropriate circumstances to take into account the presence of PCBs in a discharger's intake water.

Because due and timely execution of my functions imperatively and unavoidably so requires, I have determined in accordance with 40 CFR 104.14(c) that the preparation and filing of a tentative decision and related procedures pursuant to 40 CFR 104.14(b) should be omitted.

I. BACKGROUND

A. PARTIES AND PUBLIC PARTICIPATION IN RULEMAKING

Objections to the proposed standards were received from the following, who were made parties to the proceedings in accordance with 40 CFR 104.3(a):

The PCB Ad Hoc Committee of the Electronics Industries Association
Natural Resources Defense Council, Inc.
Environmental Defense Fund
American Paper Institute
New York State Department of Environmental Conservation
Westinghouse Electric Corporation
Cornell-Dubilier Electric Corp.
State of California Water Resources Control Board
Abrovox Industries, Inc.
Department of Public Service of the City of Akron, Ohio
Department of Natural Resources, Environmental Protection Division of the State of Georgia
Houston Research, Inc.
Westgate Research Corp.
General Electric Co.
National Council of the Paper Industry for Air and Stream Improvement, Inc.
Ford Motor Co.

In addition, in accordance with 40 CFR 104.3(b), written comments were received by the hearing clerk from the following interested persons and were made part of the record:

General Motors Corp.
Dow Chemical, USA
P. R. Mallory and Co. Inc.

A summary of the principal comments and the Agency's response thereto are set forth below.

B. DEVELOPMENT OF PROPOSED STANDARDS; RULEMAKING

Pursuant to section 307(a)(1) of the Act, the Agency published in the FEDERAL REGISTER on July 6, 1973, a list of nine pollutants (aldrin/dieldrin, benzidine, cadmium, cyanide, DDT (DDD, DDE), endrin, mercury, polychlorinated biphenyls, and toxaphene) (38 FR 18044). On September 7, 1973, this list was promulgated by the Agency as proposed, together with a discussion of the Agency's selection criteria and a response to the public comments received on the proposed list (38 FR 24342). On December 27, 1973, the Agency published proposed toxic pollutant standards for each of the nine listed substances, together with a discussion of the factors considered in setting the standards, and a list of point source categories of dischargers proposed to be covered. (38 FR 35388)

In accordance with section 307(a)(2) of the Act, a prehearing conference was held on January 25, 1974, followed by a 30-day evidentiary hearing during April and May, 1974. Following review of the record of the 1974 hearings, the Agency concluded that the record did not contain sufficient evidence upon which responsible and defensible standards could be promulgated, owing to insufficient data in certain areas. The Agency then undertook to substantially expand its data concerning the toxicity and environmental behavior and effects of PCBs. Thus, the rulemaking proceedings which commenced with the proposal of standards on July 23, 1976 supersede the PCBs portion of the proposal of December 27, 1973.

The standards proposed on July 23, 1976 were developed in the context of careful consideration of 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 the extent of the effect of the toxic pollutant on such organisms", as required by section 307(a)(2) of the Act. In light of the Act's manifest concern for public health, which is discernible both on the face of the statute and in its legislative history, the Agency also considered available data concerning human health effects attributable to PCBs.

In its data gathering, the Agency was assisted by numerous persons within and outside the Agency, including biologists, chemists, and other experts in the various EPA laboratories. Particularly in the area of toxicity and environmental behavior and effects of PCBs, the Agency was assisted by Ian C. T. Nisbet, Ph. D., of the Massachusetts Audubon Society. Dr. Nisbet is a nationally recognized expert on the toxicity of PCBs and is the principal author of the Agency's "Criteria Document for PCBs", which was incorporated by reference as part of the statement of basis and purpose for the standards proposed on July 23, 1976. Dr. Nisbet worked closely with key personnel in the Agency's Office of Water Planning and Standards and Office of Toxic Substances in developing major portions of the criteria document.

Based upon the data in the Criteria Document, the Agency established an "ambient water criterion" for PCBs of 1 part per trillion (0.001 micrograms per liter). Although it was "virtually impossible to state with confidence that any number above zero provides an ample margin of safety for man," the Agency nevertheless concluded that the ambient water criterion would provide the requisite degree of safety for aquatic organisms and most consumers thereof likely to be affected, assuming a continuing or chronic presence at that level in the water. Though not required by the Act, the setting of an ambient water criterion was utilized by the Agency as a step in arriving at an effluent standard which would apply at the point of the effluent discharge.

Based on the ambient water criterion the Agency proposed effluent standard for existing and new sources taking into account the likely effects of dilution and dispersion following discharge into areas of mixing in the receiving waters immediately surrounding the outfall. The proposed standards included a prohibition on discharge of PCBs by any PCB manufacturer. With respect to any manufacturer of transformers or capacitors, a prohibition of any PCBs in any discharge of process wastes was proposed with limited exceptions, and an average daily concentration limit per month of 1 part per billion (1 ppb or 1 microgram per liter) was proposed for any other discharge. For new sources a prohibition on discharge of PCBs in process wastes in combination with an average daily concentration limit per month of a tenth of a part per billion, was proposed.

In developing the proposed standards the Agency investigated and gave limited consideration to technical feasibility of compliance and economic impact.

On August 20, 1976, the rulemaking hearings required by section 307(a) were commenced. The hearings continued on September 27, 28, 29, and 30; October 5, 12, 14, 15, 18, 19, 20, 21 and 22, and November 15, 16, 17, 19, 22, 23, and 30. The Agency presented the testimony of 22 expert witnesses. The PCB Ad Hoc Committee of the Electronics Industries ("EIA") presented seven witnesses. The Environmental Defense Fund ("EDF") presented one witness. None of the other objectors presented any witnesses. At the conclusion of the hearing, a briefing schedule was established. Except for the

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New York State Department of Environmental Conservation, all parties submitted briefs and reply briefs. The American Paper Institute ("API") submitted no reply brief.

II Findings

A Relevance of Toxic Substances Control Act

In their post-hearing briefs, both FIA and Westinghouse Electric Corporation argued that when Congress passed the Toxic Substances Control Act (Pub. L. 94-469, 90 Stat. 2003 (October 11, 1976)), it provided an exclusive means of regulating PCBs. Section 6(e) of the Toxic Substances Control Act provides for a phase-out of the use of PCBs over a two and one-half year period, with provisions for exemptions.

Section 6(e)(5) of the Toxic Substances Control Act provides that:

> This subsection 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.

Similarly, section 9 of that Act provides as follows:

> Sec. 9. RELATIONSHIP TO OTHER FEDERAL LAWS
>
> * * * * *
>
> (b) *Laws Administered by the Administrator.* The Administrator shall coordinate actions taken under this Act with actions taken under other Federal laws administered in whole or in part by the Administrator. If the Administrator determines that a risk to health or the environment could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws, the Administrator shall use such authorities to protect against such risk unless the Administrator determines, in the Administrator's discretion, that it is in the public interest to protect against such risk by actions taken under this Act. This subsection shall not be construed to relieve the Administrator of any requirement imposed on the Administrator by such other Federal laws.

Sections 6 and 9 of the Toxic Substances Control Act clearly establish my authority to take action with regard to PCBs under section 307 of the Federal Water Pollution Control Act. If it had chosen to do so, Congress could clearly have precluded further Agency action with regard to the control of PCB-laden discharges into the nation's waters. Instead, Congress appears to have done precisely the opposite: It expressly granted me the authority to harmonize the provisions of the Toxic Substances Control Act with my authority to regulate toxic substances under other laws.

The Supreme Court has recently affirmed that "repeals by implication are disfavored" and that when statutes are capable of coexistence, each must be viewed as effective "absent a clearly expressed congressional intention to the contrary." *Administrator, Federal Aviation Administration v. Robertson*, 422 U.S. 255, 265–6 (1975). I find nothing in the Toxic Substances Control Act which relieves me of my express responsibility under section 307 of the Federal Water Control Act for setting effluent limitations on the discharge of PCBs into U.S. waters.

B The Nature and Use of PCBs

PCBs are mixtures of chlorinated biphenyls with varying degrees of chlorination and isomeric substitution. PCBs are manufactured by the reaction of biphenyl with chlorine in the presence of a catalyst. (A biphenyl is a hydrocarbon consisting of two six-membered carbon rings—or phenyl rings—joined together.) During the formation of PCBs, chlorine atoms are substituted for hydrogen atoms successively at one or more of the 10 available positions on the biphenyl molecule. Chlorinated biphenyls (CBs) are substances composed of biphenyl molecules with 1 to 10 chlorine substitutions. CBs with the same number of chlorine atoms in the molecule are known as homologs (or congeners) and are named according to number of chlorine atoms (e.g., the homologs with 4 chlorine atoms per molecule are called tetra-chlorobiphenyls or tetra-CBs). Each homolog may exist in a number of different forms, known as isomers, in which the chlorine atoms are attached to the molecules at different points. Each isomer is named according to the positions of substitution, following a standardized number scheme. PCBs are mixtures, each of which contains several homologs, each of which is represented by a number of isomers.

PCB mixtures are usually analyzed by gas-liquid chromatography, and the pattern of peaks on a gas-liquid chromatogram constitutes a "fingerprint" which is characteristic of the PCB mixture under study and can be used to identify the homologs and isomers contained in it. By means of gas-liquid chromatography, in combination with other techniques, the homologs and isomers present in the major commercial PCB mixtures have been isolated and identified.

PCBs are manufactured in the United States solely by Monsanto Industrial Chemicals Corporation, which markets commercial mixtures under the tradename Aroclor. The constitution of the four Aroclor mixtures now manufactured and sold in the United States can be summarized as follows.

Aroclor	Percent chlorine	Percent homologs with number of chlorine atoms							
		0	1	2	3	4	5	6	7
1 (2)	21	11	51	32.0	4	2	0.5	...	
1,016	41	(1)	1	20.0	57	21	1.0	(1)	...
1,242	42	(1)	1	16.0	49	25	8.0	1	(1)
1,254	54	(1)	(1)	1	1	21	48.0	23	6

[1] Trace.

Other PCB mixtures manufactured in the past and used in the United States include Aroclors 1232 (32% chlorine), 1248 (48% chlorine), 1260 (60% chlorine), 1262 (62% chlorine), 1268 (68% chlorine), and 1270 (71% chlorine). PCB mixtures have also been manufactured in several overseas countries and sold under other trade-names, including Clophen, Phenoclor and Kanechlor. Some of these mixtures are being imported into the U.S. in small quantities. The constitution of these mixtures is very similar to that of corresponding Aroclor mixtures. In addition to commercial mixtures, a number of individual chlorobiphenyl isomers have been synthesized for research purposes and used for studies for PCBs.

Successive members of the Aroclor series overlap very substantially in constitution and contain a number of homologs and isomers in common. As an example, Aroclor 1016—the principal commercial mixture—is almost identical in molecular and isometric constitution to Aroclor 1242, except that it contains slightly fewer of the higher boiling point constituents and, specifically, fewer pentachlorobiphenyls; it does, however, overlap substantially in constitution with Aroclor 1242 and shares at least one major component in common with Aroclor 1254. One specific isomer (2,5,2',5'-tetrachlorobiphenyl), which is present as a substantial component of Aroclors 1016, 1242, and 1254, has been used in a number of studies, and forms a useful indicator of the environmental behavior of the components of at least the three mentioned mixtures. Because of this overlap between PCB mixtures, it is not possible to distinguish completely between them in weighing their environmental behavior and toxic hazards.

PCBs are now used in the U.S. primarily as insulating fluids in electrical equipment. In 1974 approximately 40 million pounds were manufactured in the U.S. and approximately 450,000 pounds were imported. Between 65 and 70 percent of domestic sales are to manufacturers of capacitors, most of the remainder to manufacturers of transformers, and about 1 percent to other users.

Presently 90–95% of all impregnated capacitors manufactured in the U.S. are of the PCB type, and Aroclor 1016 is the principal mixture used. (Aroclors 1242 and 1221 are used in limited quantities.) PCBs are used as the dielectric fluids in 5–10 percent of the transformers manufactured in the U.S. The transformer oils are blends of 60–70 percent PCBs (Aroclors 1254 or 1212) and 30–40 percent trichlorobenzene. Domestic sales of PCBs in 1974 (excluding imports) consisted of 21,955,000 lbs. of Aroclor 1016, 6,207,000 lbs. of Aroclor 1242, 6,185,000 lbs. of Aroclor 1254, and 57,000 lbs. of Aroclor 1221.

Small quantities of PCBs are used in the investment casting industry and as hydraulic and heat transfer fluids. They have been used in the past for many other applications. Studies of the behavior of PCBs in the environment resulting from discharges due to these applications provide useful information for evaluating the behavior of PCBs dis-

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charged from capacitor and transformer manufacturing plants.

PCBs are mobile oils or viscous liquids at room temperature. They volatilize slowly at normal ambient temperature, and have very low solubility in water. (The less chlorinated components appear to be more soluble than the chlorinated components). PCBs are freely soluble in organic solvents. They are strongly partitioned from water into lipids (fats) in biological systems, resulting in large degrees of bio-accumulation. PCBs are strongly adsorbed onto solids, sediments, and airborne and waterborne particulates. In aquatic environments, the adsorption leads to their passive transport with moving sediments and inhibits volatilization of PCBs from water surfaces. PCBs that are adsorbed in sediments can be released into the water and taken up by fish, even where the fish do not contact the sediments. Experiments have shown that fish and shrimps kept in aquaria with contaminated sediments accumulate PCBs to high levels.

PCBs are chemically stable and resistant to oxidation, reduction and other chemical reactions (they will undergo photochemical reactions when irradiated with ultra-violet light or sunlight, however, experimentation indicates little overall degradation of Aroclor 1254 after exposure to sunlight for 3 weeks). Photochemical degradation of PCBs gives rise to, inter alia, small quantities of polychlorinated dibenzofurans ("PCDFs"), which are toxic impurities. In at least one reported instance, PCDFs were formed in toxicologically significant quantities from PCBs during service in a heat exchanger.

Environmental residues of PCBs do not correspond to commercial mixtures very well, because of changes that occur after discharge. There are differences in the way less chlorinated components and more chlorinated components are volatilized, become soluble, and are adsorbed. Bacterial metabolism affects primarily mono- and dichlorobiphenyls; trichlorobiphenyls are metabolized much more slowly and higher chlorobiphenyls hardly at all. Tetra- and higher chlorobiphenyls are well retained by fish; lesser chlorobiphenyls are not as well retained. It is therefore impracticable and confusing to attempt to distinguish environmental residues derived from discharges of various PCBs (and therefore impracticable to establish criteria or standards for specific Aroclors).

C. THE TOXICITY AND OTHER ADVERSE EFFECTS OF PCBS

1. *In bacteria and phytoplankton.* Experiments and laboratory culture tests have established the following: PCBs inhibited the growth of estuarine bacteria in laboratory cultures; Aroclor 1242 stimulated the growth of *E. coli* at low concentrations and (together with a constituent of Aroclor 1016) inhibited predation on *E coli* by other bacteria. (This is evidence of a potential effect on estuarine self-purification rates.) Also, PCBs have been shown to interfere with photosynthetic mechanisms in certain species of phytoplankton and to reduce rates of cell growth and division in phytoplankton; sensitive diatoms mixed with phytoplankton are replaced by resistant green algae at PCB concentrations far below those required to affect either species when cultured alone. Reductions in growth and other effects have been reported at PCB concentrations as low as one-tenth of one part per billion (the lowest concentration tested). Aroclor 1242, which, with Aroclor 1016, is the subject of further specific comment infra, has been shown to depress the rate of photosynthesis by a marine community of phytoplankton at lower concentrations than Aroclor 1254. This can have profound effects on the productivity of an entire marine ecosystem.

2. *In aquatic invertebrates and fish.* The acute toxicity of various PCB mixtures to a variety of aquatic invertebrates and fish is well established. PCBs are generally toxic to aquatic organisms at much lower concentrations in chronic exposures than in short-term exposures. A number of species tested are affected by chronic exposure to PCBs at concentrations of a few parts per billion, and the reproduction of the invertebrate *Daphnia magna* was impaired at concentrations as low as 0.48–1.0 parts per billion of Aroclors 1248 and 1254. The midge *Tanytarsus dissimilis* was tested through its full life-cycle and found to be affected by Aroclor 1254 at levels below 1 part per billion (survival and growth were reduced 50 percent at the lowest test concentration of 0.45 parts per billion). Reproduction in the mosquito *Culex tarsalis* was adversely affected at concentrations of Aroclor 1254 as low as 1.5 parts per billion. The same mixture is toxic to commercially valuable penaeid shrimp and grass shrimp at concentrations as low as 0.9—1.4 parts per billion. Brown shrimp exposed to sublethal levels of Aroclor 1254 for 7 days died when the salinity of the water was decreased, and important result because shrimps need to adapt rapidly to changing salinity in their extensive euryhaline migrations. Aroclor 1254 markedly reduced the number and variety of species of estuarine animals developed from planktonic larvae at concentrations as low as 0.1 parts per billion, the lowest concentration tested, and the fry of sheepshead minnows suffered significant mortality when raised in water containing a measured concentration of 0.16 parts per billion of Aroclor 1254. Residues of PCBs in eggs from adult sheepshead minnows exposed to as little as 0.14 ppb of Aroclor 1254 resulted in decreased survival of embryos and fry. Inclusion of Aroclor 1254 in fish food at a level of 0.48 ppb resulted in a 52 percent increase in thyroid activity in coho salmon, and thyroid activity was similarly increased in lake trout by dietary exposure to 1.2 parts per million (ppm) Aroclor 1248, and growth was depressed. Rainbow trout eggs hatching from eggs containing 2.7 ppm of a PCB mixture comparable to Aroclor 1242 suffered a 75 percent mortality in the first 30 days after hatching, with 60–70 percent of the survivors being deformed. Swedish investigators have reported a statistically significant association between hatching failure of Atlantic salmon and PCB residues in the range 0.4 to 1.9 ppm. The "fin rot syndrome," a fungal disease, has been reported in fish exposed to PCBs in both laboratory and field observations. Reproductive failure of several species of fish in Lake Michigan is associated with PCB residues in the lake water in the low parts per trillion.

The evidence of record shows adverse effects of PCBs at ambient concentrations as low as 0.1–0.14 parts per billion in laboratory bioassays and leaves little doubt that PCBs at concentrations below even 1 part per billion have adverse effects on aquatic insects, crustaceans, invertebrate communities and fish.

3. *In birds.* PCBs are very toxic to chickens, causing deaths within a few weeks at dietary concentrations as low as 30-40 parts per million. Aroclor 1242 has been found to be more toxic to chickens than Aroclors 1254 and 1260. In several instances, wild fish-eating birds have been found dead with lethal concentrations of PCBs in their tissues. Two incidents involved the bald eagle, an endangered species, one of these was from the northern part of the Lake Michigan where the general level of PCBs in the ambient water is probably in the low parts per trillion. PCBs have marked effects on reproduction in chickens at dietary levels as low as 8–10 parts per million, corresponding to residues as low as 1-2 parts per million in their eggs. Aroclors 1242 and 1248 have been the most potent PCBs in the chicken dietary results; Aroclor 1016 was much less active than Aroclor 1242. In one test Ring doves exposed to PCBs at 10 parts per million for two generations suffered severe reproductive failure; most of the eggs in the second generation failed to hatch and the embryos exhibited chromosomal abnormalities. Similar results have been found in American kestrels. A variety of other sublethal effects in birds have been found including the induction of hepatic microsomal enzymes, the induction of porphyria, changes in thyroid activity, adverse behavior effects, reduction in size of the spleen and bursa of Fabricius, and increased susceptibility to viral disease and vitamin E-selenium deficiency.

4. *In mammals.* Extensive data on the toxicity of PCBs in mammals were summarized in the Agency's Criteria Document and in the testimony of expert witnesses. Witnesses who testified for the Agency concerning their own work on the toxicity of PCBs and its relevance for the assessment of human risk included Dr. Wilbur P. McNulty, Chairman of the Laboratory of Pathology at the Oregon Regional Primate Center; Dr. Ronald D. Kimbrough, Medical Research Officer in the Toxicology Branch of the Center for Disease Control, U.S. Department of Health, Education, and Welfare. Dr. Robert A. Squire, Head of the Tumor Pathology Section, Associate Chief of the Experimental Pathology Branch, and Acting Chief of the Carcinogenic Bioassay and Program Resources Branch in the National Cancer Institute. Dr.

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Harry V Gelboin, Chief of the Chemistry Branch, Division of Cancer Cause and Prevention, National Cancer Institute, Dr James R. Allen, Professor in the Department of Pathology and Food Microbiology and Toxicology at the University of Wisconsin, Madison and Senior Scientist at the Wisconsin Regional Primate Center; and Dr. Robert K Ringer, Professor in the Departments of Physiology and Poultry Science in the Colleges of Veterinary Medicine, Human Medicine, Osteopathic Medicine, Natural Science, and Agriculture at Michigan State University.

EDF was the sole objector which presented an expert toxicologist as a witness (Roscoe Moore, who presented preliminary data on the incidence of cancer among occupationally exposed workers).

EIA presented one witness, Dr. Wolfgang Mueller, who criticized some of the toxicological studies and interpretations presented by EPA witnesses. Dr. Mueller is an expert in chemistry and toxicokinetics and conceded that he was not an expert in pathology, toxic effects, or carcinogenesis. He also conceded that enzyme induction is not his specialty He admitted that he had not read all the original papers supporting the conclusions which he criticized. Moreover, although he claimed familiarity with work on the toxicology of PCBs in his laboratory, he was not aware of work on the toxicology of PCBs in five species of mammals at another branch of the same institute, and had not contacted the Director of that institute for information about these studies. Dr. Mueller's testimony in regard to toxicology was limited to rats and rhesus monkeys Neither he nor any other witness attempted to refute or question the evidence introduced into the record by the Agency as to the toxicity of PCBs to other mammals, including dogs, mink, pigs, and humans.

PCBs have low acute toxicity to rats and mice In subacute toxicity studies, rats and mice proved relatively resistant to PCBs, whereas guinea pigs, rhesus monkeys, mink, and big brown bats were much more sensitive.

In chronic feeding studies, similar differences between species in susceptibility to PCBs were noted. Rats, mice, and dogs survived well for periods of up to 1–2 years at dietary levels as high as 100–300 parts per million of various PCB mixtures, although a variety of physiological and pathological changes were induced in them. In contrast, rhesus monkeys, mink, pigs, and rabbits suffered deaths and/or reproductive dysfunctions at lower levels of exposure

In studies conducted by Dr. James Allen, rhesus monkeys fed diets containing 100 and 300 ppm of Aroclor 1248 developed severe acne, swelling of the eyelids and face, loss of hair, and severe ulceration of the stomach together with thickening of the gastric mucosa. All of the animals died within 2–3 months. Female rhesus monkeys fed a diet containing 25 ppm of Aroclor 1248 developed facial lesions similar to those in animals exposed to 100 and 300 ppm within one month. After two months the animals were so ill that they were removed from the experimental diet. One animal died two months later, on autopsy it also exhibited acne and ulceration of the gastric mucosa of the stomach The female rhesus monkeys which survived 2 months' exposure to 25 ppm of Aroclor 1248 have been observed for 3 years and still show symptoms of poisoning They have given birth to six infants, all of which weighed at least 150–200 grams less than infants born to control animals.

Infant rhesus monkeys born to experimentally exposed mothers contained PCBs in their tissues at birth, indicating a transplacental movement of PCBs from the mother to the fetus. Invariably infants showed a decided increase in their tissue levels of PCBs following nursing as a result of the high levels of PCBs in the mother's milk.

Infant rhesus monkeys dosed with 35 mg/kg of Aroclor 1248 for only 4 weeks suffered skin lesions, atrophy of the thymus, edema and hyperplasia of the gastric mucosa, and enlargement of the liver with proliferation of the smooth endoplasmic reticulum Although this study may indicate the rhesus monkeys are more sensitive to PCBs when exposed naturally (via transplacental passage and mother's milk) than when dosed after birth, the study was terminated too early for definite conclusions

Female rhesus monkeys fed diets containing 2.5 and 5.0 ppm of PCBs developed the classical signs of PCB intoxication (swelling of eyelids, loss of eyelashes, edema of the face, and acne) within two months After six months, the test animals were mated to control males Of the 8 animals that received the 5 ppm diet, only one gave birth, there were five abortions and two did not conceive even after repeated breedings.

Of 8 female rhesus monkeys fed the 2.5 ppm diet, only 5 gave birth and 3 aborted The 5 live-born infants were extremely small. In addition to their difficulty in maintaining pregnancy, these animals exhibited irregular menstrual cycles and extensive menstrual bleeding.

Infant rhesus monkeys, born to mothers fed 2.5 ppm of PCBs showed a rapid increase in tissue levels as a result of ingestion of PCBs in their mother's milk Within 2 months, the infants began showing signs of PCB intoxication that progressively increased in severity Three of the six infants died within four months after birth Behavioral and learning experiments conducted on the surviving infants for one year following weaning have revealed deficits in both areas

Female rhesus monkeys which had been maintained on dietary levels of 2.5 or 5.0 ppm of PCBs for 16–18 months have been placed on normal diets for one year but have continued to give birth to affected infants.

Dr McNulty testified as to the results of a series of toxicity studies conducted with rhesus monkeys exposed to Aroclor 1242 Monkeys exposed to dietary levels of 800, 400, 200, 100, 30, 10, and 3 parts per million all died The monkeys exposed to 3 ppm and 10 ppm died after 245 and 146 days' exposure respectively. All the monkeys showed facial swelling, red and swollen eyelids, conversion of all secretory cell types of the stomach to mucous cells, growth of mucous glands into the muscular wall of the stomach, multiple ulcers in the stomach, atrophy of the thymus gland, and either disappearance of sebaceous glands or conversion of these glands to keratin cysts, particularly in the eyelids Other monkeys exposed to 10 ppm of Aroclor 1242 showed similar effects

In tests by Dr McNulty with individual chlorobiphenyl isomers, a trichlorobiphenyl and a pentachlorobiphenyl proved relatively non-toxic to rhesus monkeys, but a representative tetrachlorobiphenyl was very toxic and killed the test animal in less than 60 days' exposure to 10 ppm in the diet.

Comparison of the results of Drs Allen and McNulty suggests that Aroclor 1242 is more toxic to rhesus monkeys than Aroclor 1248, since in the experiments by Allen monkeys survived and even produced a few young on 5 ppm of Aroclor 1248, whereas in the experiments of McNulty the monkeys were severely affected by 10 ppm of Aroclor within 60 days and the animal exposed to 3 ppm died

Dr Mueller's suggestion that little weight can be placed on Dr McNulty's findings was based on the false proposition that McNulty's conclusions were based solely on the death of one monkey exposed to 3 ppm In fact, however, Dr McNulty's conclusions were based not only on the death of this animal, but also upon the deaths of animals at 10 ppm and higher doses of Aroclor 1242, upon the experiments with the pure tetrachlorobiphenyl isomers, and upon the clinical and pathological observations on the entire series of exposed animals

Dr Robert K Ringer testified as to the results of a series of studies of the toxicity of PCBs to ranch mink Mink fed on coho salmon from Lake Michigan in the late 1960's suffered from reproductive failure and kit mortality After a series of experiments the cause of the reproductive failure was traced to PCBs present at levels of 12–20 ppm in the salmon. The results of the poisoning of the mink from the contaminated Great Lake Salmon had the commercially catastrophic effect of wiping out a major segment of the Great Lakes fishfood industry.

Mink exposed experimentally by Dr Ringer to a diet containing 30 ppm of a mixture of PCBs all died between the beginning of the breeding season and the end of the whelping period Clinical signs and lesions were anorexia, pathological loss of appetite, bloody stools fatty degeneration of the liver and kidneys and hemorrhagic gastric ulcers

Mink fed Aroclor 1254 at 5 and 10 ppm in the diet suffered increased mortality enlargement of the liver, kidneys, and heart, and reduced weight gains These effects were enhanced by simultaneous feeding of DDT or dieldrin.

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Female mink fed 5 ppm of Aroclor 1254 produced no young in one test, and only 3 young were born alive from 13 females in a second test. Reproduction was also impaired at 1 ppm of Aroclor 1254, because one female died and two others produced no young.

Female mink exposed to Aroclor 1016 at 2, 10, and 25 ppm in the diet suffered impaired reproduction at all three dosage levels. Although Aroclor 1016 does not appear to be as toxic to mink as Aroclor 1254, the effect of Aroclor 1016 on reproduction was marked at 2 ppm, the lowest dose tested.[1] At this dose level the number of kits raised to 4 weeks of age was scarcely half that raised by the controls. Dr. Ringer testified that if the entire picture of reproduction performance in these experiments is considered, the reduction in the number of kits raised is very important.

In an independent series of experiments by Platonow and Karstad in which mink were fed a diet containing beef from cows which had been exposed to Aroclor 1254, all the mink fed at a dietary level of 3.57 ppm died within 105 days. Two of 12 females dosed at a dietary level of only 0.64 ppm PCBs died; only one of the 10 survivors produced a litter, and 11 of her kits died during the first day of life. Comparison of the results of the toxicity of tests carried out by Platonow indicates that the PCB mixture used became more toxic to mink during metabolism and storage in the cows.

The reproductive performance of sows was severely impaired by exposure to a dietary level of 20 ppm of Aroclor 1242 from three weeks prior to conception through gestation and nursing. One of five treated sows failed to conceive and the other four produced significantly fewer live young than controls, due to an excess of still births and fetal deaths. The principal lesions observed in sows treated with Aroclor 1242 at 20 ppm in the diet and in their offspring were erosions in the gastric mucosa. A number of offspring of treated sows, but no control offspring, died from septicemia, indicating that exposure to PCBs had increased their susceptibility to infection.

Feeding of Aroclors 1242, 1254, and 1260 to groups of beagle dogs at dietary level of 1, 10 and 100 ppm for a period of two years caused several deaths and dose-related increases in liver weight, serum alkaline phosphatase levels, and leukocyte counts. The noteworthy findings in chronically exposed dogs were numerous pinpoint nodules in the stomachs. These were observed in 22 of the 60 PCB-treated dogs, but in none of the controls.

Stomach lesions were induced in dogs by Aroclors 1242, 1254, and 1260 at all dietary levels down to 1 ppm, the lowest dose tested. Although stomach lesions were not reported in the dogs fed Aroclor 1242 at 1 ppm, Dr. Nisbet testified that this might well be due to chance, in view of the high incidence in animals fed this Aroclor mixture at 10 and 100 ppm.

Dr. Renate D. Kimbrough presented extensive testimony as to her experiments on the toxicity of PCBs to rats. Additional data on the toxicity of PCBs to rats was described in the testimony of Dr. Allen and in the Criteria Document. Sherman rats exposed to Arochlors 1254 and 1260 at dietary levels of 20, 100, 500 and 1,000 ppm for 8 months showed enlargement of the liver at all dose levels. Microscopic examination of the liver cells showed a variety of changes, including enlarged hepatocytes, inclusions in cytoplasm, foamy cytoplasm, and (at higher doses) increased lipids, brown pigment, and adenofibrosis.[2]

In a subsequent study, smaller numbers of Sherman rats were exposed to Aroclors 1242 and 1016 at 100 ppm in the diet. Changes in the liver were generally similar to those found in the rats treated with Aroclors 1254 and 1260, but were somewhat less severe. The changes were slightly, but not markedly, less severe in the rats fed Aroclor 1016 than in those fed Aroclor 1242.

Sprague-Dawley rats fed diets containing 100 ppm of Aroclors 1248, 1254 and 1260 for a period of 52 weeks also displayed enlarged livers and a variety of microscopic changes in the liver, including degeneration, enlarged cells, and focal necrosis.

Dr. Kimbrough reported a study in which Sherman rats were exposed for generations to dietary levels of 1, 5, 20, and 100 ppm of Aroclor 1254, and 2, 20, 100, and 500 ppm of Aroclor 1260. Adverse effects on reproduction were observed in the rats exposed to 20 and 100 ppm of Aroclor 1254, in that the number of pups per litter was reduced. In Dr. Kimbrough's two-generation reproduction experiments liver weights were increased in the offspring of rats fed PCBs at dietary levels as low as 1 ppm of Aroclor 1254 and 5 ppm of Aroclor 1260. Pathological changes in the livers were noted in the offspring of rats at doses as low as 1 ppm, including neoplastic nodules[3] in 3 of 7 female rats at 20 ppm of Aroclor 1254.

In a three-generation reproduction study carried out with rats, reproduction was adversely affected in the second and third generations exposed to Aroclors 1242, 1254, at 1260 and 10 and 100 ppm. The cause of the adverse effects was a decrease in the mating indices and in the incidence of pregnancy.

Exposure of rats to Aroclor 1016 at a dietary levels of 30 and 100 ppm for 90 days caused marked and significant reductions in gonad weights in the females. On prolonged exposures to Aroclors 1016, 1242, 1248, 1254, 1260 and 1262, rats have consistently developed a variety of pathological changes in the liver. Increase in liver weight in animals exposed to PCBs has been observed in a number of experiments with rats, and is also a toxic effect of PCBs in other mammals, including mice, rabbits, pigs, does, rhesus monkeys, and squirrel monkeys. Rats display marked increases in liver weight when exposed to PCBs for only a few weeks; the effects appear slightly greater with the more chlorinated mixtures, but in an experiment with Aroclor 1016, marked effects were seen in only 21 days after oral dosage of an amount equivalent to about 8 ppm in the diet for rats of the age concerned.

Extensive experiments summarized in the Agency's Criteria Document have shown that PCBs induce a variety of enzymes in the livers of rats and other species, and that PCBs are especially potent inducers of an enzyme system known as the mixed function oxidase system. Mixed function oxidases are responsible for the detoxication of foreign chemicals but may also be detrimental to an organism by metabolizing ingested chemicals to active toxic or carcinogenic forms. Both PCB mixtures and a large number of individual chlorobiphenyl isomers induce microsomal enzymes in the livers of rats and other animals, including nitroreductase, demethylases, deethylases, glucose-6-phosphatase, aryl, hydrocarbon hydroxylases, cytochrome P-450, and NADPH cytochrome reductase. Aroclor 1016, 1242, 1248, 1254 and 1260 induce several enzymes in rats after exposure to only 0.5 ppm in the diet, or 1 mg/kg/day for only 21-28 days. PCBs have been shown to enhance the metabolism of certain drugs and to promote the toxicity of vinyl chloride in rat livers by enhancing its transformation to a more toxic metabolite.

Dr. Gelboin testified that the published studies on enzyme induction by PCBs and the biochemical characteristics of the systems involved "certainly indicate that PCBs would exhibit enzyme-inducing activity in humans". Dr. Gelboin further testified: "Since there are ubiquitous low levels of chemical carcinogens in the human environment, alteration of this enzyme system would be expected to change the incidence of human cancer due to these carcinogens. Thus PCBs can be suspected of altering the incidence of cancer in humans". He added that enzyme induction by PCBs "would violate the functional integrity of the human since an enzyme inducer would be expected to change the metabolism of drugs which may be needed for therapeutic processes, the metabolism of the normal regulation steroid hormones, and carcinogenic chemicals to which man is exposed".

PCBs also cause chemical prophyria in experimental animals (rats, mice and rabbits) by stimulating the production of the enzyme delta-aminolevulinic acid synthetase, causing accumulation of porphyrins in the liver and elsewhere. PCBs have also induced other biochemical effects in experimental animals (in-

[1] Dr. Ringer also referred to another experiment at this dose level in which no significant adverse effects had been marked and suggested that the difference could be explained as due to biological variability. Since clear adverse effects were obtained in one of the two experiments 2 ppm certainly cannot be regarded as a "no-effect" level.

[2] Adenofibrosis is a term given to a greyish-white area or areas which have proliferated in the liver cells, that at times can be quite atypical, together with proliferated fibrous, scar-type tissue. It is often induced by carcinogens and is believed to be pre-cancerous.

[3] A neoplastic nodule is a nodular proliferative lesion in the liver, considered by specialists to be either precancerous or already cancer.

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cluding inhibition of immune responses in rabbits and guinea-pigs; atrophy of the thymus and/or spleen in chickens, mice, rhesus monkeys and pigs, and increased susceptibility of piglets to septicemia, of ducks to viral hepatitis, and of fish to fungal disease).

5 *Toxicity at low exposure levels.* A number of toxic effects of PCBs in mammals have been noted at very low levels of exposure For most of these critical toxicological effects, significant effects of PCBs have been noted in animals at the lowest exposure levels tested. With one exception, "no-effect" levels have not been established or reported

Mink exposed to Aroclor 1254 at 0 64 ppm in the diet suffered some mortality and total reproductive failure, and those exposed to Aroclor 1016 at 2 ppm also suffered impaired reproduction. Liver weight in weaning rats in the second generation exposed to Aroclor 1254 at 1 ppm in the diet was significantly increased, and pathological changes were also noted This is the lowest dietary level at which rats have been exposed to PCBs in multi-generational tests Stomach ulcerations and nodules were induced in dogs after exposure for two years to a dietary level of 1 ppm of Aroclors 1254 and 1260 and 10 ppm of Aroclor 1242 Rhesus monkeys exposed to 2 5 ppm Aroclor 1248 in the diet suffered dermal and stomach lesions and severe reproductive failure; several of their infants died and the survivors were impaired in behavioral and learning performance (the exposed monkeys continued to give birth to affected infants after 16–18 months on an uncontaminated diet) Rhesus monkeys exposed to 3 and 10 ppm of Aroclor 1242 suffered severe stomach and dermal lesions and died after 60–245 days These are the lowest doses to which rhesus monkeys have been exposed. Exposure of rats to 0 5 ppm (the lowest exposure level tested) of Aroclors 1242, 1248, 1254 and 1260 in the diet for 4 weeks caused significant induction of several hepatic microsomal enzymes. Exposure of male rats for 21 days to daily doses of amounts of Aroclor 1016 and 1242 comparable to 0 8 ppm in the diet has been reported as a "no-effect" level for effects on liver weight However, little weight is placed on this report because the experiment involved exposure for only 21 days, and in another experiment Aroclor 1242 had significant effects at lower doses; further, Dr. Nisbet testified that there would be no reason to doubt that Aroclor 1016 would have effects at 0.5 ppm in the diet.

Sows exposed to Aroclor 1242 at 20 ppm in the diet suffered stomach lesions and significant reproductive failure This is the lowest dose at which pigs have been tested with PCBs

6 *Toxicity in human beings.* Dr Nisbet testified that with the possible exception of the results with mink, all effects noted in mammals have relevance for humans (particularly the symptoms of PCB poisoning in monkeys)

PDCFs—which can be created by photochemical degradation of PCBs—are implicated as well as PCBs in the cause of chloracne, an occupational disease characterized by skin lesions and sometimes systemic disturbances However, the relative roles of PCDFs, PCBs and other chemicals in causing chloracne are confused

EDF's sole witness, Roscoe M Moore, Jr., an epidemiologist at the National Institute of Occupational Safety and Health (NIOSH), reported the preliminary results of an epidemiologic analysis based on medical records of two small groups of employees exposed to Aroclor 1254 at Mobil Oil Company's Paulsboro, New Jersey plant between 1949 and 1958. An elevated incidence of skin cancer (melanoma) and pancreatic cancer was found among research and development and refinery plant employees between 1957 and 1975 This was the first study associating PCBs with melanoma and/or pancreatic cancer Although the analysis is still preliminary and has limitations (including the fact that the extent of exposure of the employees to other chemicals was unknown), the findings do add to the concern expressed below with respect to potential carcinogenicity in humans.

"Yusho" is a disease reported in Japan late in 1968 and traced to consumption of rice-oil contaminated with PCBs from a leaking heat-exchanger early in that year At least 1,291 persons were severely affected, and extensive reports have been published on the episode The contaminated rice-oil is reported to have contained about 1,000 ppm of PCBs of a type equivalent to Aroclor 1248, and also contained about 5 ppm of a mixture of PCDFs.

Symptoms of Yusho are similar to those of chloracne, involving skin lesions, hyperpigmentation of the skin, and hypersecretion of the Meibomian gland of the eyelid, together with digestive disturbances, fatigue, headache, cough and abdominal pain. A number of live-born and at least two still-born children were affected. At least one baby appears to have been poisoned via its mother's milk. Recovery from Yusho has been very slow and the symptoms of internal disturbance are now more prominent than in 1968 Preliminary tabulations of deaths among Yusho victims suggest an excess of cancer, especially of the stomach and liver, but precise data are not yet available

As in the case of chloracne, the relative roles of PCDFs and PCBs in causing Yusho are uncertain. Because of the relatively large exposure of the Yusho victims to PCDFs, it is probably inappropriate to use the data from the Yusho episode to make quantitive estimates of the toxic hazard posed by PCBs to humans. However, because the PCDFs appear to have been formed in service, the Yusho episode dramatically illustrates the fact that environmentally transformed residues of PCBs may be more hazardous than the pure mixtures tested in laboratory bioassays. It also illustrates that the potential hazards of PCBs cannot be evaluated in isolation from those of the PCDFs that are usually found with them.

The work of Dr Allen and Dr McNulty indicates that the rhesus monkey is the most appropriate model for the toxic effects of PCBs in humans The skin lesions found in rhesus monkeys and their offspring fed low doses of PCBs are closely parallel to those found in humans afflicted with Yusho and chloracne. Although there are few autopsy reports on Yusho victims that specify the condition of the stomach, the long history of digestive disturbances reported in victims of Yusho and chloracne suggest a parallel with the stomach ulcerations found in rhesus monkeys

7 *Carcinogenic and related effects* Carcinogenic activity in rodents is generally accepted by the scientific community as an indicator that a chemical poses a potential carcinogenic risk to humans. This principle has been adopted as General Agency policy for evaluating carcinogenic risks,[4] has been utilized in prior Agency Decisions,[5] and has been recognized by the U.S. Court of Appeals as a matter within the Agency's expertise.[6]

On prolonged exposure to Aroclors 1016, 1242, 1248, 1254, 1260 and 1262, rats have consistently developed a variety of pathological changes in the liver, some of which represent neoplastic or preneoplastic transformations PCBs have been shown to induce carcinogenic or precarcinogenic effects in rats and mice in addition to other pathological transformations

Dr Renate Kimbrough described an experiment conducted by herself, in which Sherman rats fed 100 ppm of Aroclor 1260 in the diet for 21 months developed hepatocellular carcinomas (26/184) and neoplastic nodules (144/184) in the liver, whereas 173 control animals developed only one carcinoma and no neoplastic nodules The carcinomas were diagnosed not only by Dr Kimbrough, but also Dr Squire and two other reviewing pathologists, they were described and illustrated in detail in the report published by Drs. Kimbrough, Squire, and their co-authors As a result of this well-conducted and well-reported experiment it can be concluded that Aroclor 1260 is hepatocarcinogenic in rats.

In earlier experiments by Dr Kimbrough, exposure of rats to dietary levels of 500 ppm of Aroclor 1254 or Aroclor 1260 induced adenofibrosis in the livers of most of the animals within 6–8 months. The lesions persisted in the livers of the rats even after 10 months' maintenance on uncontaminated diets Adenofibrosis was also induced, although at lower frequency, in the livers of rats exposed to 100 ppm of Aroclor 1254 for

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[4] Interim Procedures and Guidelines for Health and Economic Impact Assessment of Suspected Carcinogens, 41 FR 21402 May 2 1976

[5] Opinion of the Administrator, Environmental Protection Agency on the Suspension of Aldrin-Dieldrin, 39 FR 37205 et seq., (Oct. 18, 1974), Decision of the Administrator on the Suspension of Heptachlor-Chlordane, 41 FR 7572, et seq (Feb 19, 1976)

[6] "EDF v EPA", 510 F 2d 1292 (D C Cir 1975), "EDF v EPA", 9 ERC 1433 (D C Cir. 1976)

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8 months. No adenofibrosis was observed in rats exposed to a similar dosage regime of Aroclors 1016 and 1242, but this is not a significant negative finding because sample sizes were very small and only males (less sensitive than females to Aroclor 1254) were tested

In one of Dr. Kimbrough's experiments in which rats were exposed to Aroclor 1254, abnormal tissues with cells similar to those in the pancreas were found growing in the livers of treated rats.

In another experiment reported by Dr. Kimbrough in which rats were exposed to PCBs for two generations, neoplastic nodules were found in the livers of the offspring treated with 100 ppm of Aroclors 1254 and 1260, 3 neoplastic nodules were found in the livers of 7 second generation rats exposed to only 20 ppm Aroclor 1254 and sacrificed at the age of only 328 days This very early development of neoplastic nodules at low dietary levels suggests that rats are more sensitive to the carcinogenic activity of PCBs when exposed in utero and in infancy than later in life.

Dr. Kimbrough also reported an experiment in which neoplastic nodules and adenofibrosis were induced in the livers of mice by exposure to a dietary level of 300 ppm Aroclor 1254 for 11 months (in one case for 6 months, followed by 5 months on uncontaminated diet).

In a comparative study carried out by Industrial Bio-Test Laboratories and summarized in detail in the Criteria Document, groups of 100 male and female Charles River strain rats were exposed for 24 months to dietary levels of 1, 10 and 100 ppm of Aroclors 1242, 1254, and 1260. Although the survival of the rats was comparatively poor and the experiment has been inconsistently reported, the most recent review of the slides by the original pathologist indicated the occurrence of liver tumors ("hepatomas" and "cholangiohepatomas") in animals treated with all three Aroclor mixtures. The incidence of liver tumors in the rats exposed to 100 ppm was 3/20 for Aroclor 1242, 6/27 for Aroclor 1254, and 7/27 for Aroclor 1260, versus 0/20 in controls.

In addition to lesions listed as tumors, the most recent report on the Industrial Bio-Test experiment shows high frequency of "nodular hyperplasia"—a lesion now authoritatively considered to be at least pre-cancerous. The reported incidence of nodular hyperplasia in the rats treated as 100 ppm was 8/20 for Aroclor 1242, 13/27 for Aroclor 1254 and 7/27 for Aroclor 1260, versus only 1/23 for controls. Nodular hyperplasia was reported as frequent even in the rats treated at 10 ppm, 2/30 for Aroclor 1242, 3/26 for Aroclor 1254, and 9/23 for Aroclor 1260, versus only 1/23 for controls. Dr Nisbet testified that although this increase in incidence was not significant for Aroclor 1242 considered alone, such a conclusion can be drawn for the three Aroclors considered together In addition to liver tumors, the incidence of tumors of the pituitary gland was elevated in all treated groups in this experiment

Although the results of the Industrial Bio-Test experiment need further re-evaluation, the reported results constitute prima facie evidence of carcinogenic effects of Aroclors 1242, 1254, and 1260 at 100 ppm and even at 10 ppm in the diet The results of the Industrial Bio-Test experiment do not suggest a marked difference between the effects of Aroclors 1242, 1254 and 1260 in inducing tumors and nodules in the livers of rats The results are therefore relevant to weighing the potential effects of Aroclor 1016, in view of the close chemical similarity between Aroclors 1016 and 1242.

In three other experiments summarized in the Criteria Document, Japanese-made PCB mixtures (Kanechlors 500, 400, and 300) are reported to have induced a variety of cancerous and precancerous lesions in the livers of rats and mice. The lesions were variously described as cholangiofibrosis, nodular hyperplasia, multiple adenomatous nodules, and hepatocellular carcinoma Although these experiments were conducted for relatively short periods at high dose-levels, they support and extend the findings that Aroclor mixtures have carcinogenic effects in rats and mice.

In another study in rats, feeding with PCBs (Kanechlor 500) appeared to delay or inhibit the action of three other liver carcinogens However, pretreatment with PCBs greatly increased the susceptibility of rat livers to acute injury by vinyl chloride monomer, a known human liver carcinogen This effect is attributable to the action of PCBs in stimulating the liver microsomal enzyme system, which oxidizes vinyl chloride to a biologically active metabolite; such activation is known to be required to convert vinyl chloride into an active mutagenic agent Numerous studies have shown that PCBs activate mutagens (i.e., carcinogens and presumptive carcinogens) to their biologically active forms in vitro by stimulating the mixed function oxidase system in liver microsomal preparations In some cases PCB-stimulated enzymes activate secondary carcinogens to biologically active forms; in other cases they de-activate primary carcinogens.

It has become standard practice to use Aroclor 1254 as a stimulator of the mixed function oxidase system in bacterial mutagensis bioassays to screen suspected carcinogens The action of PCBs in activating some carcinogens and mutagens, while de-activating others, can be understood as a result of their exceptional potency and broad-spectrum action in stimulating liver microsomal enzymes These observations are of profound importance in evaluating the environmental significance of PCBs, because PCB mixtures (including Aroclors 1254, 1242, and 1016) have been found to stimulate the mixed function oxidase system at extremely low doses According to Dr Gelboin, stimulation of the microsomal enzyme system is expected to change the incidence of cancer in humans.

In addition to the carcinogenic and co-carcinogenic effects of PCBs, the immunosuppressive effects of PCBs are also expected to be important in potentiating the effects of other carcinogens, since suppression of immune responses may make an animal more susceptible to establishment of neoplastic cell lines and development of malignant tumors

The objectors offered no evidence whatsoever that would refute or modify the evidence introduced by EPA that PCBs are carcinogenic and co-carcinogenic in animals Nor did they offer any evidence that would call into question the implication of this finding that PCBs are likely to be carcinogenic in humans PCBs have shown by adequate test animals to be carcinogenic in animals Following the consensus of scientific opinion on the subject, PCBs should therefore be regarded as a potential carcinogenic hazard to humans.

D. PERSISTANCE AND MOBILITY OF PCBS

Except for the least chlorinated homologs, PCBs are resistant to degradation by metabolism. Bacteria can metabolize biphenyls and mono- and dichlorobiphenyls fairly rapidly, but tri- and tetrachlorobiphenyls are degraded much more slowly and pentachlorobyphenyls are degraded hardly at all Aquatic invertebrates and fish can metabolize trichlorobiphenyls to a substantial degree but have little ability to metabolize tetra- or pentachlorobiphenyls. Birds and mammals can metabolize tetra- and pentachlorobiphenyls to hydroxy derivatives at varying speeds, but have little ability to metabolize hexa- or higher chlorobiphenyls.

PCBs have a long life in the environment. In one case they were identified in anaerobic marine sediments that could be dated to the mid-1940's More chlorinated homologs have a life-time of years, and perhaps decades, in the environment This storage of highly concentrated levels of PCBs in the tissue leads to exposure of organs of the animal to PCBs via the circulatory system, which in turn can cause acute or chronic adverse effects to that organism When organisms containing PCBs in their tissues are consumed, the consumers may in turn suffer chronic or acute adverse effects.

A series of experiments in which various PCBs (including Aroclor 1016) were incubated in the laboratory with anaerobic lake sediments for up to nine months showed no measurable degradation Similar experiments with various di-, tetra-, penta- and hexachlorobiphenyls involving incubation in soils with and without cattle manure for one month showed no indication of any metabolism

PCBs are mobile in the environment and are transported in solution, by motion of suspended sediments, as vapors or airborne particulates, or in the tissues of mobile animals Dr David Young described an extensive series of investigations of the occurrence and dispersal of PCBs in the coastal waters of the Southern California Bight between 1972 and 1975. These investigations showed that the principal route of entry into the

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coastal waters of PCB mixtures resembling Aroclor 1242 (tri- and tetrachlorobiphenyls) and Aroclor 1254 (penta- and hexachlorobiphenyls) was via municipal wastewater discharges through offshore sewage outfalls. As a result of the discharges, PCBs had become widely distributed in sediments and biological organisms (crabs, fish, mussels, etc.) in the whole area. The concentrations of both groups of chlorobiphenyls were highest in both sediments and biota in the vicinity of the outfalls.

Dr. Young's monitoring studies have shown a marked decline in the input of PCBs of the 1242-type. However, although the rate of input of PCBs has fallen by a factor of at least 14 since 1962, the concentration of PCBs in sediments and fish have fallen by factors of only 1.2 and 1.9 respectively. Similar findings were obtained for DDT and metabolites, adding to the degree of confidence in the data on PCBs. Dr. Young's conclusion from this study was that "contamination of sewer and ocean bottom sediments by chlorinated hydrocarbons such as PCBs can cause these synthetic compounds to persist in bottom-feeding fishes long after major reductions have been made in the dominant inputs." This conclusion about the persistence of PCBs in sediments and fish applies as much to tri- and tetrachlorobiphenyls as to penta- and hexachlorobiphenyls.

As a result of their persistence and mobility in the environment, PCBs have become widely (indeed almost universally) distributed through the world. Dr. Robert Risebrough introduced a summary of his own extensive studies which reported, *inter alia*, the identification of PCBs residues in seabirds from the Aleutian Islands, New Zealand, Iceland, Peru, Southern California, and Greenland, fish from the Aleutian Islands and Iceland, seabird eggs from the Antarctic and the South and North Atlantic Oceans, air over the North Atlantic Ocean, snow on the Antarctic Peninsula, and seawater from the Pacific Ocean off California.

PCBs are widely distributed in the environment in North America, having been found in fresh waters, river sediments, fish, birds, mammals, and human tissues, in addition to their occurrence in the marine environment described in the testimony of Dr. Young and Dr. Risebrough.

E. BIOACCUMULATION OF PCBS

One of the most important environmental properties of PCBs is their tendency to be "bioaccumulated" or "bioconcentrated" by aquatic organisms into their tissues to levels much higher than in the ambient water. This property results from the high solubility of PCBs in lipids and their low solubility in water. There is a further tendency for PCBs to be concentrated into animals to levels higher than in their food, a phenomenon known as "biomagnification." Within organisms, PCBs are further concentrated into certain areas, especially the fat.

Fish can bioaccumulate PCBs directly from the water, in addition to uptake in the food, and in most cases direct uptake from water is more rapid and leads to much higher accumulation in the tissues. This uptake is initially rapid, followed by a gradual decrease in the rate of uptake until a steady state is approached. The time required for approach to the steady state is from one day up to several months, depending on the size of the invertebrate or fish. Although the steady state is sometimes described as an "equilibrium", there is no evidence in the record from long-term studies that aquatic organisms reach true equilibrium with PCBs in the water. Dr. Nisbet characterized the steady state as "quasiequilibrium" in which concentrations of PCBs in the water and/or the fish change slowly. In one laboratory experiment PCB concentrations in fish tissue approached a steady state within 100 days but continued to rise slowly until the experiment was terminated at 250 days. In another study of lake trout of different ages taken from the same body of water, concentrations of PCBs increased steadily with age, rising from 1–2 ppm at the age of 1 year to about 20 ppm at the age of 11–12 years.

In the "steady state" condition the concentrations of PCBs in the tissues of fish exposed to different concentrations in the water are proportional to the ambient water concentrations (although "hot spots", sediments and other factors may affect proportionality). It is possible to define a "bioaccumulation factor" as the ratio between concentrations of PCBs in the fish tissues and in the water. The bioaccumulation factor is independent of the ambient levels and is characteristic of the fish and the duration of the exposure. The bioaccumulation factor is an operationally-defined ratio dependent on the circumstances of exposure.

Bioaccumulation factors for PCBs in fish, measured in laboratory conditions, were fairly extensively reported in the Agency's Criteria Document and in the testimony of a number of witnesses (including one EIA witness). With only two exceptions, none of the experiments, however, extended for more than 42 days, and they thus represent only the initial uptake of PCBs and approach to steady state. The two exceptions were the 8-month studies of fathead minnows conducted by Drs. Nebeker, Veith and others, in which residues in the fish were 2–4 times higher at the end of the 8-month experiment than in fish sampled after 30 days. Thus, data for the experiments conducted for shorter periods underestimated the potential for bioaccumulation in the tested fish.

In the 8-month experiments described above, the bioaccumulation factors measured at the end of 8 months varied between 32,000 and 274,000 for Aroclor 1242, 46,000 and 307,000 for Aroclor 1254; 60,000 and 120,000 for Aroclor 1248, and 160,000 and 270,000 for Aroclor 1260. The figure of 274,000 was discussed extensively in the record as it played an important role in the proposed standard-setting and counsel for objectors (both environmental groups and industries) objected to it. Environmental groups argued for a much higher rate of bioaccumulation, leaning heavily on field rather than laboratory data. Industry groups for a somewhat lower rate (for certain Aroclors) which is discussed *infra*. The 274,000 bioaccumulation rate was based upon the mean of 3 residue determinations of male fish exposed to the lowest concentration (0.66 parts per billion) of Aroclor 1242. Although objectors repeatedly attempted to denigrate these measurements, there is no reason to regard them as any less or more reliable than others obtained from these experiments. Although the mean figure for the six fish used in this test was reported by Dr. Nebeker as 274,000, Dr. Nisbet did testify that a scientifically meticulous averaging process would have yielded a figure of 345,000, and the average bioaccumulation factor for four of the six was 447,000.

Although all the experiments of bioaccumulation indicated biological variability in storage of PCBs, even among fish raised in the same tank, this figure of 274,000 for the male fathead minnows was felt to be as reliable as any other in the record, and is derived from the only experiment involving long-term exposure of any fish to Aroclor 1242. Short-term exposures (up to 32 days) of other fish to Aroclor 1248, 1254 and 1260 produced estimates of bioaccumulation factors in the range of 15,000–71,000.

Two experiments have been reported in which bioaccumulation of Aroclor 1016 by fish has been measured. In an experiment conducted by Mr. David Hansen, pinfish exposed to Aroclor 1016 at concentrations between 0.8 and 13 parts per billion accumulated PCBs to levels up to 65,000 times the ambient concentration within 42 days, but the data do not clearly demonstrate that a steady state had been reached. In an experiment conducted by Dr. Gilman Veith fathead minnows exposed to Aroclor 1016 for 30–32 days accumulated PCBs to levels up to 60,000 times those in the ambient water. The bioaccumulation factors increased steadily between 10 and 32 days of exposure. This degree of bioaccumulation is approximately half that reported in fathead minnows exposed to Aroclor 1248 and 1260 in the same circumstances and for the same period of time.

This is one of several pieces of evidence in the record which suggest that tri- and tetrachlorobiphenyls are stored in fish somewhat less efficiently than penta- and hexachlorobiphenyls. In comparable studies with sheepshead minnows Aroclor 1254 was bioaccumulated to levels about twice as high as those of Aroclor 1016. However, comparable studies with pinfish found similar bioaccumulation factors for Aroclor 1016 and 1254. Other relevant data, including studies with pure isomers, are included in the Criteria Document.

After reviewing all of the foregoing data Dr. Nisbet concluded that "the differences in retention between tetra- and higher chlorobiphenyls are small, no more than a factor of 2-3 in the circumstances of these experiments." EIA witnesses Drs. Lauer and Mueller conceded

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that this was a fair summary of the evidence.

The only aquatic biologist who testified on behalf of the industry objectors was Gerald J Lauer, senior scientist and Director of Operations of a private consulting firm named Ecological Analysts, Inc., of Middletown, New York. He has never actually measured bioaccumulation of PCBs in fish and has had no personal experience with PCBs except to review some literature

Some scientists conducting bioassay experiments to determine toxicity or bioaccumulation report the "nominal" or pre-determined concentration levels with which the water is dosed; some report the actual measured concentrations in the water; sometimes both figures are reported It is generally preferable to use the measured concentration because during the course of the tests PCBs tend to some degree to adsorb to container walls, or settle out. Consequently the measured concentration is likely to be lower than the nominal concentration The use of the "measured" concentration is more likely to reflect the level to which the organism was actually exposed, and this is a critical piece of data in establishing bioaccumulation factors as well as toxicity levels.

In his affidavit as originally filed in these proceedings Dr. Lauer tabulated some data on bioaccumulation using the "nominal" exposure levels He then concluded on cross-examination that if one is seeking to determine what the organism was actually exposed to during the bioassay test, one should measure the actual concentration in the water Therefore, while on the stand Dr. Lauer revised the presentation of data in his affidavit so as to recalculate bioaccumulation factors for Aroclor 1016 based upon measured water concentration.

Moreover, if one is making a comparison between the bioaccumulation factors for Aroclor 1016 and any of the more highly chlorinated Aroclors, the scientifically sound way to do this is to compare tests using the same species, the same life stage of that species; and a similar exposure time. This principle was accepted by Dr. Lauer. Thus when Dr. Lauer drew n comparison of the relative bioconcentration factors of Aroclors 1254 and 1016, he used the data presented by Hansen involving adult sheepshead minnows, wherein each group of test organisms was exposed for 28 days. In his affidavit, using nominal concentrations, he found a concentration factor for Aroclor 1254 of 23,000 and for 1016 of 8,000 or a 2.8 to 1 ratio. At the hearing, during cross-examination, he testified further that if one were to compute the respective bioaccumulation factors based upon actual measured concentrations in the water, the average factor for 1254 would be approximately 50,000 and that for 1016 it would be approximately 24,000. This would indicate that the bioaccumulation factor for Aroclor 1254 is approximately twice that of Aroclor 1016

Dr Nisbet testified that the concentrations of PCBs in the edible tissue of fish were usually lower than the average concentrations in the whole fish—typically by a factor of about 3 This has relevance in calculating safety factors for human exposure or in evaluating risks to humans, but is not found to be relevant in calculating the margin of safety for wild birds and mammals which eat whole fish

Studies demonstrating bioaccumulation of PCBs by aquatic invertebrates were entered into the record, and showed that invertebrates such as crabs and shrimp absorb PCBs not only from water but also from contaminated food and sediments. Reported bioaccumulation factors range up to 47,000 in *Daphnia magna*, 108,000 in scuds, 60,000 in snails, 26,000 in shrimps, and 165,000 in the edible tissues of oysters There is little or no differentiation of lower and higher chlorobiphenyl homologs during uptake and storage by invertebrates, in fact, in one study with a fresh-water crustacean, the tri- and tetrachlorobiphenyls in Aroclor 1254 were differentially accumulated by factors 2–8 times greater than the hexa- and heptachlorobiphenyls

The objectors introduced no evidence whatsoever that would rebut, modify, or weaken the evidence entered into the record by EPA witnesses, that both lower and higher chlorinated biphenyls are bioaccumulated by high factors into the edible tissues of oysters and other aquatic invertebrates

The Criteria Document sets forth extensive evidence that aquatic organisms, including fish, in natural waters frequently bioaccumulate PCBs to much higher levels than have been measured under controlled conditions of exposure in the laboratory. This evidence includes, *inter alia*, bioaccumulation factors exceeding 470,000 for shrimps, 230,000 for crabs, and 670,000 for fishes collected in Escambia Bay, Florida Additional new data were provided in the testimony of Dr. Risebrough, who reported measurements of bioaccumulation of PCBs by oysters by factors ranging up to 690,000.

Although Dr. Nisbet expressed reservations in his prepared statement about two superficially discrepant sets of data from natural water, new data introduced during the hearing resolved these discrepancies. In particular, Dr. Veith and Dr. Risebrough reported measurements of PCB levels in the water of Lake Ontario Dr. Veith's data showed the concentrations to be less than 6 parts per trillion, while Dr. Risebrough presented precise measurements of concentrations in two water samples in the range of 2.9–3.4 parts per billion Relating these water concentrations to reports of PCB levels in fish from the lake ranging up to 30 ppm (0.74–17 ppm in edible tissue of various species), these data suggest bioaccumulation factors in the range of 1-10 million. Dr. Nisbet testified that the data of Drs. Veith and Risebrough "have cleared up the last two remaining substantial pieces of evidence which have cast doubt upon that conclusion . . ."

Several reasons have been given as to why wild fish should bio-accumulate PCBs to a greater degree than experimentally exposed fish in the laboratory Wild fish are exposed to PCBs not only in water but also in food and sediments at least some fish continue to accumulate PCBs over a period of years as they grow older and fatter. Moreover, PCBs are patchily distributed in the environment and the levels in the fish may reflect their integrated history of exposure as they have moved through natural waters rather than strict equilibrium with the levels in the ambient waters where they are caught.

Dr Nisbet testified that in attempting to predict the degree of exposure to PCBs of consumers of fish from natural waters, estimates of typical bioaccumulation factors obtained from field measurements are more relevant than those obtained in the laboratory While laboratory measurements made under controlled conditions are precise and provide significant information, they do not constitute a good model of the situation in the field, including multiple routes of exposure, patchy distribution of PCBs and lifetime exposures. No assumptions covering the circumstances are necessary to extrapolate from field measurements to predict the situation in the field

Dr. Nisbet pointed out that residues of PCBs in wild fish, molluscs, and crustaceans are quite variable, representing bioaccumulation factors as low as 300,000 to as high as 10 million, but testified that in his scientific judgment a 'value of 3 million would be an appropriate figure to use as a 'typical' bioaccumulation factor" for predictive purposes He specified that his figure of 3 million represented his best judgment for penta- and hexachlorobiphenyls, whereas a figure of 1 million would be his best estimate for tri- and tetrachlorobiphenyls While emphasizing the variability in bioaccumulation factors, he stated "I do not think that a responsible, well-informed scientist would question the evidence that bioaccumulation factors for this and other chemicals in wild fish would frequently exceed those observed in laboratory experiments conducted for only a few weeks."

Extensive data have been incorporated into the record on the intake, storage, and excretion of PCBs in birds and mammals Testimony in this proceeding focused upon the storage of PCBs in mammalian tissue as a putative measure of hazard. Humans appear to retain PCBs in their tissues more efficiently than any other mammals that have been studied to date Insofar as the tissue levels that have been sampled represent the quantities of PCBs that are circulating within the organism, with consequent exposure of critical target organs to PCBs, this implies that for a given dietary concentration humans will have tissue levels up to 10 or more times those of other experimental animals

Although the human population is widely exposed to tri- and tetrachlorobiphenyls as a result of their widespread distribution in fish, tri- and tetrachlorobiphenyls appear to be comparatively poorly represented in human fat samples EIA witness Dr Wolfgang Mueller attempted to argue that lack of storage of tetrachlorobiphenyls implies a lack of toxic effects However, in fact it is

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exposure rather than storage that is significant in determining the degree of hazard. When asked to explain the significance of human exposure to tetrachlorobiphenyls, Dr. Nisbet stated that "the significance is that after they are exposed, the tetrachlorobiphenyls are circulated throughout the body [in] the blood and therefore the various target organs which they might affect within the human body are exposed to them." For example, many of the studies of the toxic effects of PCBs show effects on the liver of mammals.

With respect to the industry position on accumulation tendencies (presented in the context of argument for different standards for certain Aroclors, which is discussed below), Dr. Lauer testified that Aroclor 1016 has been shown to bioaccumulate by at least a factor of 73,000 based upon measured concentrations in laboratory tests. His evidence indicates that Aroclor 1016 accumulates at a factor half to two-thirds that of the highly chlorinated Aroclor 1254. He conceded that the bioaccumulation factor of fish in the Hudson River, where Aroclor 1016 is discharged from the General Electric Corporation capacitor plants, could be as high as 1 million based upon levels found in water and in fish. Based on Dr. Lauer's own testimony, there is no ground for the assertion by EIA and Westinghouse that Aroclor 1016 will not bioaccumulate at factors above 50,000. Even using laboratory figures alone which were discussed by Dr. Lauer, the highest bioaccumulation figure he discussed for Aroclor 1254 was 307,000. Using the ratio between 1254 and 1016 of 2 to 1 which he described in his testimony, this would suggest a bioaccumulation potential for 1016 of over 150,000; using the 3 to 2 ratio suggested in the Westinghouse brief, a bioaccumulation potential of over 200,000 would result.

F. SEPARATE CRITERIA AND STANDARDS FOR CERTAIN AROCLORS UNWARRANTED

Both EIA and Westinghouse urge the establishment of separate, less stringent standards for Aroclor 1016, and Westinghouse suggests a separate standard for Aroclor 1242 as well. This contention has received considerable attention in Agency testimony and evidence.

Much of the evidence of the harmful properties of PCBs has been established by reference to experiments and data-gathering involving Aroclors 1016 and 1242. All PCB mixtures currently in use, including Aroclors 1016 and 1242, are capable of inducing severe toxic effects at low levels, with only minor variations in behavior in some instances; there is therefore not sufficient justification for establishing separate standards for various mixtures.

All PCBs are mixtures of biphenyl molecules which have varying numbers of chlorine atoms substituted in place of hydrogen atoms at certain locations on the molecules. The mixtures presently marketed by Monsanto—Aroclors 1221, 1016, 1242 and 1254—are four out of several hundred possible mixtures. With respect to these mixtures, Aroclors 1016 and 1242 are very similar in molecular and isomeric constitution, the most important difference being that 1016 contains only 1 percent of pentachlorobiphenyls while 1242 contains 8 percent. Aroclors 1016, 1242 and 1254 contain 21, 25 and 21 percent respectively of tetrachlorobiphenyls. Tetrachlorobiphenyls have been utilized in a number of studies discussed in the findings above. In addition, the constitution of PCB mixtures changes after they are released into the environment, so that environmental residues usually do not correspond to commercial mixtures. In their effort to have the Agency carve out special standards for 1016 and 1242, EIA and Westinghouse have ignored these critical characteristics of PCBs.

As mentioned, tetrachlorobiphenyls are important elements of 1016 and 1242, tetrachlorobiphenyls are persistent and hardly degraded at all by bacteria. In an experiment in which 1016 was incubated with activated sludge, 14 days' incubation had little effect on the tetrachlorobiphenyls and other higher components. While pentachlorobiphenyls and higher CBs are taken up and stored by fish and other aquatic organisms more efficiently than trichlorobiphenyls and lower CBs, differences in retention between tetrachlorobiphenyls and higher chlorobiphenyls are small, no more than a factor of two or three. Although most environmental residues of PCBs are in the form of pentachlorobiphenyls and higher CBs, trichlorobiphenyls and tetrachlorobiphenyls are widely stored in fish in the U.S. As explained elsewhere herein exposure to tetrachlorobiphenyls is harmful (even if they are stored less efficiently than higher chlorobiphenyls) because after ingestion, the tetrachlorobiphenyls are circulated through the body in the blood, with consequent exposure to critical target organs.

Extensive data on the toxicity of Aroclor 1016 to aquatic organisms were incorporated into the record in the Criteria Document and in the testimony of two EPA expert witnesses. There is little significant difference between the toxicities of 1016 and 1242, 1248 and 1254 to aquatic organisms. Only three reported studies suggest any appreciable difference and the results are inconclusive:

(a) Aroclor 1016 was about 8 times more toxic than Aroclor 1248 in an acute toxicity test with channel catfish.

(b) In chronic bioassays with pinfish, Aroclor 1016 was somewhat less toxic than Aroclor 1254.

(c) In bioassays with sheepshead minnows, Aroclor 1016 appeared significantly less toxic to the eggs than Aroclor 1254. However, it is questionable whether this difference (observed in laboratory tests) would be relevant to field conditions, because another report showed hatching failure in rainbow trout eggs containing PCB residues similar to Aroclor 1242 at concentrations of only about 2 to 7 ppm.

The testimony of Dr. Lauer that "the more recent and, for the most part, the more reliable data indicate that Aroclor 1016 ranges from slightly less toxic to one hundred times less toxic than the more chlorinated Aroclors, e.g., Aroclor 1254 [sic]" relies solely on an article by David Hansen entitled "Effects of Aroclor 1016 on Embryos, Fry, Juveniles, and Adults of Sheepshead Minnows (*Cyprinodon variegatus*)" (1975). In fact the referenced Hansen study shows that although the toxicity of Aroclor 1016 is substantially less than that for 1254 for newly hatched fry, the toxicity of Aroclor 1016 is comparable to that of 1242 and 1254 for all other life stages. Thus Hansen in this article gave the following summary with respect to 1016:

> In the laboratory, however, it (Aroclor 1016) is as acutely toxic to oysters, brown shrimp (*Penaeus aztecus*) and pinfish as Aroclor 1242 and as toxic to oysters and pinfish as Aroclor 1254 (Hansen, Parrish and Forrester, 1974). Its delayed toxicity to pinfish in exposures lasting 14 or more days is similar to that found with Aroclor 1254 (Hansen, Parrish, and Forrester, 1974).

Dr. Nisbet, on cross-examination, testified to the same effect. In reaching his conclusion, Dr. Lauer apparently overlooked the additional studies, cited above, which showed adverse effects from Aroclors 1016 and 1242 at low levels.

There is no sound basis for concluding that Aroclor 1016 is significantly less effective than the higher chlorinated PCB mixtures in causing critical toxic effects in mammals. There are several reasons why this is so:

(a) In cases where toxicity data for Aroclor 1016 are not available, it is reasonable to estimate the toxicity of Aroclor 1016 by extrapolation from the toxicity of Aroclor 1242, since the two mixtures are very similar in constitution. If a toxic effect were caused by higher chlorinated compounds (not present or present only at low levels in Aroclor 1016), it would be expected to be manifested by a difference in toxicity between Aroclors 1242 and 1254. Aroclor 1242 has 8 percent pentachlorobiphenyls versus 48 percent for Aroclor 1254, and 1 percent hexachlorobiphenyls versus 23 percent for Aroclor 1254. Yet Aroclor 1254 has not been demonstrated to be significantly more toxic than Aroclor 1242.

(b) The critical toxic effects in mammals relied upon by the Agency in formulating its ambient water criterion are relevant to Aroclor 1016, as follows:

(1) Dr. Robert Ringer noted reproductive failure in mink at dietary levels of Aroclor 1016 at 2 ppm, only a slightly higher dose than the dietary level of 1 ppm Aroclor 1254 which he found to be toxic for the same conditions or the dietary level of 0.64 ppm which platonow and Karstad found using Aroclor 1254.

(2) Increased liver weight in young rats was found by Iverson after dosage at 1 mg/kg of Aroclor 1016 and 1242 per day (comparable to 8 ppm in the diet) for 21 days.

(3) Although no studies are known to have been conducted on dogs with Aroclor 1016, a high incidence of stomach nodules and ulcerations have been reported in dogs fed 10 and 100 ppm Aroclor 1242.

(4) Dr. Wilbur McNulty found rhesus monkey mortality occurrence in eight

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months from exposure to 30 ppm of Aroclor 1242 and to 10 ppm in shorter periods. In light of studies performed on monkeys with both Aroclors 1242 and 1248, monkeys appeared to be more sensitive to Aroclor 1242, the mixture most similar to Aroclor 1016.

(5) Increased activity of hepatic microsomal enzymes has been reported by Iverson in rats treated with Aroclor 1016 at dosage levels as low as 1 mg/kg per day.

(6) The effects on liver weight and enzyme activity for Aroclor 1016 were similar to those observed for Aroclor 1242 in the comparative study performed by Iverson on male rats, and were at least comparable to those observed in other experiments with Aroclors 1254 and 1260.

(7) Observations as to the similar enzyme inducing effects of Aroclors 1016 and 1242 warrant a conclusion that since 0.5 ppm of Aroclor 1242 considerably increased rat microsomal enzyme activity after four weeks, similar effects can be expected from similar low doses of Aroclor 1016. The degree of increased activity of various enzymes to be protected from such a dosage would be between 10 and 60 percent. Thus, it appears that chronic exposure to low dose levels of Aroclor 1016 is likely to cause an effect on enzyme activity in the human liver.

(8) The results of the Industrial Bio-Test rat experiment did not suggest a marked difference between the effects of Aroclors 1242, 1254 and 1260 in inducing pathological changes in the livers of rats.

(9) Tumors have been produced in rats treated with Aroclor 1242. Nodular hyperplasia, a term now generally understood to refer to neoplastic changes, has been reported in rats treated with Aroclor 1242 at only 10 ppm.

(c) Only three experiments have been reported in the record which suggest differences in toxicity to mammals between Aroclors 1016 and 1242.

(1) Mueller, the EIA witness, pointed out differences in the pathological changes induced in rat livers by exposure to Aroclors 1016 and 1242, as summarized in Tables III 9 4 and III 9 5 in the Criteria Document. However, Dr. Kimbrough, who conducted the experiment in question, stated that the differences were minor and that the small sizes of the sample groups precluded firm conclusions.

(2) An experiment has shown some apparent differences in the induction of liver enzymes and porphyria in rats by Aroclors 1016 and 1242. However, the rats were examined only after 7 days and 6 months of exposure, and because of differences in the temporal course of induction, it appeared that firm conclusions could not be drawn.

(3) Aroclor 1016 markedly reduced the gonad weights of female rats after 90 days' exposure to 30 and 100 ppm in the diet, whereas under the same conditions Aroclor 1242, 1254, and 1260 did not. Thus in this case Aroclor 1016 produced an adverse effect not produced by the other mixtures.

The biological degradability of the lower chlorinated components of Aroclor 1016 may not represent detoxification because the lower biphenyls may form metabolites which can lead to increased toxic effects. One experiment indicated that the acute toxicity of the primary metabolite of a tetrachlorobiphenyl isomer was five times higher than that of the parent compound. There is ample other evidence in the record that metabolism of tetrachlorobiphenyls proceeds via toxic intermediates, including arene oxide intermediates which have been implicated as a causative agent in toxic, carcinogenic and mutagenic effects.

EIA claims in its post-hearing brief that 99 percent of Aroclor 1016 consists of mono-, di-, tri- and tetrachlorobiphenyls which are rapidly metabolized with little accumulation. As previously stated, the record establishes that trichlorobiphenyls are metabolized much more slowly than mono- and dichlorobiphenyls and higher CBs (including tetrachlorobiphenyls) hardly at all. Tri- and tetrachlorobiphenyls are widely stored in fish throughout the U.S. On cross-examination at the hearing both of EIA's witnesses, Dr. Lauer and Dr. Mueller, were shown this data, and each testified that they had no reason to disagree with it. Dr. Lauer also testified that Aroclor 1016 has been shown to bioaccumulate by at least a factor of 73,300, based upon conservative laboratory tests, and he conceded that the bioaccumulation factor for fish in the Hudson River (where Aroclor 1016 is discharged from General Electric Corporation plants) could be as high as 1 million based upon levels found in water and in fish.

Westinghouse alleges that two comparison studies conducted by Dr. Renate Kimbrough on rats show that lower chlorinated PCB mixtures are less hepatotoxic than the higher chlorinated mixtures. With respect to Dr. Kimbrough's comparative study of the effects of Aroclors 1016 and 1242 on male rats, Dr. Mueller conceded on cross-examination that hepatotoxic effects more serious than enlarged hepatocytes were noted for Aroclor 1016 at other exposure periods, as well as at 8 months.

Contrary to Dr. Mueller's conclusions, the hepatotoxic effects found for male rats in Dr. Kimbrough's 1016/1242 study were not substantially different from those found for male rats in their earlier study with Aroclors 1254 and 1260. Dr. Mueller conceded that in fact vacuolated cytoplasm, which admittedly referred to the same phenomenon as an increase in lipids, was found by Dr. Kimbrough in both studies, and that the absence of adenofibrosis in the 1016/1242 study did not create a significant difference between the two studies once one fairly compared the results for male rats at the same dose levels and for the same time period.

Finally, as to a comparison between Aroclors 1016 and 1242, Dr. Mueller was shown to be in error when he concluded that Aroclor 1242 would be expected to be retained to much higher levels of Aroclor 1016. Dr. Kimbrough found residue levels of Aroclor 1016 in the adipose tissue of rats to be almost double those for 1242.

Contrary to EIA's claim in its brief, the Iverson study has found both 1016 and 1242 to cause significant enzyme induction in male rats after 21 days at daily dose levels as low as an equivalent of 8 ppm. Dr. Harry Gelboin, EPA's expert witness on enzyme induction testified that the Iverson study demonstrated that Aroclors 1242 and 1016 were equally potent as enzyme inducers and that the twenty percent increase in enzyme induction over controls found for male rats could be very significant over an extended period of time. Dr. Gelboin further noted that based on his studies with enzyme inducers of the same class as PCBs, in virtually all cases, a compound which was an enzyme inducer in rats and mice was also found to be an enzyme inducer in primate or human cells.

EIA attempted to refute the findings from the Iverson study with "two similar studies" in which no similar effects were found. The first study was one conducted for only 6 days by Bickers, et al. As was pointed out in the Criteria Document, the disparity in results was probably due to the more extended dosage regime in the Iverson experiment. The second study by Goldstein, et al. was performed on female rats. Dr. Gelboin testified that male rats would be expected to be more responsive to enzyme inducers than female rats. Nevertheless, Goldstein noted marked increases in liver weight and all drug metabolizing systems from exposure to Aroclor 1242. In the beginning of the study Aroclor 1242 has more severe effects than Aroclor 1016. However, after six months exposure, the effects of Aroclor 1016 were much more similar to those of Aroclor 1242.

EIA erroneously argued that Dr. Robert Ringer in his Aroclor 1016 tests on mink found no significant adverse effects at or below 25 ppm. In fact he found impairment of reproductive performance in the females at levels as low as 2 ppm. Although no statistical analysis has been performed on the results in Table 1 to his Exhibit F, Dr. Ringer testified that looking at the table as a whole it was significant to note that, as dosage increased, poorer reproduction resulted—the number of females that whelped out of those that were mated was reduced, the number of kits born alive decreased, the average number of kits born per mated female decreased and the number of kits alive at four weeks of age also decreased. Dr. Ringer testified that results from an earlier unpublished study with Aroclor 1016 in which no adverse effects were found at the 2 ppm level did not draw into question his more recent conclusions. Since adverse effects were noted in at least one study, 2 ppm cannot be considered a "no effect" level.

In addition to the information set forth above, derived from laboratory experiments, there are important data derived from field observations which further support the proposition that it would be inappropriate to establish separate and different criteria of effluent standards for different commercial mixtures

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The constitution of commercial mixtures of PCBs changes as they pass through the environment, so that plants, animals and humans are exposed to mixtures whose constitution differs from those whose toxicity has been tested in laboratory experiments.

The record contains ample evidence to sustain the Agency's original conclusion that there is no justification for setting separate and more relaxed standards for Aroclors 1016 and 1242. Indeed, in light of the statutory mandate to provide an "ample margin of safety", any doubts in this area should be resolved in favor of protection, and against making distinctions among Aroclors.

C. PRESENCE OF TOXIC IMPURITIES IN PCBS

Most commercial PCB mixtures contain small quantities of polychlorinated dibenzofurans (PCDFs) as impurities. PCDF content in PCB mixtures is subject to considerable variation and uncertainty. PCDFs can be formed by photochemical reactions in the environment in sunlight and as a result of metabolism. PCDFs are potentially much more toxic than the parent CB, but it is unlikely that the low levels of PCDFs present in PCBs are a significant factor in the mixtures' high toxicity in rhesus monkeys, the valuable animal model for human poisoning by PCBs. In any event, it appears impossible to disentangle the toxic effects of PCDFs from those of PCBs. In setting criteria and standards for PCBs, it is necessary to recognize that the mixtures found in the environment may be more (or less) toxic than the commercial products studied in the laboratory. This adds an additional degree of uncertainty to the assessment of potential environmental hazards, making it inappropriate to set different standards for different Aroclor mixtures, and difficult to establish definitive standards above zero.

II. MONITORING CAPABILITY

In its proposed standards for PCB manufacturers, electrical capacitor manufacturers, and electrical transformer manufacturers, the Agency specified that the acceptable analytical method is that identified in Part 136 of Title 40 of the Code of Federal Regulations, "except that a one liter sample size is required to increase analytical sensitivity." (Section 129.105 (b) (2), (c) (2), and (d) (2).) 40 CFR Part 136 includes express provision for application for and approval of alternate test procedures. (40 CFR 136.4 and 136.5, as amended, 41 FR 52780.)

The official EPA analytical method for sampling and analyzing commercial PCB mixtures, as identified in 40 CFR Part 136, is contained in a document entitled "Method for Polychlorinated Biphenyls (PCBs) In Industrial Effluents." The basic methodology set forth therein is the standard analytical method currently in use for the detection and analysis of chlorinated organic compounds, including PCBs, namely gas chromatography. Gas chromatography is the science of separating chemicals which can be heated to the point at which they exist as a vapor, or gas, much like the formation of water vapor or steam when water is heated. The gas chromatograph is an instrument which consists of an oven, a long thin tube called a column, a gas regulator which permits a carrier gas such as nitrogen to flow steadily through the column, and a detector which detects when a chemical other than the nitrogen carrier exists from the column. When mixtures of chemicals are introduced into the column, each chemical will, depending on its boiling point separate and elute (escape) from the column individually at different times. Each time a chemical thus escapes from the column, the detector produces a peak on a chart paper recorder. The resulting tracing on the chart paper showing a peak for each chemical separated is called a "gas chromatogram." The intensity of the peak on the chart recorded is proportional to the quantity of chemical placed on the column. Consequently gas chromatography permits the analyst to separate mixtures of many chemicals and determine the indentity and quantity of each in the mixture. By use of gas chromatography, it is possible to identify the various PCB isomers present in a sample, and thereby to identify which of the commercial mixtures, or Aroclors, appear to be present, as well as the quantity thereof present in the sample. This method may be used to analyze for PCBs in water, fish or animal tissue, sediments, or other substances.

The basic EPA method document suggests a detection limit of approximately 1 microgram per liter using a sample of 100 milliliters to 1,000 milliliters. However, the method can readily be adapted to larger sample volumes to provide reasonable reliability at much lower water concentrations.

The EPA method is flexible and provides a basic framework for an analytical chemist. This framework allows sufficient flexibility so that he can make minor modifications within the procedure to tailor such things as sample size, extraction, and clean-up procedure to the particular circumstances and objectives of the analysis.

Dr. Gilman D. Veith, a research analytical chemist at the EPA Environmental Research Laboratory, Duluth, testified that by increasing the sample size, one can enhance the sensitivity (or detection limits) of the process. Thus, using the standard EPA method and a 1 liter sample size would provide a detection limit of 0.1 micrograms per liter. Using a sample size of 1 gallon, which is approximately 4 liters, will provide a detection limit of 0.025 micrograms per liter. The detection limit can be further reduced by collecting 5 gallon samples of water and/or by concentrating the final extract from 10 milliliters to a smaller volume. Dr. Veith testified further that for natural waters such as lakes and streams, cleanup of sample is minimal and a PCB detection limit of 0.01 micrograms per liter is commonly used. He added that: "however, when an effluent sample containing comparatively large amounts of chemicals other than PCBs is analyzed, such as sometimes is found at the discharge point from an industrial plant the lower limit of detection may be sacrificed in the process of removing possible interferences." Thus, "experience with effluents from capacitor and transformer facilities indicates * * * detection limits of approximately 0.1 micrograms per liter should be attainable on a consistent basis for 1 gallon effluent samples."

Dr. Thomas O. Munson, a biochemist employed in EPA's Region III Field Office at Annapolis, Maryland, and who from 1969 through May, 1976, was employed by Westinghouse Electric Company (an objector in these proceedings) at its Westinghouse Ocean Research Laboratory, testified to the same effect as Dr. Veith with respect to use of the EPA analytical method. In particular, he testified that: "With a sufficient amount of care, most analysts familiar with the techniques of determining chlorinated pesticides should be able to measure PCBs to about 0.1 parts per billion (ppb) in most industrial effluents. At the Annapolis Field Office of EPA, the analysts routinely measure PCBs in industrial effluent with a detection limit of about 0.05 ppb using this method." In those samples, many of which were "very oily and contained large amounts of interfering sulfur material," Dr. Munson utilized a modification of the standard EPA procedure as a result of which he was able to measure PCBs at a "working level" of 1 part per trillion (ppt) with a detection limit of 0.1 ppt. The modifications utilized to achieve this are increasing the sample size to 4 liters, extraction of the sample directly in the sample collection vessel, and minimization of contact with glassware during the clean-up procedure. Dr. Munson noted that "it may be that not all laboratories given their large volume of business and monitoring requirements of numerous effluents for a variety of substances, can routinely achieve these results, but an experienced analyst given sufficient time to take the necessary steps" which Dr. Munson described "should be able to achieve or closely approach these levels."

Both EIA and Westinghouse argue that there does not exist reliable measuring and analytical capability for PCBs at and below one microgram per liter, so that it would be improper to establish standards below at least 20 micrograms per liter.

However, they did not at the hearing present any competent, credible evidence to support this proposition or to undercut the validity of the approved EPA method and the testimony of Drs. Veith and Munson. EIA presented two witnesses on the subject, only one of whom had any first-hand experience in conducting analyses for PCBs.

The first EIA witness was Dr. Eunice M. Moore, Director of Research and Development for the Electrical Utilities Company of LaSalle, Illinois. Dr. Moore does not do tests or analyses and has never conducted an analysis of an industrial effluent for PCBs. In October 1976 Dr. Moore was asked by EIA to contact various capacitor manufacturers and have them send effluent samples to two

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or more laboratories of their choice to determine the extent to which similar analytical results were obtained by these laboratories. The laboratories selected were four EPA Regional laboratories, six commercial laboratories, and two company laboratories. Dr. Moore testified with respect to this survey that her only information on the quality control of the commercial and company laboratories was conversations with the companies. She made no independent effort to assure herself of good quality except at the Warf Institute. She did not know what analytical methods were followed by the various laboratories. Most of the sample sizes were 1 gallon, but some were 1 liter. Most of the samples were composite, but at least one was not. None of the samples were replicate samples (2 samples taken at the same place and time). She did not know whether the divisions of the 1 gallon samples among the laboratories were even. Many figures in the report of the survey show levels substantially above the solubility levels of PCBs, which is 250 micrograms per liter and below. She conceded that when the PCB volume in the sample is above the solubility level, this makes the analytical results unreliable, which might well explain the disparity of results between the laboratories for samples in excess of 200 parts per billion. No statistical analysis was done of the results.

Although the results reported by Dr. Moore do show some disparities in the results obtained by the various laboratories, all of the above-mentioned limitations raise serious questions about the reliability of the data set forth therein. Moreover, Dr. Moore testified that she was not aware of any efforts by EIA to find a laboratory which would give more reliable results following the testing set forth in her report and so far as she knows no one from EIA has contacted EPA's Environmental Monitoring and Support Laboratory in Cincinnati for guidance, nor has anyone gone back to look at the various laboratories to find out why the results were disparate.

The second witness presented by EIA on analytical techniques and measuring capability was Dr. James Laubscher of the Woodson-Tenent Laboratories of Memphis, Tennessee. The thrust of his testimony is set forth in paragraph 6 of his affidavit:

> 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.

Testimony elicited on cross-examination of Dr. Laubscher offers illuminating evidence concerning his professed inability. The principal evidence offered by Dr. Laubscher to support his contention that different laboratories get varying results when analyzing similar samples of PCBs is a round robin test conducted by Monsanto Industrial Chemical Company among twelve laboratories using a method developed and published by the American Society for Testing and Materials, referred to as ASTM D-3304. Woodson-Tenent is laboratory "K" on the Monsanto round robin report. The results from laboratory K "were rejected when it was learned that one critical step of the method was omitted." Dr. Laubscher stated that in performing his work one of Woodson-Tenent's laboratory technicians had not extracted the sample properly, which was "a major deviation from the accepted procedure."

Dr. Laubscher, apart from the work of his laboratory, had no first hand knowledge of any other aspects of this testing. He had no idea what amount of time elapsed between the taking of the samples and the analyzing of them, or the number of transfers of the sample from vessel to vessel. He did not know the identity of the laboratories doing the tests, other than his own. He did not know whether the samples were replicate or split, or who prepared them, or how they were prepared. Although most of the results actually range within 10 to 25 percent of the mean, he has no basis for independently validating any of the data reported in the Monsanto round robin test.

Dr. Laubscher testified that Woodson-Tenent does not use the EPA method for sampling and analysis. Moreover he has rejected the ASTM method used in the Monsanto round robin as unsatisfactory because of the amount of glassware involved. He testified that sidewall adsorption to glassware is why one must avoid multiple glassware exposure, for such sidewall adsorption results in "dramatically reduced levels" in the analysis, which in turn would reduce his confidence in the results obtained by any such method. Woodson-Tenent uses instead an analytical method developed ten years ago by someone named "Bill" in the National Center for Communicable Diseases. Although he has used this method to report to commercial customers PCB analysis accurate to 2 decimal places in micrograms per liter (i.e., to 100th of a microgram per liter), he gave conflicting testimony as to his degree of confidence in the reliability of these results.

Woodson-Tenent's analytical performance over the last several years has not been impressive. Two years ago they submitted analytical test results on three chlorinated organic compounds, aldrin, dieldrin, and DDT, to EPA's Cincinnati laboratory, using a gas chromatography analytical technique which is essentially the same as that used for PCBs. The results of Woodson-Tenent's analysis as compared with the actual spiked values placed in the samples by the EPA Cincinnati laboratory indicate a very substantial difference between the values reported by Woodson-Tenent and the values actually present in the samples. Woodson-Tenent also did some analyses on Hudson River water in connection with the proceedings by the State of New York against the General Electric capacitor plants. However, the laboratory incorrectly used the wrong size injection syringe, which allowed the needle through which the sample is injected to the chromatograph to be plugged up, so that no sample was injected into the chromatograph, and thereby "botched up" the job.

Of the "over 5,000 analyses" for PCBs which Dr. Laubscher stated in his affidavit that he has "personally conducted", most of these have in fact been performed by others under his general direction, and only three or four have actually been conducted by him on the effluents from capacitor manufacturers. He testified that on drinking water samples he could reach detection levels of 75-100 ppt, but offered no explanation as to why he apparently could not achieve anything close to these levels when measuring in industrial effluents—particularly in light of his testimony that there is not a lot of interference in the extracts from samples taken from capacitor plant effluent.

No evidence was presented which suggested that a commercial laboratory, using the EPA method and a degree of care comparable to that described by Drs. Veith and Munson, could not achieve detection levels comparable to theirs. For point sources subject to a prohibition on discharge of PCBs in their effluent, while it is reasonable to expect improvement, existing methods are adequate to monitor for compliance.

I. INDUSTRYWIDE STANDARDS

Both EIA and Westinghouse contend that the Administrator is without authority to establish national or industrywide toxic pollutant effluent standards for PCBs, but may proceed under section 307(a) only on a plant-by-plant basis. This argument is contrary to both the law and the evidence.

Section 307(a)(5) expressly provides as follows:

> When proposing or promulgating any effluent standard (or prohibition) under this Section, the Administrator shall designate the category or categories of sources to which the effluent standards (or prohibition) shall apply. Any disposal of dredged material may be included in such a category of sources after consultation with the Secretary of the Army.

Thus the effluent standards by law are to be applicable to a "category or categories of sources," and are not to be set on a plant-by-plant basis.

EIA quite incorrectly asserts that Dr. William Brungs testified that there is a need for "local regulation" and that it is "difficult to assess the environmental implications of a given discharge by means of a national effluent standard." In fact, Dr. Brungs' testimony was that it is appropriate to establish mixing zones on a site-by-site basis; nowhere does he suggest that it would be inappropriate to establish a toxic pollutant effluent standard which would be applicable on a national, or industrywide, basis.

EIA also asserts that "the record contains no specific information concerning the bodies of water into which the capacitor and transformer plants affected by the proposed regulation discharge." This again is quite incorrect. Dr. Gilman Veith presented considerable information showing that PCB concentrations in the ambient waters and fish are con-

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sistently very high in areas where plants which manufacture PCBs or PCB-filled transformers or capacitors are or have been located

There are some compounds which are so toxic, persistent, and mobile that they should be regulated through a national or industrywide standard, including, where justified, a prohibition Section 307(a) confers this express authority on the Administrator As the evidence in this proceeding abundantly demonstrates, it is hard to imagine a compound for which regulation on a national basis is more appropriate, in view of the extraordinary persistence and mobility of PCBs

J SUBSTITUTE MATERIALS

Although neither the Agency's proposed standards nor my decision here were based upon the availability of substitutes for PCBs for use in transformers and capacitors, evidence indicates there are some substitutes presently available, and industry is proceeding to develop others

All transformers used in the electrical industry have provision for cooling, based on either gaseous or liquid coolant, because the efficiency of a transformer is maximized if it is kept at a low operating temperature. The coolants in common use today are mineral oil and PCBs for liquid cooled transformers, and air and gas for dry-type transformers.

PCB-cooled transformers account for about 6 percent of all electrical transformers in service The PCB coolant in these transformers is a mixture of 60 to 70 percent PCBs and 40 to 30 percent trichlorobenzene and is commonly known by the generic term "askarel" The PCBs currently used in these mixtures are Aroclor 1242 and Aroclor 1254.

Askarels produce highly corrosive hydrochloric acid when arcing takes place and cost about eight times as much as mineral oil on a volume basis. For these reasons, askarel-filled transformers are only used where considerations of fire safety, reliability, availability, and cost make such a unit preferable to an oil-filled or a dry-type transformer. They are also limited by the dielectric strength of the liquid to ratings below 69,000 volts.

Oil-filled and dry-type transformers are currently used in 95 percent of all applications and could, with proper engineering design, be used to replace most of the remaining askarel-filled units. Mineral oil-filled transformers are the same size as the askarel units, are considerably lighter in weight, and have somewhat better heat transfer characteristics. Moreover, an electrical arc in mineral oil results in non-corrosive breakdown products. Furthermore, askarel-filled transformers cost about 1 3 times as much as oil-filled units of the same capacity Thus the oil-filled transformers actually have a number of advantages over those which use PCBs

The major disadvantage to mineral oil is its flammability. However, the issue of flammability only becomes important where the distribution transformer must be buried, as in many urban applications, or located close to, within or on the roof of the building which it serves Oil-filled transformers are used in almost all power transformer applications, for most substation distribution applications where the high voltage from the transmission lines is reduced to 12 8 kilovolts for local distribution, and for most rural pole-mounted transformers which reduce the voltage to 220 volts. For those applications, the transformers must be suitably isolated from flammable structures or the structures must be suitably safeguarded against fires

For certain uses, air-cooled or gas-filled transformers are employed, which do not require askarels Use of open air-cooled transformers is generally limited to dry, clean locations where the load requirements are fairly even and constant, and where the maximum voltage does not exceed 30 kilovolts They have been successfully used in large office buildings, particularly in tall buildings where the transformers are located every few floors They are about equal in price to askarel-filled transformers of the same kilovar rating.

Closed gas-filled transformers use a dry gas as a heat transfer medium. Because they must be installed in pressure-tight containers due to the changes in the gas pressure caused by changes in temperature, they are 30 to 40 percent heavier and cost two-thirds more than askarel transformers (and twice as much as oil-filled transformers). The maximum voltage ratings of these gas-filled transformers can be equal to those of liquid-filled units. They also avoid the maintenance problems caused by moisture and dust in open air-cooled transformers.

Very few distribution transformers presently use askarels. Most distribution transformers are installed at the site of major generating plants and there would be little difficulty in designing new plants so that mineral oil cooled transformers could be used safely. Those which do have askarels are located inside or on the rooftops of public, commercial, or industrial buildings.

Most power transformers are situated in remote locations where fire or explosions are not a threat to property. Mineral oils are commonly used in power transformers in these safe locations Askarel-cooled power transformers are used to supply high-voltage electricity to electrostatic precipitators, which are usually mounted on or near industrial stacks. Evidence indicates it should be possible to use mineral oil-cooled transformers in all such applications.

Railroad locomotive engines are equipped with askarel-filled distribution transformers due to Penn-Central Railroad regulations. However, foreign experience indicates that there is no significant fire risk from the use of more flammable liquids in these transformers. European practice has traditionally been to use mineral oil locomotive transformers The Japanese have been using silicone oils in new railroad transformers for the past four years and no service problems have been reported.

In situations where askarel-filled transformers are used (in hazardous locations), low viscosity silicone fluids such as polydimethyl siloxane could be used as substitutes. Little information is available concerning the fate of silicones in the environment or the toxicity of their breakdown products Extended feeding studies revealed polydimethyl siloxane to be relatively non-toxic No tendancy for bioaccumulation occurred in experiments Known chemisty suggests that environmental degradation would occur through sunlight exposure Dow Corning has indicated that its present domestic capacity for polydimethyl siloxane production would be adequate to supply new transformers

High flash-point mineral oils have been developed by RTE Corporation using the tradename "RTEMP" as a possible replacement for PCBs in transformer applications The primary advantages of the high flash silicone mineral oil are price relative to biodegradability and low toxicity.

High flash-point synthetic hydrocarbons are being studied by Monsanto as a possible CB substitute in transformers using the trade name "MCS-1866". These mixtures are purported to be environmentally acceptable and to have the high flash-point characteristics of RTEMP or silicone with relatively low viscosity and satisfactory heat transfer characteristics at a much lower cost

Manufacturers of capacitors and their suppliers are actively engaged in developing environmentally acceptable substitutes. Four capacitor manufacturers recently entered into a joint venture agreement with Justice Department approval for the development of an alternative.

PCB-filled capacitors are presently being used in three principal categories of applications high voltage power factor correction; fluorescent ballast and high intensity discharge lighting, and other capacitor applications such as "motor run" circuits, low voltage power correction, and electronic filter capacitors.

Large, high voltage (4,800 to 13 800 volts) power factor correction capacitors are used by electrical utility companies to improve the efficiency of their system operations They are generally installed outdoors in non-hazardous locations such as in banks in a substation or mounted in groups on utility poles Their location thus minimizes the importance of fire resistance Butylated monochlorodiphenyl oxide is being marketed by Dow Chemical Company under the tradename "XFS-4169L" and by McGraw-Edison under the tradename "EDISOL" as a viable substitute for PCBs in high voltage power capacitors Power capacitors impregnated with XFS-4169L have been found to be more reliable than the same type of capacitor impregnated with Aroclor 1016 after 3 years of accelerated life tests and more than 18 million kilovar hours in full-sized units without failures The size of the XFS-4169L capacitors is the same as PCB capacitors at equal kilovar ratings Furthermore XFS-4169L has been found to be environmentally acceptable based on an assessment of its biodegrad-

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ability, bioconcentration in fish, toxicity to animals, and toxicity to fish. The Dow fluid is readily available to meet increased market demand The long-range price of power capacitors impregnated with XFS-4169L should be reasonable

Industry witnesses expressed optimism that an acceptable substitute to PCBs for use in small and medium AC capacitor applications would be available in the reasonably near future. There is no shortage generally of the substances presently under consideration or in use as substitutes to PCBs in capacitors At this time, the industry-wide preference for use of a dielectric liquid to replace Aroclor 1016 in small industrial capacitors, including low voltage power factor correction, ballast lighting, motor run circuit and electric filter capacitors, would be phthalate esters plus additives.

Phthalate esters have been used in small industrial capacitors in Japan for several years and are currently being marketed for use in the United States by several manufacturers. Phthalate ester capacitors would be the closest in size to PCB capacitors This substitute is the least expensive of the possible alternatives, is readily available in large production quantities and appears to be environmentally acceptable. In those cases where phthalate esters are in use, no evidence of fire hazard has been reported Protective devices are available for use with phthalate ester capacitors which prevent case rupture and fire by removing the capacitor from the source of electricity in the event of capacitor failure.

Metallized polypropylene film has been widely used in Europe in low voltage capacitors This new design is actively being developed in the United States, with test marketing of both dry and liquid-filled capacitors by some capacitor manufacturers Although their use is presently limited to below 330 volts, they would eliminate PCBs and are small in size, capable of operating at high temperatures and have a normal end-of-life failure mode of an open circuit. This makes them suitable for low voltage applications such as fluorescent lighting ballasts and air conditioners, and, placed in series, for higher voltage applications.

K AVAILABLE CONTROL TECHNOLOGY AND PROCESS CHANGES

As a preliminary matter, it should be noted that while I am adopting a prohibition on discharge of PCBs (with an adjustment for influent PCB levels), I continue to believe that although Congress obviously did not intend that the objective of protecting the environment and human health be compromised on solely economic grounds, it is not inconsistent with Section 307(a) for the Agency in developing its proposed standards to investigate and, where possible, identify promising technology and give limited consideration to the likely economic impact associated with its standards The Agency's authority to take into account these factors was noted in the preamble to the standards proposed on July 23, 1976, and discussed more fully in the June 10, 1976, notice of proposed standards for four pesticides (41 FR 23578-9). This issue has been dealt with at length in my Final Decision of December 30, 1976, concerning effluent standards for aldrin/dieldrin and other compounds (FWPCA (307) Docket No 2, pp 46-50), 42 F.R. 2598 (January 12, 1977).

In order to obtain information as to the availability of various methods of control and related technology by which discharges of PCBs might be eliminated or reduced, the Agency engaged the services of Versar, Inc ("Versar"), of Springfield, Virginia, who are recognized experts in the study of waste water treatment technology and the control of pollutants discharged by industrial sources. Versar prepared and submitted to the Agency a report concerning the industrial discharge of PCBs and the assessment of wastewater management and treatment technology, including technologies which are actually in use or which are or may be available to industries to control or eliminate the discharge of PCBs. This report, entitled "Assessment of Wastewater Management, Treatment Technology, and Associated Costs for Abatement of PCBs Concentrations in Industrial Effluents," was completed on February 3, 1976. It was supplemented with a report dated July 2, 1976, entitled "PCBs Water Elimination/Reduction Technology and Associated Costs, Manufacturers of the Electrical Capacitors and Transformers, Addendum to Final Report, Task II". Both of these documents were incorporated as part of the Agency's statement of basis and purpose for the proposed standards, and went into evidence at the commencement of the proceedings The data reported by Versar, as amplified by the 3 witnesses presented by EPA who testified at the hearing concerning control technology, form the principal basis for the following discussion of technology.

The domestic annual production of PCBs in 1974 was 40,466,000 pounds, of which approximately 22 million pounds were used by capacitor manufacturers and 12 million pounds were used by transformer industries. The balance reflects inventory changes and about 5,395,000 pounds of export sales. There are a total of 37 PCB user plants (capacitor and transformer) in the United States and 1 PCB manufacturer. Of the 38 plants, at least 11 directly discharge their effluents to the navigable waters; the remainder of discharge into publicly-owned treatment works The sole PCB manufacturer, Monsanto, discharges a daily average of 3 06 pounds of PCBs to a publicly-owned treatment works The daily discharges of PCBs by the capacitor industry average 5.86 pounds and by the transformer industry 0 17 pounds per day Monsanto has announced its intention to cease the manufacture and distribution of PCBs as of October 31, 1977. Consequently there is no present PCB manufacturer with a direct discharge into navigable waters, and it is expected that there will be no domestic manufacture of PCBs at all after October 31, 1977.

With respect to discharges to the navigable waters by manufacturers of capacitors or transformers utilizing PCBs, the discharges generally come from one or more of the following sources within the various plants Non-contact cooling water, water-sealed vacuum pumps and steam jet ejectors, detergent washing of components and assemblies, boiler blowdowns, air conditioning condensates, contact cooling water from welding and soldering operations, certain contaminated process wastewaters (including vacuum pump condensates, laboratory wastewaters and wastewaters from surface treatment operations such as plating, phosphatizing, painting, fluoride treatment, and caustic baths), sanitary and personal hygiene wastewaters, and in the case of one plant which has a waste incinerator, the wet scrubber However, not all plants have wastewater streams containing PCBs from all these sources Most plants have eliminated PCBs from many if not most, and in a few cases all, of these sources.

Water is not an essential component of the transformer manufacturing process Similarly, there is no need to utilize water in the manufacture of capacitors filled with PCBs The principal use for water in capacitor manufacturing plants is as non-contact cooling water, which normally should not expose the water stream to PCBs. Even non-contact cooling water can be eliminated by use of a heat exchanger, or a cooling tower, or a "chiller", which is like a refrigerator. Nathan Rey Clark of Universal Manufacturing Corporation described at the hearing the chiller in use at his company's capacitor manufacturing plant in Totowa, N.J. which results in a completely closed system, with no effluent discharge whatsoever except for sanitary wastes which go to a publicly owned treatment works.

For those plants which do have discharges of effluents which may contain PCBs from one or more of the various processes enumerated above, there are existing technologies and feasible in-plant modifications so as to eliminate each These may be briefly summarized as follows:

(a) Non-contact cooling water should be segregated from all other plant waters and recycled As noted previously, this process can be aided by use of cooling towers or heat exchangers, or a "chiller".

(b) Water-sealed vacuum pumps and steam-jet systems can be replaced with mechanical, oil-sealed vacuum pumps, which are presently in wide use in the industry

(c) All aqueous detergent washing operations can be replaced with organic-vapor degreasing Solvent recovery would be accomplished by distillation, and still bottoms, or sludges, would be incinerated At some locations, the detergent washing of components can be completely segregated physically from any areas where PCBs are used, so as to avoid the possibility of contamination

(d) With respect to boiler blow downs, as well as any bleed from the closed non-contact cooling water circuit, air condi-

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tioning condensates, and any contact cooling waters (though in fact there is no need for contact cooling water and it should be eliminated), these can be collected in an equalization basin, and thereafter filtered, demineralized, and returned to the non-contact cooling water circuit.

(e) Any remaining small amounts of contaminated water or other contaminated waste may be incinerated or disposed of by contract services

(f) One option to avoid contamination of wastewater streams from plating operations is to completely segregate them physically.

(g) This can also be done with respect to painting operations. Still another alternative to avoid contamination of waste streams from painting is to replace conventional painting operations, which require a water spray, with a dry electrostatic painting and labeling process Such conversion has been made in the industry, but it is not known to what extent it can be applied to all plants.

(h) Sanitary and personal hygiene facilities should be installed which use a minimum amount of water. Disposal of these waters can be by incineration or to a publicly owned treatment works.

(i) For the one plant with a waste incinerator using a wet scrubber, the scrubber liquor can be collected in an equalization basin, filtered and treated by carbon adsorption. There does not appear to be an alternative dry process to replace wet scrubbing.

Contaminated stormwater runoff into point source discharge conduits can be eliminated by diking or curbing and, where necessary, roofing over loading areas, storage areas, and other sources of contamination

Use of the foregoing technologies and process changes can be expected to result in achievement of prohibition of PCBs in process wastes (except for certain process wastes, specifically water used in welding, plating, or painting operations, and scrubber and quench water from incinerator operations), and reduction of all other discharges to 1 μg/l or less using a treatment system based upon activated carbon A more stringent effluent limitation should be achievable using either carbon adsorption or ultraviolet-assisted ozonation treatment, discussed more fully below. Any source should be able to eliminate any process discharge resulting from welding, plating and painting operations using the technologies previously outlined

The capabilities of a wastewater treatment system based upon granular activated carbon was investigated and discussed at length. With respect to the feasibility of the carbon adsorption treatment technology, Versar reached the following conclusion:

> Our survey of wastewater treatment technology was most extensive, and excellent potential for current, near and long term methods was found The longer term pilot or research scale methods hold great promise of allowing zero discharge
>
> In this category, our prime recommendation is carbon adsorption This technology has been proved over most of this century in a wide variety of industrial adsorption problems It is being applied successfully to the removal of new organics from water on a continual basis. Our cooperative laboratory work with several suppliers has confirmed preliminary published reports of success in removing PCBs All of the aspects of commercial carbon adsorption from favorable capital and operating economics to reasonable operating methods, materials of construction, and lack of transport of pollution to air or land, have been proven for PCBs-like materials There is every reason to believe that there will be commercial success with PCBs removal from wastewater

This technology was further described at the hearing by Joseph L. Rizzo, of Calgon Corporation Calgon Corporation has pioneered the development and use of the carbon adsorption technology, and Mr Rizzo has been one of the principal individuals involved in this development effort.

Calgon Corporation presently has a contract with General Electric Co to install a treatment system for the treatment of effluent containing PCBs from the General Electric capacitor plants at Hudson Falls and Fort Edward, New York

General Electric is already in the process of taking a number of remedial steps described above to reduce or eliminate wastewater flows containing PCBs Among other things, they are segregating contaminated and uncontaminated streams and changing the cooling water from once-through to a recycled system, thereby avoiding a discharge They are eliminating contaminated water wherever possible, and replacing open trenches and sewers with drip pans The detergent washing machine for capacitor cleaning is being replaced with a vapor degreasing unit, while other washing machines are using three independent closed water systems PCB contaminated wastes are being sent to a disposal contractor. Wastewater will be impounded in basins and then treated by the granular activated carbon adsorption columns furnished by Calgon. The Calgon contract includes off-site spent carbon regeneration.

Houston Research, Inc., of Houston, Texas and Westgate Research Corp of Marina Del Ray, Calif., have developed a technology which brings together two previously proven water purification technologies, ultraviolet radiation and ozonation, to form a synergistic combination to destroy organic compounds, including PCBs.

Because UV-ozonation actually destroys the PCB by a dechlorination reaction, thereby converting it to relatively non-toxic products, it would appear to be capable of reducing PCBs to any desired level At the hearing, Dr. Mauk testified that PCBs could be reduced to any detection level, even 0.1 parts per trillion, and that their laboratory results were consistently below the .1 part per billion detection limits of their analytical equipment.

1 *Economic impact* An assessment of the economic impact of the Agency's proposed standards entitled "Economic Analysis of Proposed Toxic Pollutant Effluent Standards for Polychlorinated Biphenyls' Transformer, Capacitor, and PCB Manufacturers" was prepared for the Agency by Jack Faucett Associates, Inc., under the supervision of EPA's Office of Water Planning and Standards. This report also satisfied any requirement under Executive Order 11821 that an Inflation Impact Statement be prepared although it does not appear that the impact of these regulations is sufficient to impose a formal requirement for such a statement

When the standards were proposed, the economic assessment was not yet complete Indeed, the report was not available until early November, at which time it was placed in evidence at the hearing, the project officer in charge was made available for cross-examination, and public notice of the availability of the report was published in the FEDERAL REGISTER with opportunity for comment (The absence of the report was one of the reasons why the Agency elected not to include in its July 23 proposal a prohibition on discharges by manufacturers of capacitors and transformers.)

The Faucett report concluded that most of the transformer and capacitor manufacturers could financially afford to install the technology outlined in the Versar report which would enable them to achieve compliance with the standards proposed by the Agency on July 23, 1976. The report further concluded, however, that few if any would actually install this control technology Rather they would discontinue the use of PCBs altogether when these regulations take effect, as a result of the combined impact of two factors which crystallized during the pendency of these proceedings The first was passage of the Toxic Substances Control Act, Pub L 94-469, 90 Stat 2003 (October 11, 1976), which requires a phase-out of the "distribution in commerce" of PCBs by July 1, 1979 The second was the decision by Monsanto to cease supplying PCBs as of October 31, 1977.

This conclusion is entirely consistent with the evidence presented by the Electronic Industries Association Philip Murray of the Cornell-Dubilier Electric Corporation testified that by late 1978 his company would discontinue the use of PCBs in capacitors because of Monsanto's decision to discontinue the distribution of PCBs, and apart from any consideration of section 307(a) standards Thus the only impact of the proposed 307(a) standards on this company would be that the company would stop using PCBs a few months earlier, i.e. the difference between the time when the company would cease using them in response to the Monsanto decision and the time when the 307(a) standards would go into effect

Similarly, Nathan Ray Clark of the Universal Manufacturing Corporation testified that his capacitor manufacturing plant in Bridgeport, Connecticut would, in response to the Agency's proposed standards, cease using PCBs in their capacitors a few months earlier than they otherwise would in response to the Monsanto decision, rather than install treatment technology. Both Mr Murray and Mr Clark testified that their

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industry has no plans to import PCBs, and that they are looking as rapidly as possible for substitutes, which they expect they will have.

Dr Ernest Mosback, who is with Jack Faucett Associates, Inc and was project leader responsible for preparation of the economic assessment report, testified that he had reviewed the testimony of Messrs Murray and Clark in this regard, and that their decision to stop using PCBs in mid-1978 was consistent with his findings with respect to the rest of the transformer and capacitor manufacturing industry generally. Thus the economic assessment report concluded that decisions by the companies were primarily influenced by "(1) Monsanto's announcement that it, the sole producer of PCBs in the U.S., would stop selling PCBs on October 13, 1977, Ref. 40, and (2) the Toxic Substances Control Act just signed by President Ford which forbids production of PCBs in the U S. after January 1, 1979, or their sale after June 30, 1979. Imports would be forbidden by June 30, 1979 The economically useful life of effluent treatment facilities appears to be so short that investment in treatment is unlikely."

The Faucett report also concluded that the proposed standards themselves would result in price increases industry-wide for capacitors of less than 5 percent in 1977, and little price increase with respect to the transformer industry Further, the report concluded that "there are no significant effects on energy consumption, balance of payments, or employment. The announced and apparent shifts to non-PCBs and the expected demand for capacitors and transformers are likely to increase rather than decrease sales and industry-wide employment" Testimony and evidence indicate that there appears to be no threat to the domestic transformer and capacitor industry from foreign competition, and it is unlikely that the 307(a) standards would interfere with energy conservation efforts.

M. THE AMBIENT WATER CRITERION

In its July 23, 1976 proposal, the Agency provided for an "ambient water criterion" for PCBs of 1 part per trillion (0 001 micrograms per liter). Although an ambient water criterion is not expressly required under section 307(a), the Agency concluded that the establishment of such a criterion would be an important ingredient in carrying out the mandate of that section to provide "an ample margin of safety" for organisms which might be affected by discharges of PCBs to the aquatic environment. The rationale for the establishment of this ambient water criterion is discussed in the preamble portion of that notice of proposed rulemaking, 41 FR at 30479 and 30473, as well as in the preamble to the Agency's notice of proposed toxic pollutant effluent standards for aldrin/dieldrin, DDT (DDD, DDE), endrin, and toxaphene published on June 10, 1976, at 41 FR 23570, 23570-23500.

Water criteria are meant to reflect an estimated safe level of a pollutant in an aquatic environment which will protect against adverse effects from chronic exposure. If there are enough data to establish a "no-effect level" for a substance, that level can be used as the water quality criterion However, there are rarely enough data to predict with confidence the "no-effect level" for all affected species In such cases, it is a recognized and sound scientific practice (and one recommended by the National Academy of Sciences) to derive a water quality criterion for a particular substance by multiplying an "application factor" by the acute toxicity value for the most sensitive species sought to be protected. The application factor may be an experimentally derived factor or, more commonly, a factor set at a level judged by general experience with the effects of pollutants on aquatic organisms to provide adequate protection (The criterion determined by this method would have been higher than the 0 001 μg/l criterion proposed by the Agency.)

In establishing a criterion for PCBs, however, it was determined that this approach would not provide adequate protection against possible harm resulting from chronic exposure, due to the extraordinary bioaccumulation potential of PCBs Accordingly, the Agency considered bioaccumulation as well as chronic effects in determining the proper ambient water criterion for PCBs As discussed elsewhere herein, the bioaccumulation potential of PCBs has been demonstrated in the laboratory to be up to 274,000 times the measured PCB concentration in the water. (This figure, described above, was developed from a long-term study with Aroclor 1242 During the hearings, EPA introduced evidence through Dr Lauer that laboratory bioaccumulation factors for Aroclor 1254 may be as high as 307,000) The evidence also shows that bioaccumulation "in the field" may be substantially higher than these levels Thus the Agency concluded that it would not be unreasonable to use the highest demonstrated laboratory bioaccumulation factor in deriving its ambient water criterion.

The ambient water criterion of 0 001 proposed by the Agency was derived by examining the lowest documented chronic effects levels in aquatic organisms, as well as the lowest no effect levels in consumers of aquatic organisms. It was determined that the criterion must be at a level which, if bioaccumulated 274,000 times, would result in tissue levels below the lowest level at which adverse results in consumers of aquatic organisms were reported

The proposed criterion of 0 001 μg/l multiplied by 274,000, produces a tissue level of 0 274 parts per million (ppm). This is below any of the reported effects levels relied on by the Agency in developing the criterion, exemplified by the following.

At 0 04 ppm (milligrams per kilogram in the food), total reproductive failure was observed in mink

At 3 57 ppm (milligrams per kilogram in the food) mink died

At 2 5 ppm (milligrams per kilogram in the food) reproductive disfunction occurred in the rhesus monkey

At 8 ppm (milligrams per kilogram in the food) mortality was seen in the rhesus monkey

In rats, 0 5 ppm (milligrams per kilogram in food) resulted in the induction of liver enzymes

At levels of between 40 and 300 ppm PCBs in chicken feed, deaths of chickens occurred

Reproductive failures in chickens occurred at between 8 and 10 ppm PCBs in the food,

Ulceration in the stomachs of dogs occurred after long-term feeding at 1 ppm PCB in feed.

Furthermore, a criterion of 0 001 μg/l is substantially below the lowest observed effect levels in aquatic organisms For example it is well below the following documented effect levels:

0 1 μg/l of PCBs will cause population shifts in phytoplankton,

0 4 to 0 5 μg/l lowers the reproductive potential of some invertebrates

0 1 μg/l will lower the species diversity of some invertebrates

Development of the ambient water criterion was the initial responsibility of Dr. Leonard J. Guarraia, Chief of the Criteria Branch, Office of Water Planning and Standards, EPA This effort was carried out thoroughly and carefully, in consultation with many scientists (including aquatic biologists, toxicologists, and chemists) both inside and outside EPA These scientists concurred in the judgment of EPA that the proposed ambient water criterion of 0 001 μg/l should provide an ample margin of safety for aquatic organisms and most consumers thereof.[1]

The factors which the Administrator must consider in establishing toxic pollutant effluent standards under section 307(a)(2) are "the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms" The level of control must be one which the Administrator determines provides "an ample margin of safety" for organisms to be protected, as required by section 307(a)(4).

Although human health is not expressly mentioned in section 307(a), other sections of the Act, coupled with the legislative history, leave no doubt that humans are among the organisms to be protected See sections 402(k) and 502 (13) of the Act, and "A Legislative History of the Water Pollution Control Act Amendments of 1972," pp 1421-3, 1495 6 (S. Rept No. 92-414, 92d Cong., 1st Sess., October 28, 1971, pp 3-4, 77-81.

According to the latter, the Administrator must consider under section 307 (a), among other things, "the seriousness and irreversibility of any effects on man or the environment that might occur and "the possibility for incorporation into biological organisms and man in concentrations which the latest scien-

[1] Under section 304(a) of the Act the Agency has also established an ambient water criterion of 0 001 μg/l (See "Quality Criteria for Water (1976)").

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tific knowledge suggest will produce effects on man and organisms." *Id.*, p. 78.

However, in preparing the Criteria Document, the Agency acknowledged that the proposed criterion of 0.001 μg/l might not in fact provide assurance of an "ample" margin of safety for humans and some consumers of aquatic organand some consumers of aquatic organisms. Section V of the Criteria Document stated:

> The chronic effects of PCBs in man may occur at extremely low concentrations. Although it becomes virtually impossible to state with confidence that any PCB concentration above zero provides an ample margin of safety for man, the PCB criterion number is believed to provide protection for the aquatic environment. (p. 354)

The basis for the Agency's reservations about the margin of safety provided for humans and certain other consumers are expressed in the July 23, 1976 notice of proposed rulemaking and in a report prepared for the Agency by Dr. Ian Nisbet on the basis of Sections I–IV of the Criteria Document and may be summarized as follows:

(a) Effects of PCBs in mammalian test species have been noted at very low levels of exposure;

(b) "No-effect levels" for toxic effects of PCBs in mammals have not been established in most cases;

(c) Humans are exposed for much longer periods (including pre-natal exposure) than the experimental animals;

(d) Humans are known to retain PCBs in their tissues more efficiently than the experimental animals, with consequent greater exposure to sensitive organs;

(e) Human breast-fed infants probably ingest 30–40 times as much PCBs as their mothers on a mg/kg basis;

(f) Synergistic effects with drugs or other pollutants are likely in the human population and indeed have been demonstrated in several experiments with animals;

(g) The presence of toxic contaminants and metabolites in variable concentrations means that environmental residues of PCBs may be more toxic than the mixtures tested in the laboratory;

(h) There is some evidence that bioaccumulation factors in wild fish exceed the laboratory-based figure of 274,000 utilized in establishing the 0.001 μg/l criterion.

In the course of this hearing, additional evidence was presented which confirmed the soundness of the grounds for the reservations expressed by the Agency in this regard. On the basis of this record, it becomes even more difficult to assert with confidence that an ambient water criterion of 0.001 μg/l for discharges would provide the requisite ample margin of safety for all consumers of fish.

The testimony of Dr. Veith and Dr. Risebrough reporting improved measurements of levels of PCBs in the natural waters of the Atlantic and Pacific Oceans and Lake Ontario, adds considerably to the evidence that bioaccumulation factors in wild fish in many cases appear to exceed 274,000. Dr. Nisbet, who had previously expressed reservations about certain aspects of this evidence, testified that the new data had "cleared up the last two remaining substantial pieces of evidence which have cast doubt upon that conclusion". Consequently Dr. Nisbet testified that a figure in the range of 1–3 million would be an appropriate number to use as a bioaccumulation factor to predict exposures of consumers of fish. If these bioaccumulation figures are correct, then a criterion of 0.001 μg/l would probably not provide an ample margin of safety for certain fish-eating birds and fish-eating mammals, especially species demonstrated to be sensitive, such as mink and bald eagles. Dr. Nisbet testified that in his scientific opinion a criterion of 0.0001 μg/l (0.1 parts per trillion) or lower would "probably be necessary" to provide an ample margin of safety for such species. Further, the reproductive failures in herring gulls in Lake Ontario are now associated with PCB levels in the water as low as 0.003 μg/l, so it is questionable whether this species also would be protected by a criterion of 0.001 μg/l.

The testimony of Dr. Allen provided additional evidence of the hazards of low-level exposure to PCBs, in that the offspring of rhesus monkeys exposed to 2.5 ppm in the diet are now known to be suffering from learning and behavioral deficits, and that the treated monkeys are continuing to give birth to affected infants after a year on uncontaminated diets. Dr. Allen's recent work on metabolism of tetrachlorobiphenyl has extended and confirmed the evidence that the less chlorinated biphenyls are metabolized via highly toxic intermediates.

Dr. Gelboin provided expert testimony at the hearing that the effects of PCBs, including Aroclor 1016, in inducing hepatic microsomal enzymes in rats at very low dose levels would not only have direct predictive relevance for enzyme induction in humans, but would imply substantial risk to humans because of the expectation that induced enzymes in humans would enhance the metabolism of drugs and carcinogens. Dr. Gelboin testified that alteration of this enzyme system "would be expected to change the incidence of cancer in humans." A series of calculations performed by Dr. Nisbet during cross-examination would tend to indicate that a person with average consumption of fish would be at risk from those effects. These calculations assumed an ambient water concentration of 0.001 μg/l and a bioaccumulation factor of 274,000, the evidence that actual bioaccumulation factors may be substantially higher than this would increase the implied risk.

Additional evidence was introduced at the hearing which increases the degree of confidence that PCBs are carcinogenic in rodents. Dr. Kimbrough not only introduced her own study of the carcinogenicity of Aroclor 1260 in rats; she also testified that she had diagnosed neoplastic nodules (characterized by Dr. Squire as "precancerous, if not already cancer") in rats treated in another experiment with Aroclors 1260 and 1254, in the case of Aroclor 1254 at only 20 ppm in the diet. Moreover, PCBs have been shown to induce neoplastic nodules in rats at levels as low as 10 ppm in the diet. The significance of these findings is that it is impossible on the basis of existing knowledge to establish "threshold" or "no effect" levels for chronic exposure to PCBs. Calculations performed by EDF and reviewed by EDF with Dr. Nisbet during cross-examination suggested that the hypothetical carcinogenic risk posed by PCBs to the human population might be substantial, especially if a figure of 1–3 million were adopted for the bioaccumulation factor used in predicting exposure.

New evidence that PCBs are associated with elevated cancer incidence in man, both in the Yusho episode and in occupational exposures, although inconclusive on the basis of the information presented, nevertheless adds considerably to the degree of concern for the risks of low-level exposures.

The foregoing evidence makes it very difficult to state with confidence that any ambient criterion above zero would provide an ample margin of safety to man. Nevertheless, although I regard the 0.001 criterion with considerable reservations, I am not prepared to change it at this time pending further development of the scientific data. My decision not to change this number at this time is prompted by two considerations. First, our knowledge at this time is not adequate to pick a specific number below .001 μg/l as being safe. Second, and somewhat more significantly, the question of the level at which the ambient criterion is set is largely academic in view of the fact, discussed elsewhere herein, that a prohibition on discharges of PCBs is being established for manufacturers of PCBs and manufacturers of transformers and capacitors. This prohibition reflects the import of the evidence reviewed above, namely, that every reasonable effort should be made to eliminate any further discharges of PCBs to the environment, and to minimize the risks of human exposure.

N. MODIFICATION OF PROPOSED STANDARDS

In proposing standards for the capacitor and transformer manufacturers on July 23, I considered imposing a prohibition on any PCBs in their discharge. I refrained from doing so in part because the data then available indicated that a prohibition under section 307(a) "at this time would probably cause a severe impact on the transformer and capacitor manufacturing industries which utilize PCBs, and deprive the nation of the future availability of products which utilize such transformers and capacitors." Accordingly, in the proposed standards I required that discharges be prohibited where possible, and that other discharges comply with the very best results which available technology can achieve.

As noted earlier, when the Agency proposed an ambient water criterion of 0.001 μg/l, it cautioned that for protection of human health and particularly for some other organisms as well, a criterion even

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lower than this might be necessary. In fact, the present problem of PCB contamination in the environment is so severe that in many waters throughout the United States PCB loads are already in excess of this number, in some cases by as much as three orders of magnitude. A survey completed by EPA's Office of Toxic Substances in January, 1976, entitled "Review of PCB Levels in the Environment", reported widespread presence of PCBs in the Nation's waters at levels far exceeding 0.001 μg/l, and in some cases levels at or above 1 μg/l.

Although point source discharges represent a relatively small part of the total environmental PCBs problem, discharges from plants manufacturing capacitors and transformers which utilize PCBs as a dielectric or heat transfer fluid represent the largest industrial categories. Moreover, discharges from such facilities are having profound adverse effects on the aquatic ecosystems into which they are discharging. Dr. Gilman D. Veith, a research chemist at the EPA Environmental Research Laboratory—Duluth, Minnesota presented at the hearing a group of chromatograms of fish extracts from approximately 25 watersheds. He testified that "in each of the watersheds in which the very high concentrations of PCBs were observed, a capacitor or transformer manufacturing or production plant is or has been located in the watershed." He noted by way of example that fish in the Coosa River and Choccolocco Creek contained PCBs in excess of 25 parts per million (ppm). In their issue Fish from Lake Hartwell, Georgia, contained 41 ppm of the PCB Aroclor 1242, while the Hudson River showed fish containing Aroclor 1016 at levels as high as 350 ppm. PCB levels in the Acushnet River, where General Electric manufactures PCB-filled transformers, are so high that the river has been closed for fishing by EPA Region IV. All of these levels are substantially above the 5 ppm temporary tolerance, or "seizure level", for PCBs in fish established for the protection of public health by the Food and Drug Administration (FDA) of the Department of Health, Education and Welfare, 21 CFR 122.10 (July 0, 1973). (It should be noted that the FDA announced on February 20, 1976, that it is actively considering a lower temporary tolerance for fish in light of recent toxicological data concerning PCBs, 41 FR 8409.)

Moreover, because of the extraordinary longevity, persistence, and mobility of PCBs in the environment, once there is a discharge of PCBs into a particular aquatic environment the threat of exposure is not limited to the immediate area, but in fact is virtually unlimited in terms of potential transport and exposure.

In a situation where all of the evidence relating to toxicity, bioaccumulation, persistence, and transport indicates that ambient levels must not exceed 0.001 μg/l and perhaps should be well below that, while at the same time evidence from the "field" indicates that this level is already exceeded in many parts of the Nation's waters, it is exceedingly difficult to justify any discharge of PCBs whatsoever which would necessarily further increase this already dangerous environmental burden.

The standards proposed on July 23, 1976, included a prohibition on the discharge from any PCB manufacturer. This is consistent with the purpose of the Act, and imposes no economic hardship since there is no present PCB manufacturer with a direct discharge. For manufacturers of transformers and capacitors, the Agency proposed a prohibition on PCBs in the discharge of most process wastes, and for all other discharges from existing sources, a maximum PCB concentration of 1 μg/l as a daily average, calculated over any calendar month, with occasional excursions not to exceed 5 μg/l. For new sources the standards were proposed as 0.1 μg/l maximum daily average with occasional excursions not to exceed .5 μg/l.

In making the translation from the desired ambient water criterion to the "end-of-the-pipe" effluent standard required by section 307(a), the Agency considered mixing zones and the constraints of technology and economics. With respect to mixing zones, the Agency took into account the fact that following discharge from a point source a pollutant normally becomes dispersed and diluted in the receiving waters, with the result that as much as a 1,000-fold dispersion or more of the pollutant concentration may take place within the bounds of a reasonable mixing zone. In some instances, because of local hydrologic or hydrographic conditions, there may not exist adequate dispersion and dilution to achieve the desired ambient concentration of 0.001 μg/l. To deal with these situations, the Agency relied upon the "tightening variance clause" set forth in § 129.7 of the general implementing regulations to provide establishment of a more stringent effluent limitation where necessary to achieve this objective. In doing so, however, the Agency expressed the following concerns:

> Because of the extraordinary persistence of PCBs, reliance on mixing zones, while of assistance in the immediate future, cannot be regarded as a long-term solution to the problem * * *
>
> Finally, it is recognized that to allow a discharge at the proposed levels may pose some risk of adverse effects (to some organisms, particularly those located near the outfall, and possibly to the consumers thereof (41 FR at 30476).

As discussed elsewhere in this Decision, the constraints of technology and economic impact do not appear at this time to be as severe as was feared at the time of the proposal of the standards. Because of the Toxic Substances Control Act and Monsanto's decision to stop supplying PCBs, transformer and capacitor manufacturers will phase out their use of PCBs by mid-1978. Therefore, a prohibition on discharge of PCBs effective in the year will have no greater economic impact than that of the standards originally proposed on July 23, 1976.

As noted above, the argument for a prohibition based on considerations of toxicity is compelling. Only the most severe adverse economic impact should be allowed to override these toxicity considerations, which Congress strongly emphasized (both in the language and the legislative history of section 307(a)) must be paramount. It now appears that no such severe adverse economic impact is likely. Accordingly, I believe the standards proposed on July 23 should be modified to provide for a prohibition on any PCBs in discharges by manufacturers of capacitors and transformers.

The setting of stringent standards in this proceeding will have an additional impact on the control of the discharge of PCBs beyond the coverage of the three industrial categories whose direct discharges are regulated under these standards. As noted in the preamble on July 23, the Agency is presently developing pretreatment standards for manufacturers of PCBs and manufacturers of transformers and capacitors which utilize PCBs and who discharge their effluents into publicly owned treatment works. The level of control prescribed under those regulations will be influenced by the approach reflected in the standards promulgated in these proceedings.

Second, there are other industrial point source categories which are discharging PCBs and which are not subject to the present standards. These industrial categories include manufacturers of some machinery and mechanical products, transformer and capacitor reclamation and repair facilities, investment casting operations, paper mills using recycled paper and facilities utilizing PCB-filled hydraulic and heat transfer systems. Contrary to the assertions of EDF and NRDC, insufficient data presently exist upon which the Agency can reasonably base an expansion of the scope of coverage of the regulations at issue here to additional industrial point source categories. In the absence of standards promulgated under section 307(a) for PCBs which expressly apply to discharges from these operations, they will be regulated under the NPDES permit system, with limitations established on a case-by-case basis. Under section 402(a)(1) of the Act, the cognizant permit-issuing authority must issue a permit with "such conditions as the Administrator (or Regional Administrator or state director of an approved permit program) determines are necessary to carry out the provisions of this Act", including compliance with requirements under section 307. The standards set in these proceedings will provide major guidance to the permit-issuing authorities across the country in setting appropriately protective effluent limitations for other industries with PCBs in their discharge in order to carry out the purposes of Section 307.

Furthermore, once the transformer and capacitor manufacturers cease using PCBs, they will technically cease to be governed by the toxic pollutant effluent standards promulgated at this time.

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since they will no longer be "electrical capacitor manufacturers" or "electrical transformer manufacturers" producing or assembling products "in which PCB or PCB-containing compounds are part of the dielectric". (See the specialized definitions, § 129.105(a)(2) and (3) of the proposed standards.) At that point they, too, will be subject to the consistency limiting authority under section 402(a)(1) as described above. Control will be needed even after the cessation of use of PCBs, since PCBs will remain in the pipes and system, and may thereby continue to contaminate the effluent.

Thus the standards established in these proceedings will provide a vital foundation for the control of the discharge of PCBs from all other point sources. Accordingly, it is imperative that these standards be sufficiently stringent to provide "an ample margin of safety" for any important organism likely to be affected, including humans.

Because of the extraordinary and perhaps unique persistence, mobility, and environmental transport of PCBs, they are frequently found in the intake waters of industrial plants. In the general implementing regulations proposed on June 10, 1976, and promulgated on January 12, 1977, 42 FR 2588, § 129.6 included a provision for adjustment of the effluent standards for the presence of a toxic pollutant in the intake water. Essentially, this section is modeled after the Agency's "net-gross" regulations for NPDES permits issued under section 402 of the Act, 40 CFR 125.28. Section 129.6 of these general implementing regulations allows a credit for presence of pollutants in a facility's intake water if the following conditions are met:

(1) The source of the owner's or operator's water supply is the same body of water into which the discharge is made and if (2) it is demonstrated to the Regional Administrator (or State Director, if appropriate), that the toxic pollutant(s) present in the owner's or operator's intake water will not be removed by any wastewater treatment systems whose design capacity and operation were such as to reduce toxic pollutants to the levels required by the applicable toxic pollutant effluent standards in the absence of the toxic pollutant in the intake water.

The Agency has interpreted "wastewater treatment systems" to include process changes or other controls. In this section, as in the comparable provisions of 40 CFR 125.28, the Agency does not allow "net" treatment where the source of the intake is a different water body than the receiving waters into which the effluent is discharged. A principal reason for this is to prevent degradation or pollution from the receiving waters with waters from other sources which may be chemically or biologically "different" and hence harmful to the receiving water ecosystem.

EIA argued that it would be inequitable to require a plant not only to reduce or eliminate any and all additions of PCBs from that plant's own operation and facilities, but also to clean up the pollution of others which may have contaminated the plant's intake waters. I find that this argument has special force where a zero discharge is being set and where process controls (which may include elimination of the use of PCBs) are the likely response of industry to the Agency's standards. In light of the widespread presence of PCBs in influent waters I believe that an exception should be made to the Agency's policy so as to allow a credit for PCBs in the influent in appropriate circumstances, including those where the source of the intake waters is not the same as the receiving waters. This can be achieved by adding a new section to the regulations, as follows:

(Section 129.105(e)) *Adjustment of Effluent Standard for Presence of PCBs in Intake Water*

Whenever a facility which is subject to these standards has PCBs in its effluent which result from the presence of PCBs in its intake waters, the requirement of subsection (1) of § 129.6(a), relating to the source of the water supply, shall be waived, and such facility shall be eligible to apply for a credit under § 129.6, upon a showing by the owner or operator of such facility to the Regional Administrator (or State Director, if appropriate) that the concentration of PCBs in the intake water supply of such facility does not exceed the concentration of PCBs in the receiving water body effluent to which the plant discharges its effluent.

The provisions of this section are, of course, subject to the requirement that any applicable state water quality standards or other applicable standard be complied with. (See § 129.5(e) of the general implementing regulations.) In addition, it is expected that appropriate monitoring will be performed or required by the permit issuing authority to insure that the anti-degradation policy reflected in this section is not violated. (See §§ 129.5 and 129.6.)

Section 307(a)(6) of the Act provides that any effluent standard or prohibition shall take effect on such date or dates as specified in the order promulgating the standards, but in no case more than one year from the date of promulgation. In order to permit manufacturers to change over to substitute materials or to install technology to attain a prohibition on PCBs in their discharge, I am allowing a one-year period for compliance.

III. Summary of Principal Comments to Proposed Toxic Pollutant Effluent Standards for PCBs and the Agency's Responses Thereto

The principal comments of a substantive nature, together with the Agency's responses thereto, including any revisions to the proposed regulations in light of such comments are summarized below:

(1) Comments were received from the General Electric Company recommending that the Agency develop separate criteria for different Aroclor mixtures because mixtures containing or capable of degrading to penta- and hexachlorinated dibenzofurans (PCDFs) pose a more serious hazard than do such mixtures as Aroclor 1016, which contains fewer penta- and hexachlorobiphenyls (the substances associated with the corresponding PCDFs).

The Agency does not find any merit in this objection. Most commercial PCB mixtures are now known to contain small quantities of polychlorinated dibenzofurans (PCDFs) as impurities. One study with Aroclor 1016 did not show PCDFs present but only one sample was tested and the results proved inconclusive. Small quantities of PCDFs appear to be formed from PCBs in service by photochemical reactions and by metabolism. Hence PCBs in the environment are likely to contain small, but variable quantities of PCDFs.

There is little precise information about the toxicity of PCDFs, only one isomer has been tested and only in short-term tests. It was found to be extremely toxic to chickens and guinea pigs but not to rats or mice. PCDFs are said to be particularly toxic and acnelgenic in man and to have been abandoned by industry for that reason. Although there is evidence that PCDFs may play a role in the observed toxicity of commercial PCB mixtures, some of the observed symptoms are also produced by pure chlorobiphenyl isomers or by PCB mixtures with extremely low levels of PCDFs.

It is impossible to disentangle the toxic effects of PCDFs from those of PCBs. Likewise it is not possible with our present knowledge and capabilities to predict or measure the exposure of humans or other vulnerable species to PCDFs. In regulating PCBs, therefore it is necessary to recognize that the mixtures found in the environment may be more (or less) toxic than the commercial products whose toxicity has been studied in the laboratory. Although the lower chlorinated components of PCB mixtures are less persistent and less bioaccumulated than the higher chlorinated compounds, tetra- and even trichlorobiphenyls are sufficiently persistent and bioaccumulated to lead to significant human exposure.

As regards toxicity, several of the critical toxic effects in mammals were reported in experiments conducted with Aroclor 1254, or in some cases Aroclors 1260 and 1248. Since much of the material subject to discharge now consists of Aroclors 1242 and 1016, the Agency considered whether their toxicity was substantially different. Given the molecular constitution of Aroclor 1016 it was reasonable to assume that its toxicity would be generally similar to that of Aroclor 1242. Although differences were noted between the toxicity of Aroclors 1016 and 1242 and that of the higher chlorinated PCB mixtures, there is insufficient evidence on which to base a conclusion that Aroclor 1016 is significantly less effective than higher chlorinated mixtures in causing the critical toxic effects under consideration.

Furthermore, studies have shown metabolism of PCBs appears to proceed via toxic, possibly carcinogenic intermediates. This suggests that the degradability and metabolism of Aroclor 1016 may be associated with increased toxicity. Accordingly in establishing toxic pollutant effluent standard for PCBs there appears no convincing basis

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for setting different standards for the various isomers or Aroclor mixtures

(2) General Electric also commented that the Agency failed to provide any rational basis for choosing .001 μg/l as the ambient water quality criterion

The Agency set forth in great detail its consideration of "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," as required by section 307(a)(2) of the Act, in the PCB Criteria Document. The Criteria Document concluded, "Based upon the proven bioaccumulation potential of 274,000 times the ambient water concentration in controlled conditions the level of 0.001 μg/l PCBs should afford protection for consumers whose sole diet consists of aquatic organisms contaminated at the "worst or maximal level predicted by the laboratory data." This "worst or maximal level" can be calculated to be 0.274 mg/kg of fish flesh, lower by a factor of approximately 2 than the 0.64 ppm which caused total reproductive failure in mink and the 0.5 ppm which caused hepatic enzyme induction in rats. A more detailed discussion of the Agency's derivation of the criterion number and the data upon which it was based can be found in Chapter V of the Criteria Document filed as part of the Agency's statement of basis and purpose in these proceedings.

(3) The National Council of the Paper Industry for Air and Stream Improvement (NCASI) commented that the Agency's standards were arbitrary and capricious because they were based on the belief that bioaccumulation factors derived from experimental data were 10 to 30 times those observed in the laboratory.

The Agency's ambient water criterion was based primarily on laboratory data, as noted above. "Field" data taken from the wild indicated that actual bioaccumulation levels experienced by wild fish may be considerably higher than levels reported in the laboratory—possibly as high as 10 million. These data confirmed the soundness of the Agency's selection of a bioaccumulation figure at the high end of the spectrum of laboratory-derived data, namely, a figure of 274,000. It was this laboratory number, however, rather than field numbers, which were used in the Agency's calculation.

(4) NCASI faulted the Agency for having failed to justify the differences between the criteria and standards as currently proposed and those proposed in December 1973.

The Agency need not justify changes from earlier proposals. The Agency's decision to gather new data and to repropose the regulations is set forth in the Preamble to the Notice of Proposed Toxic Pollutant Effluent Standards for Aldrin/Dieldrin, DDT, Endrin and Toxaphene which were published in the FEDERAL REGISTER on June 10, 1976, 41 FR 23570. The subject regulations are based on more extensive information and the most recent data available to the Agency as set forth in the Criteria Document and the hearing record.

(5) NCASI commented that the Agency had not related its proposed ambient water criterion and standards to any predicted or demonstrated need for water quality improvement in water bodies adjacent to PCB discharge.

The Agency is not required to consider the need for water quality improvement in specific water bodies under section 307(a) of the Act. The Agency based its ambient water criterion on the available information on the toxicity and bioaccumulative effects on PCBs in both laboratory and natural systems. The technology report prepared for the Agency presented data demonstrating substantial discharges of PCBs from transformer and capacitor manufacturing industries into the navigable waters. It is believed that the Agency's regulatory action will reduce the adverse impact of PCBs in those receiving waters although estimates of rates of improvement have not been made. Since in some water bodies the existing PCB levels already exceed the Agency's proposed ambient water criterion, every reasonable effort should be made to reduce or eliminate any further discharge of this highly toxic and persistent compound.

(6) NCASI also criticized the Agency's ambient water criterion for not referring to the EPA guidelines for fish flesh.

Although the Agency noted the FDA action level of 5μg/g for fish flesh, its criterion derivation is not dependent upon such a level. The Agency has proposed a criterion intended to be protective in a "worst case" situation (i.e., .001μg/l of PCB in water and a 274,000 bioaccumulation factor). FDA guidelines are seizure levels and are not intended to be levels safe for chronic consumption.

(7) Comments from the Ford Motor Company objected to the Agency's inclusion of an ambient water criterion as unnecessary, scientifically inappropriate, and exceeding the authority of section 307(a) of the Act. They feared that the criteria would be misinterpreted as setting uniform federal-state water quality standards. They also urged that the Agency's proposed standard take into consideration the extent and probability of environmental exposure to PCBs.

Section 307(a) does not preclude the use of an ambient water criterion in the process of establishing toxic pollutant effluent standards. For the reasons set forth in the preamble to the notice of proposed rulemaking published on June 10, 1976, the use of this approach is scientifically sound in light of the primary emphasis of section 307(a) in protecting against the effects of toxicity, which is, in turn to a large extent a function of concentration of the pollutant. The Agency, in setting nationally applicable toxic pollutant effluent standards, is not constrained to consider site-specific circumstances. Indeed section 307(a) urges the setting of national standards. In arriving at these standards, extensive consideration has been given to environmental exposure, as reflected in the Criteria Document for PCBs, the preamble referred to above, and the Decision accompanying promulgation of the standards. The criterion number of .001μg/l is the same as the federal water quality standard for PCBs which appears in the Agency's "Quality Criteria for Water (1976)" published pursuant to section 304(a) of the Act but is intended to have independent significance.

The Agency has also determined that 307(a) standards are necessary to restrict the addition of PCBs into our Nation's waterways because of the potentially serious threat to human health posed by the accumulated and widespread presence of PCBs in the environment.

(8) General Motors recommended that the Agency recognize the existence of an often significant background level of PCBs in natural waters in establishing its ambient water criterion.

As previously noted, the Agency's establishment of an ambient water criterion is designed to provide an ample margin of safety for aquatic organisms and most consumers thereof and does not take into consideration actual ambient levels of PCBs found in the environment. The fact that some water bodies contain levels of PCBs higher than the criterion level was recognized by Congress when it passed the Toxic Substances Control Act of 1976, including section 6 which requires the eventual elimination of PCB use. Through regulatory action it is hoped that overall levels of PCBs in the environment will be reduced over time.

As discussed elsewhere herein the Agency has recognized the often significant background level by allowing a credit for PCBs in the influent in circumstances not otherwise violative of the Agency's antidegradation policies.

(9) Comments were received from the City of Akron Department of Public Service citing the presence of PCB levels in the Cuyahoga River which exceed the Agency's ambient water criterion of .001μg/l but which is not attributable to any known point source of PCBs.

The Agency recognizes the presence in the ambient waters of high levels of PCBs even in areas where no known source of PCBs has been determined. It is indeed likely that significant amounts of PCBs are contained in air fallout and rainfall. The data have shown that PCBs have a high propensity for biological transport.

(10) Several commenters asked the Agency to provide more detail concerning the analytical procedures which it expected to be used to detect PCBs at levels below 1μg/l (1 ppb). Particular concern was raised about the presence of other chlorinated organic compounds in industrial effluents which could interfere with analytical methods.

The EPA analytical method acceptable for sampling and analyzing PCB mixtures is that specified in Part 136 of Title 40 of the Code of Federal Regulations, with the additional requirement of the use of a one liter sample size to increase analytical sensitivity. The basic methodology of gas chromatography is used to analyze for PCBs in ambient waters,

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fish or other animal tissue, and sediments, as well as industrial effluents. Although the EPA method is designed to achieve a detection limit of approximately 1μg/l, several EPA witnesses testified at the hearings that reasonable reliability could be achieved at levels as low as .001μg/l (1 ppt) by adapting the EPA method to larger sample volumes. At the 1μg/l level, interference is not expected to be as serious an analytical problem as at lower levels of detection. In any event, it is recognized that mass spectroscopy is capable of separating out PCBs from other chlorinated organic compounds at the lower levels. According to the analytical witness who testified on behalf of the electrical capacitor industry, interfering compounds are not a major problem with effluent from capacitor manufacturing plants. The commenters are advised to refer their specific questions concerning the EPA method to the EPA Environmental Monitoring and Support Laboratory in Cincinnati, Ohio.

(11) Another comment from General Electric disagreed with the Agency's inclusion of process changes in conjunction with add-on treatment in the technology identified for existing plants. General Electric suggested that such process changes only be required for new sources thereby only requiring existing sources to consider add-on treatment technologies.

The Agency, by its contractors, has evaluated several technologies available for reducing PCBs in waste discharges including those leading to elimination of the discharge of PCBs. Since the Agency's stated goal is to reduce all designated section 307(a) toxic pollutants to a concentration level of approximately the acceptable criterion number for that substance, the Agency has investigated process changes as well as add-on treatment. The identified technology upon which the Agency bases the proposed effluent standard includes process changes where it appears that such changes could be installed within one year, where equivalent PCB removals could be achieved and where such changes appear less costly than end-of-pipe treatment. The Agency interprets section 307 requirements separate and apart from the effluent limitation guidelines requirements of sections 301, 304 and 306 of the Act.

(12) Comments from Edison Electric Institute stated that even if proven acceptable substitute dielectric and insulating fluids are available for new electrical equipment, substitution of the fluid or replacement of the equipment would not be an acceptable solution for existing capacitors and transformers. They also noted that EPA must provide assurance that substitute fluids are environmentally acceptable and that "normal methods for handling, storing and disposal of these substitutes" can be used. An immediate problem facing users of PCB-filled equipment was said to relate to proper methods for disposal of retired or failed units.

The standards here at issue control effluent discharges into navigable waters and do not require substitution of fluids in capacitors and transformers already in use at this time. The Agency has not banned the use of PCBs by industry but rather has put forward effluent standards for PCBs to meet the environmental requirements set forth in the statute. The statute carries no obligation to provide assurances with respect to substitutes. It would be expected that any consideration of replacement fluid environmental acceptability would be in compliance with the requirements of the Toxic Substances Control Act and/or other relevant federal and state statutes.

In addition to the treatment technology identified in the contractors report prepared in support of these regulations, the Agency has published guidance for disposal of PCB contaminated units in a notice entitled, "Polychlorinated Biphenyl-containing Wastes, Disposal Procedures" in 41 FR 14134 (April 1, 1976). In addition, the Agency is required to prescribe methods for disposal of PCBs by June 30, 1977 under section 6(e)(1)(a) of the 1976 Toxic Substances Control Act (Pub. L. 94-469, 90 Stat. 2003). These regulations are in the process of being developed at this time.

(13) Dow Chemical Company U.S.A. objected to the Agency's statement that satisfactory PCB substitutes are not readily available and claimed that they produce a PCB substitute "which has been found environmentally acceptable and to perform equal to or better than capacitor grade PCBs."

The Administrator lacks authority in this standard-setting process to pass judgment on the technical or environmental acceptability of any potential PCB substitute. However, the information submitted by Dow is helpful and will no doubt be of interest to those manufacturers of transformers and capacitors who are actively engaged in seeking acceptable substitutes. The Agency notes that evidence adduced at the hearing suggests that the Dow substitute may not be satisfactory for use in small low voltage capacitors. Phthalate esters were considered to be the most promising alternative in such low voltage uses.

(14) Comments were submitted by several capacitor manufacturers who were also represented at the hearings by the Electronics Industry Association. They noted that the sole producer of PCBs (i.e., Monsanto) has announced its discontinuance of PCB production by October 31, 1977 and that capacitor manufacture after July 1, 1978 will by necessity use dielectrics other than PCBs. They argued that the installation of treatment technology similar to that identified by the Agency for such a short period would be impractical and uneconomical. These commenters thus anticipated that their production facilities would be closed from the point in time when the standards become effective until a suitable replacement fluid becomes available.

These same facts were brought to the Agency's attention at the hearings. The Agency's economic impact statement prepared in support of these standards (Notice of availability published at 41 FR 51048 (November 19, 1976)) has taken these considerations into account in determining that no significant economic impact will result from the promulgation of the Agency's proposed standards.

Even though the section 307(a) requirements may not apply once use of PCBs in the manufacturing process ceases, National Pollutant Discharge Elimination System (NPDES) permit requirements may require achievement of comparable limitations, which may in turn prompt the affected plants to consider utilization of treatment technologies similar to those discussed in the Agency's statement of basis and purpose to control the discharge of PCB residues in manufacturing systems. Such technology might be required for several years until residues are totally flushed from contaminated systems. At least one manufacturer has agreed to install the requested technology, partially at least, for this reason.

(15) P. R. Mallory & Co., Inc. commented that the proposed standards give no consideration to the volume of water discharged by a particular manufacturer and thereby encourage a presently small water user to use more water in order to dilute PCB concentrations in their discharge.

The proposed regulations combine a prohibition of discharge of certain wastes with certain exceptions wherein a 1μg/l concentration must be achieved. Because wastewater quantities and feasible control alternatives appear to vary widely among plants, it was not feasible to include a mass limitation similar to that proposed in other section 307(a) standards. However, it should be noted that recycling would be required for large volume water uses (e.g., cooling water) to reduce the final discharge volumes. The standards as promulgated are sufficiently stringent as to make it virtually impossible to comply with them by means of dilution.

(16) The State of California Water Resources Control Board urged the Agency to include firms engaged in the repair, remanufacture, salvage, and/or disposal of PCB-filled transformers and/or capacitors when it promulgated its final PCB standards.

The Agency recognizes that other discharges of PCBs exist. The proposed regulations were not intended to include all sources of PCB discharges, but were limited to PCB manufacturers, capacitor manufacturers and transformer manufacturers based on available data. Upon obtaining additional information on other PCB sources and the relevant extent of their discharge, the Agency will take appropriate regulatory measures to limit the addition of PCBs from other sources into the environment.

(17) General Motors noted several operational difficulties with the treatment technology for PCB removal which the Agency briefly described in its Notice of Proposed Rulemaking on July 23, 1976. They questioned the effectiveness of carbon adsorption for removal of PCBs in the presence of other organic compounds; the availability of other treatment technologies such as oil extraction for PCB removal, the Agency's cost estimates for a PCB treatment system; and the impact of PCB disposal problems on domestic electric consumption.

Evidence presented at the hearings by a representative of Calgon Corporation, an acknowledged leader in carbon adsorption technology, indicated that rel-

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bon adsorption will treat PCB containing effluents down to the 1 μg/l level. The presence of other chlorinated organic compounds is not believed to be a major problem in the control of effluent from capacitor manufacturers. In any event, biological processes can be utilized to reduce levels of such other compounds prior to carbon adsorption treatment. By increasing the mass of carbon in the system, effluents with increased degrees of chlorination are capable of being treated.

The Agency's contractors considered liquid/liquid extraction using oils during the course of its study of treatment technologies for PCB-containing effluents. However, their study was not intended to be an exhaustive listing of potential treatment alternatives. Rather their purpose was to show that particular technologies were available. Because no laboratory or pilot data were available on oil extraction technology, it was not deemed fruitful to explore a hypothetical process. Furthermore, the partition coefficient for oils is much higher than that for carbon, potentially resulting in greater cost and disposal problems.

The Agency arrived at its cost figures based on the most current information available from suppliers of treatment systems. It therefore believes that its cost estimates were reasonable.

The disposal problem associated with PCBs was raised by other comments as well as by General Motors and was addressed more fully above. As noted previously, the Agency is required under TOSCA to study this issue but it is not a relevant concern in the context of these proceedings.

(18) Comments were received from both Westgate Research and Houston Research disagreeing with the Agency's conclusions with respect to the feasibility of ultraviolet-assisted ozonation as a PCB treatment technology.

The Agency has re-evaluated its technical basis for UV-ozonation, in light of the present comments as well as the affidavit and testimony of a UV-ozonation equipment manufacturer (Houston Research) who furnished additional technical and cost information which is now in the hearing record. The Agency believes that the performance capability of UV-ozonation is now well documented in the record in this proceeding.

(19) Dow Chemical urged the Agency to revise its definition of PCBs to exclude chlorinated biphenyls "that have functional groups attached other than chlorine unless that functional group * * * is determined to be dangerous to the public health, safety and welfare * * *."

The Agency's definition of PCBs is "a mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees." The biphenyl molecule has a total of ten carbon-hydrogen bonds at which chlorine substitution is possible. The exclusion suggested by Dow is determined by the Agency to be unnecessary and inappropriate.

IV. Conclusions

1. The toxic pollutant effluent standards proposed by the Agency for PCBs (§ 129.105) by publication in the FEDERAL REGISTER on July 23, 1976, 41 FR 30466 et seq., together with the Agency's supporting statement of basis and purpose, embody a careful and thorough consideration of the toxicity of PCBs, their persistence, degradability, the usual or potential presence of affected organisms in any waters, the importance of the affected organisms, and the nature and extent of the effect of PCBs on such organisms, as required by section 307(a) of the Act. The evidence presented at the rulemaking hearings by the Agency and also by the various objecting parties expanded upon and added to the extensive data base which was set forth by the Agency in its statement of basis and purpose.

2. The Findings set forth above are based upon substantial evidence in the record concerning the extraordinary toxicity, persistence, and mobility, the low degradability, and the severe bioaccumulation properties of PCBs, as well as their serious human health implications. When the Agency issued its proposed standards for PCBs on July 23, 1976, it stated in connection with the ambient water criterion that it was "virtually impossible to state with confidence that any number above zero provided an ample margin of safety for man" (41 FR 30470). Additional evidence introduced at the hearing confirmed the soundness of that reservation, and the seriousness of the PCBs problem. This included substantiation of earlier preliminary evidence that PCBs may bioaccumulate in the field at substantially higher rates than those experienced in laboratory tests upon which the Agency placed primary reliance in developing its proposed standards, additional evidence of the hazards of low-level exposure to PCBs to a wide range of organisms, and additional evidence of carcinogenicity.

3. Evidence presented at the hearings also showed that the impact of a prohibition of PCBs on the industries in question would be no greater than the impact of the effluent standards proposed by the Agency on July 23, 1976. As discussed in the Findings above, this alters the picture from that which confronted the Agency at the time of proposal, when it appeared that the incremental impact of a prohibition on discharge of PCBs by transformer and capacitor manufacturers would have a far more adverse economic effect than standards at the levels proposed. As set forth in the Findings, the reasons for the concern I expressed in the preamble to the proposed standards regarding such incremental impact (which led the Agency to not propose a prohibition at that time on PCBs in the discharges from capacitor and transformer manufacturers (41 FR 30474-30475)) have largely ceased to exist.

4. Based upon a preponderance of the evidence on the record adduced at the hearings, as discussed in the preceding Findings, I have concluded that the toxic pollutant effluent standards as originally proposed should be modified so as to establish a prohibition on PCBs in any discharge by any manufacturer of PCBs or any electrical transformer or electrical capacitor manufacturer, in order to provide an ample margin of safety for the protection of aquatic and other organisms and consumers thereof, including humans, who may be affected by discharges from such manufacturers.

5. In addition for the reasons set forth in the preceding Findings, I have concluded that because of the extraordinary persistence and mobility of PCBs which often results in the presence of PCBs in intake water supplies, the proposed standards should be modified so as to include a new § 129.105(c) which would allow, for PCBs only, a credit for pollutants in the intake waters where the source of those intake waters is other than the waterbody to which the effluent is discharged, so long as the PCB concentration in such intake waters does not exceed and thereby degrade that of the receiving waters. Such a credit is already available where the source of the intake water is the same as the receiving waterbody, under 40 CFR 129.6 (the general implementing regulations, promulgated on January 12, 1977, 42 FR 2588, 2614).

6. In subsections (b)(1)(i), (c)(1)(i), and (d)(1)(i) of § 129.105 as proposed, there was the following language setting forth the application of the standards to stormwater and other runoff.

These standards or prohibitions apply to

* * * * *

(B) All discharges from the manufacturing areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to: (1) stormwater and other runoff,

Subsection (ii) of each of those sections then provided as follows:

These standards do not apply to stormwater runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs, or to stormwater runoff that exceeds that from the ten year 24-hour rainfall event.

For clarification, each of the subsections first mentioned above should be modified by inserting after the words "stormwater and other runoff" the following language: "except as hereinafter provided in subsection (ii)."

7. The toxic pollutant effluent standards proposed by the Agency for PCBs with the foregoing modifications, are fully supported by substantial evidence on the record as a whole. No further modification of such standards is justified "based upon a preponderance of evidence" adduced at the hearings within the meaning of section 307(a)(2) of the Act, and accordingly the standards, with the foregoing modifications, should be promulgated.

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8. Under section 307(a)(6) of the Act, toxic pollutant effluent standards are to be complied with "in no case more than one year from the date of such promulgation." Although I have the authority under that section to require compliance with these standards in a shorter period of time, it is my conclusion that the full statutory period should be allowed to enable plants to either phase out their use of PCBs, convert to substitutes, make appropriate technological or process changes, or take such other steps as they may decide upon in order to achieve compliance.

9. It is my further conclusion, based upon the Findings set forth above and the evidence of record, that the standards as thus promulgated fully satisfy the requirements of section 307(a) of the Act, that compliance therewith is achievable within the prescribed time frame, and that the standards which are promulgated at this time are not likely to cause serious adverse economic impact to the Nation or to the industries which are subject to their provisions.

Effective date. The amendment as hereinafter promulgated will become effective February 2, 1977. Due to the operation of § 129.6, the compliance date for the standards promulgated below will be February 2, 1978.

Dated: January 18, 1977.

RUSSELL E. TRAIN,
Administrator.

1. In 40 CFR Part 129, Subpart A (as promulgated at 42 FR 2568 et seq. January 12, 1977, and amended at 42 FR 2617 et seq. January 12, 1977), the table of contents is further amended to read as follows:

Subpart A—Toxic Pollutant Effluent Standards and Prohibitions

Sec	
129.1	Scope and purpose.
129.2	Definitions.
129.3	Abbreviations.
129.4	Toxic pollutants.
129.5	Compliance.
129.6	Adjustment of effluent standard for presence of toxic pollutant in the intake water.
129.7	Requirement and procedure for establishing a more stringent effluent limitation.
129.8	Compliance date.
129.9-129.99	[Reserved]
129.100	Aldrin/dieldrin.
129.101	DDT, DDD and DDE.
129.102	Endrin.
129.103	Toxaphene.
129.104	Benzidine.
129.105	Polychlorinated Biphenyls (PCBs).

AUTHORITY: Sec. 307, 308, 501, Federal Water Pollution Control Act Amendments of 1972 (Pub. L. 92-500, 86 Stat. 816, (33 U.S.C. 1251 et seq.)).

2. Subpart A of Part 129 is further amended by adding a new paragraph (f) to § 129.4 to read as follows.

§ 129.4 Toxic pollutants.

* * * * *

(f) Polychlorinated Biphenyls (PCBs)—polychlorinated biphenyls (PCBs) means a mixture of compounds composed of the biphenyl molecule which has been chlorinated to varying degrees.

3. Subpart A of Part 129 is further amended by adding a new § 129.105 to read as follows:

§ 129.105 Polychlorinated biphenyls (PCBs).

(a) *Specialized definitions.* (1) "PCB Manufacturer" means a manufacturer who produces polychlorinated biphenyls.

(2) "Electrical capacitor manufacturer" means a manufacturer who produces or assembles electrical capacitors in which PCB or PCB-containing compounds are part of the dielectric.

(3) "Electrical transformer manufacturer" means a manufacturer who produces or assembles electrical transformers in which PCB or PCB-containing compounds are part of the dielectric.

(4) The ambient water criterion for PCBs in navigable waters is 0.001 *ng/l.*

(b) *PCB Manufacturer*—(1) *Applicability.* (i) These standards or prohibitions apply to:

(A) All discharges of process wastes;

(B) All discharges from the manufacturing or incinerator areas, loading and unloading areas, storage areas, and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to:

(*1*) Stormwater and other runoff except as hereinafter provided in subparagraph (ii); and

(*2*) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to stormwater runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs; or to stormwater runoff that exceeds that from the ten-year 24-hour rainfall event.

(2) Analytical Method Acceptable—Environmental Protection Agency method specified in 40 CFR Part 136 except that a 1-liter sample size is required to increase analytical sensitivity.

(3) Effluent Standards: (i) *Existing Sources.* PCBs are prohibited in any discharge from any PCB manufacturer; (ii) *New Sources.* PCBs are prohibited in any discharge from any PCB manufacturer.

(c) *Electrical Capacitor Manufacturer*—(1) *Applicability.* (i) These standards or prohibitions apply to:

(A) All discharges of process wastes, and

(B) All discharges from the manufacturing or incineration areas, loading and unloading areas, storage areas and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to:

(*1*) Stormwater and other runoff except as hereinafter provided in subparagraph (ii); and

(*2*) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to stormwater runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs, or to stormwater runoff that exceeds that from the ten-year 24-hour rainfall event.

(2) *Analytical Method Acceptable* Environmental Protection Agency method specified in 40 CFR Part 136 except that a 1-liter sample size is required to increase analytical sensitivity.

(3) *Effluent Standards*—(i) *Existing Sources* PCBs are prohibited in any discharge from any electrical capacitor manufacturer; (ii) *New Sources* PCBs are prohibited in any discharge from any electrical capacitor manufacturer.

(d) *Electrical Transformer Manufacturer*—(1) *Applicability.* (i) These standards or prohibitions apply to:

(A) All discharges of process wastes, and

(B) All discharges from the manufacturing or incineration areas, loading and unloading areas, storage areas, and other areas which are subject to direct contamination by PCBs as a result of the manufacturing process, including but not limited to: (*1*) Stormwater and other runoff except as hereinafter provided in subparagraph (ii); and (*2*) Water used for routine cleanup or cleanup of spills.

(ii) These standards do not apply to stormwater runoff or other discharges from areas subject to contamination solely by fallout from air emissions of PCBs; or to stormwater runoff that exceeds that from the ten-year 24-hour rainfall event.

(2) *Analytical Method Acceptable* Environmental Protection Agency method specified in 40 CFR Part 136, except that a 1-liter sample size is required to increase analytical sensitivity.

(3) *Effluent Standards*—(i) *Existing Sources* PCBs are prohibited in any discharge from any electrical transformer manufacturer; (ii) *New Sources* PCBs are prohibited in any discharge from any electrical transformer manufacturer.

(e) *Adjustment of effluent standard for presence of PCBs in intake water.* Whenever a facility which is subject to these standards has PCBs in its effluent which result from the presence of PCBs in its intake waters, the owner may apply to the Regional Administrator (or State Director, if appropriate), for a credit pursuant to the provisions of § 129.6, where the source of the water supply is the same body of water into which the discharge is made. The requirement of subparagraph (1) of § 129.6(a), relating to the source of the water supply, shall be waived and such facility shall be eligible to apply for a credit under § 129.6, upon a showing by the owner or operator of such facility to the Regional Administrator (or State Director, if appropriate) that the concentration of PCBs in the intake water supply of such facility does not exceed the concentration of PCBs in the receiving water body to which the plant discharges its effluent.

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