DRAFT

1. INTRODUCTION

Polychlorinated biphenyls (PCB's) are a class of compounds produced by the chlorination of biphenyls. PCB's manufactured in the United States are registered under the trade name Aroclors® The degree of chlorination determines their chemical properties and generally their composition may be identified by the numerical nomenclature e.g. Aroclor 1242, Aroclor 1254 etc. The first two digits represent the molecular type and the last two digits the average percentage by weight of chlorine. Each biphenyl group may have from one to ten chlorine atoms.

There are 210 possible different PCB compounds of which only four Aroclors are presently being manufactured and sold in the United States. A major contention of the Monsanto company, the sole U. S. Manufacturer as well as several electrical manufacturers, is that Aroclors having four or less chlorine atoms per biphenyl group are degradable and do not persist in the environment as they acknowledge is true of higher chlorinated PCB homologs.

PCB compounds are slightly soluble in water and their solubility decreases with increase in chlorine content. Conversely the specific gravity, boiling point, and melting point increase with chlorine content. PCB compounds are highly soluble in fats, oils and nonpolar liquids and have excellent dielectric properties. Their resistance to heat

MONS 041787

and biological degradation has been shown to vary directly as their chlorine content.

Because of their relatively non-flammable nature and dielectric properties, PCB's are widely used by the electrical industry in the manufacture of capacitors and transformers. As part of an agreement with several agencies of the Federal Government, Monsanto, in 1971, discontinued the sale of PCB's for all other uses, ~~such as~~ Some examples are additives to paints, plasticizers, pesticides and the encapsulating of carbonless carbon paper. This restriction in the sale of PCB compounds came about after an assessment by the Interdepartmental Task Force on PCB's of studies that indicated a tendency of PCB's to bio accumulate in the environment.

It is the intent of the Environmental Protection Agency (EPA) by issuance of a toxic effluent standard for PCB's under Section 307 of PL 92-500 to regulate the discharge of PCB's to levels that protect the health and welfare of the aquatic environment and man.

II. THE PROPOSED STANDARD

DRAFT

On December 27, 1973 a proposed toxic effluent standard for PCB compounds was published in the Federal Register (38 F.R. 35 388, 35 392-93). The summary of the basis and purpose of the proposed toxic effluent standard states that "The primary toxicological basis for the standard was proposed EPA Water Quality Criteria" which were based in part on the National Academy of Sciences - National Academy of Engineering report, Water Quality Criteria, 1972 Ex. 12 at 177) hereafter "NAS Report."

2 ppt

For freshwater the recommendation of the NAS Report states "aquatic life should be protected where the maximum concentration of total PCB in unfiltered water does not exceed 0.002 ug/l at any time or place and the residues in the general body tissues of any aquatic organism do not exceed 0.5 ug/g." An acceptable chronic toxicity for receiving waters of 0.002 ug/l was established as the basis for the effluent standard. The acceptable acute toxicity was established at 280 ug/l, which was derived from an averaging of short term (96 hr or less) PCB bioassay data on freshwater fish.

0.5 ppm

=?

The NAS report made no PCB recommendation for ambient water concentrations to protect marine aquatic life, but did make the following recommendation for the protection of wildlife: "that PCB concentrations in any sample consisting

MONS 041789

of a homogenate of 25 or more whole fish of any species that is consumed by fish-eating birds mammals, within the same size range as the fish consumed by any bird or mammal, be no greater than those of 0.5 mg/kg of the wet weight.* EPA therefore arrived at a chronic toxicity of 0.0167 ug/l in receiving waters by establishing an upper concentration factor of 30,000 for PCB's in marine fish (based on available data) and dividing this number into the NAS recommended 0.5 ug/g in fish flesh consumed by birds and mammals. The 10 ug/l acute toxicity for marine waters was obtained by utilizing the bioassay data at which a 41 percent reduction in growth of the shells of oysters was sustained in 96 hours.

III. MAJOR ISSUES RAISED BY OBJECTORS

A number of issues were raised by objectors at the hearings on the proposed standards. Among the most important of the industry arguments are the following:

A. The definition of PCB's was objected to because it classifies all PCB's into one group without allowances for their differences in chemical and physical properties, persistence, and effects on the environment.-

MONS 041790

B. On the basis of the above objection the concept of a single standard for PCB's was challenged by several of the objectors.

C. Objections were raised to the alleged basing of standards on laboratory studies unsubstantiated by field data.

D. The use of 200,000 as the accumulation factor for assessing possible concentrations of PCB's in fish body tissue was challenged on the basis of its alleged indefensible data base.

E. Several objectors stated that the acute toxicity of PCBs is too variable to justify across-the-boards standards and therefore argued for a case-by-case approach to the development of the standards.

F. The standards were alleged to have a certain ambiguity with respect to their end result relative to protecting the aquatic environment vis-a-vis protecting consumers of aquatic life. For example, one objector stated that there is "fuzziness" in the chronic portion whereby aquatic toxicity limits are "threaded amongst" accumulation factors and FDA action levels established for tissue body

burdens to protect man as the ultimate consumer of aquatic life.

G. It was alleged by some objectors that the proposed standards are based on inaccurate toxicity information and on non-typical fish [Relative to those found in a given area]. - Salmon 6895.

H. Objectors alleged that available monitoring techniques do not permit detection at the levels proposed in the standards except under laboratory conditions with sophisticated analytical techniques.

I. It was alleged by some objectors that the technology does not presently exist to permit the standards to be met.

Those issues will be discussed further on in this document.

IV. A. RECEIVING WATER QUALITY CRITERIA

MONS 041792

Freshwater - 0.003 ug/l for salmonids
- 0.01 ug/l for other aquatic species

DRAFT

Marine Water - 0.01 ug/l

D. RATIONALE FOR THE CRITERIA

From an analysis of both objector and EPA affidavits the following general statement can be made without challenge: PCB's exhibit a wide variation in toxicity to aquatic species depending upon such variables as 1) the chlorine content of the homologs 2) chemical and physical properties of the receiving water 3) the biochemistry of the affected organism and 4) the duration of exposure to the chemical. For example Dr. Gerald Lauer in his arridavit (Sec. 3 of Ex 82 at 2) on behalf of the General Electric Company pointed out that toxicity values for single homologs frequently vary as much as 100,000 between the highest and the lowest LC_{50} value. From the PCB data presented to the toxic effluent hearings (Ex. 82 at 2 and 5 of Table 1 to Sec. 3, Ex. 105 at 5, and Ex. 102 at 15), the lowest LC_{50} values for exposure of 7 days or less appear to be in the range of 3 to 10 ug/l for both freshwater and marine organisms.

For the protection of the aquatic environment it would seem reasonable therefore to establish an ambient criterion by the application of a safety factor to the minimum short-term LC_{50} toxicity values. Unfortunately this approach

MONS 041793

is not possible for PCB's, however, because equally * 159
important characteristics of these compounds are their 159
persistence and their tendency to accumulate in higher order 160
organisms. 160

Dr. Gilman Voith of EPA stated (Ex. 103 at 7) that while * 162
much of the early literature assumed bioconcentration in the * 163
aquatic environment was based on the trophic level or food 164
chain concepts, recent research on fish containing many 165
hydraphobic chemicals demonstrated that fish can 165
bioconcentrate chemicals directly from the water. He stated 167
that uptake can be approximated by a first order process 167
which appears to be chemical partitioning from the water and 168
the lipids in the tissue. He concluded with the observation * 169
that PCB bioconcentrations have been studied under * 169
laboratory conditions during which PCB mixtures are added to 170
the water only and observed bioconcentraion factors for 171
PCB's in the aquatic environment may differ in different * 172
organisms depending upon conditions. * 172

Dr. Lauer during cross-examination about marine 174
bioconcentration data developed by Dr. Tom Duke of * 175
EPA(Transcript Proceedings of May 9, 1974 at 2903, 2904, and * 175
2905) was asked if he had developed on his own any data on * 175.1
bioconcentrations apart from that presented by EPA. He 177
indicated that he had not, that he had high regard for EPA 177

DRAFT

researchers, but that there was some more relevant data developed by the EPA Duluth Laboratory that he would have picked to have applied to freshwater situations. He finally stated that he concurred totally with Veith testimony regarding the potential for accumulation based on the conditions existing in the ecosystems in question. This endorsement would seem by the same logic extendable to Dr. Duke, an EPA researcher whose statement was based on an evaluation of PCB effects on various species under existing field conditions in the manner suggested by Dr. Lauer.

Having discussed two of the selection alternatives used by EPA in establishing water quality criteria--- i.e. direct toxicity to aquatic life and protection of consumers of aquatic life, actual derivation of the numerical criteria is presented below.

Research on the effects of PCB compounds on freshwater aquatic life was initiated at the EPA National Water Quality Laboratory in 1970 (Ex. 105 at 1-7), when Dr. Alan Nebeker began static bioassay tests of eight Aroclor (1221, 1232, 1242, 1248, 1254, 1260, 1262, and 1268). The 3-week LC_{50} toxicity was 25 ug/l, with Aroclor 1248 found to be the most toxic. Continuous-flow bioassays Aroclor 1254 were the most toxic with a 3-week LC_{50} value of 1.3 ug/l. Later studies

MONS 041795

were conducted on freshwater scud or shrimp, midges, and fathead minnows. Continuous flow 96-hr LC_{50} bioassay values for Aroclors 1242 and 1248 on scud were 73 and 20 ug/l. For fathead minnows, values of 7.5 ug/l and 15 ug/l were calculated for Aroclor 1254 and 1242.

Dr. Hebeker also indicated that much excellent PCB freshwater effects data have been produced at the Fish-Pesticide Research Laboratory of the Bureau of Sports Fisheries and Wildlife, Columbia, Missouri (Ex. 105 at 7 & 9). An example of their findings is the following comparison of results from 96 hr LC_{50} studies of Aroclors 1242 and 1016 on rainbow trout and bluegill :

	Aroclor 1242	Aroclor 1016
Rainbow Trout	67 ug/l	100 ug/l
	109 ug/l	440 ug/l
Bluegill	125 ug/l	46 ug/l
	154 ug/l	420 ug/l

DRAFT

Analyses of 40 fishes from the 1970 National Pesticide Monitoring Program indicated only one fish to contain less than 1 ug/g PCB with the ten highest residues ranging from 19 ug/g to 213 ug/g whole body weight (Ex. 12 at 176). From samplings of Lake Michigan during 1969 to 1971, concentrations of PCB's appear to be less than 0.01 ug/l in the open waters and less than 0.1 ug/l in near-shore waters (1 of Ex. 32 to Ex. 103). In Lake Michigan PCB's resembling Aroclor 1254 were found at mean concentrations ranging from 2.7 ug/g in smelt to 15 ug/g in lake trout (Ex. 103 at 9). Data on the Saginaw River shed (Ex. 103 at 9) indicate typical Aroclor 1254 concentrations of 1.1 ug/l to 2.9 ug/l.

Dr. Vieth (Ex. 103 at 9) stated "some evidence exists that bioconcentration factors measured in the laboratory are essentially the same as that found in the river environment." He presented data to show that goldfish in the lower Milwaukee River accumulated Aroclor 1248 approximately 0.7×10^5 to 2×10^5 times depending upon the ~~liquid~~ lipid content. His summary relative to bioconcentration of PCB's is that from both laboratory and river system studies, many of the aquatic organisms appear to bioconcentrate PCB mixtures containing 3,4,5, and 6 chlorine atoms per molecule approximately 3×10^3 to 2×10^5 times the concentration in the water.

DRAFT

Dr. Hebeker reported (Ex. 105 at 5) that tissue
esidues in fathead minnows ranged from 0.7 ug/g of Aroclor
248 in control fish to 1036 ug/g of Aroclor 1254 in fish
eld for 8 months in water containing 4.6 ug/l of Aroclor
254. The latter case indicates a bioconcentration factor
f 2.3×10^5 .

Based on mean concentration data for Lake Michigan fish,
n average water concentration of 0.01 ug/l, and the FDA
ction level of 5 ug/g in fish tissue residues for
rotecting human consumers of fish, a criterion of 0.003 ug/l
ppears warranted for salmonids. On the basis of the FDA
ction level of 5 ug/g in fish tissue and both laboratory
id field derived bioconcentration levels for fathead
innows and goldfish in the range of 0.7×10^3 to 2.3×10^5 ,
i ambient water concentration of no more than 0.025 ug/l
ould be possible. However, since monitoring data on Lake
chigan indicate open water levels of 0.01 ug/l, a level of
01 ug/l for all fishes other than salmonids appears
asonable.

Median PCB concentrations in whole fish of eight species
om Long Island Sound obtained in 1970 were reported to be
the order of 1 ug/g, as were comparable concentrations
f the coast of Southern California. Generally, residues
ocean fish have been below 1 ug/g (Ex. 12 at 176).

MONS 041798

DRAFT

Surveys of Escambia Bay (Florida) by the EPA Gulf Breeze Laboratory during the period September 1969 to December 1971 have produced some of the most recent data on the pathways and effects of PCB's in the estuarine and marine environments. Aroclors 1016, 1221, 1242, 1248, 1254 and 1260 were examined. Test organisms were oysters, pink shrimp, pinfish, killifish, crabs, sheephead minnow and spot. From the Escambia Bay data, which include flow-through bioassays with residue analyses where possible, the following conclusions were reached: (1) all of the Aroclors tested are acutely toxic for certain estuarine organisms; (2) bioassays lasting longer than 96 hours demonstrated that Aroclor 1254 is toxic to commercial shrimp at less than 1 ug/l; (3) fish, particularly sheephead minnows, are extremely sensitive to Aroclor 1254 with 0.1 ug/l being lethal to fry; and (4) acute toxicity of Aroclor 1016 to estuarine organisms is similar to the toxicity of other Aroclors but appears less toxic to fish in long-term exposures than does Aroclor 1254 (Ex. 102 at 12-13).

The bioaccumulation factors (Ex. 102 at 15-23) for the different flow-through bioassays were reported to be as follows:

DRAFT

Aroclor	Organism	Time	Accumulation Factors (as a multiplier of test water concentrations)
1254	Oyster	30 days	1.01×10^5 101,000
1254	Blue Crab	20 days	4×10^3 4,000
1254	Grass Shrimp	7 days	3.2×10^3 to 11×10^3 3,200 11,000
1254	Spot	14-28 days	37×10^3 37,000
1254	Pinfish	35 days	21.8×10^3 21,800
1016	Pinfish	42 days	11×10^3 to 24×10^3 11,000 24,000
1016	Sheephead Minnow		2.5×10^3 to 8.1×10^3 2,500 8,100

Based upon an accumulation factor of 100,000 in the oyster, it is necessary to limit the marine water concentration of PCB's to a maximun of 0.01 ug/l to protect the human consumer.

MONS 041800

Evidence is accumulating that PCB's do not contribute to shell thinning of bird eggs. However, other pathological

DRAFT

deficiencies are reported to be attributable to PCB's. This may increase susceptibility to infectous agents such as viral diseases, and increase the activity of liver enzymes that degrade steriods, including sex hormones. Also laboratory studies have indicated that PCB's with their derivatives or metabolities, causes embryonic death of birds (Ex. 12 at 226).

V. ANALYTICAL TECHNIQUES

Based upon the testimony of Dr. E. S. Tucker on behalf of the Monsanto Company (Ex. 83 at 7-9), as well as EPA PCB affidavits (Ex. 103 at 2-7; Ex. 104 at 3-6), there is common agreement that electron capture-gas chromatography is the dominant technique used in the identification and quantification of PCB compounds. Monsanto expressed concern, however, with respect to five general facets of the EPA test method for PCB's which are:

A. Alleged lack of properly designed sampling procedures to ensure that samples found bear proper relationship to the amount discharged.

B. Alleged absence of recommended provisions for correcting apparent PCB levels found in samples for laboratory and reagent background to assure

MONS 041801

DRAFT

reasonably high confidence limits at the parts per trillion (ppt) level.

C. Alleged failure to address interferences likely to be in industrial waste streams and thereby requiring absolute verification of all compounds by an alternative technique such as gas chromatograph/mass spectrometry.

D. Alleged failure to determine via an alternate procedure the closeness of calculated PCB levels to real PCB levels

E. Suggested that the precision and accuracy of the proposed procedure undergo inter-laboratory evaluation if this has not been done.

EPA recognizes at least the partial validity of some of these changes such as, _____ and _____, is modifying our proposed methods accordingly. The change _____ is unfounded for the following reasons:

A. Etc.

B. etc. _____.

MONS 041802

DRAFT

I. RESPONSE TO ISSUES RAISED BY OBJECTORS

A. We agree that the PCB definition in the Federal Register of December 27, 1973 lacks enough detail to make the uninitiated aware of the fact that PCB compounds have different physical, chemical, and biological properties. We disagree, however, that the definition should exclude identifying the pentachloro to tetra chloro biphenyls because conclusive evidence has not been presented to support objector claims that the lower chloro biphenyls do not bioconcentrate sufficiently to be harmful to consumers of aquatic life.

B. We agree with objector affidavits and testimony to the extent of acknowledging that the individual Aroclors have different degradation rates and toxicities in addition to their already recognized different physical and chemical properties. On the other hand the data do not appear to be adequate to permit issuance of a two part standard e.g. with a break point at the tetra chlorobiphenyls. Dr. Lauer in his testimony (Transcript Proceedings May 9, 1974 at 2908 and 2909) agreed that while homologs containing less than four chlorine atoms do not accumulate in tissues of fish and wildlife

MONS 041803

DRAFT

at as great a rate as do those containing more * 368
chlorine atoms per biphenyl, you can't say that * 369
they do not accumulate. He then stated there is a 370
remarkable lack of data in the literature that is 370
available, on the lower homologs as far as 371
reporting residuals is concerned. He concludes 372
with the statement he thinks there is still more * 373
work that needs to be done to find out the * 373
respective roles played by more rapid degradation * 374
and lack of uptake in effecting the fact of lower * 375
chlorine residuals in biota. Finally, data * 376
submitted by Monsanto (Ex. 83-21 at 6) indicate an 376
improvement in degradability of only 7 percent i.e. 377
from 33 percent to 26 percent by Monsanto's 377
substituting Aroclor 1016 for Aroclor 1242 in the 378
manufacture of capacitors. 378

C. We think the objections to our alleged basing of 380
standards on laboratory studies unsubstantiated by 381
field data are unfounded. Dr. Donald Mount of EPA 382
stated (Ex. 94 at 2, 4, 9) that most laboratory 382
bioassays have been performed in water that is 383
relatively free of large concentrations of organic * 384
matter, suspended solids, and other materials that * 384
might render toxicants less potent. It has caused * 386
many to conclude that laboratory results are 386

MONS 041804

involved. To insure against such erroneous claims many labs including the EPA National Water Quality Laboratory utilize a natural surface water containing modest amounts of organic and inorganic constituents so that data developed will be representative of natural conditions. He further stated "to suggest that laboratory bioassay data when properly used cannot be used to predict effects in the field is contradictory to scientific approach that has been so successful in the field of mammalian toxicology and pharmacology."

D. We do not think an accumulation factor of 200,000 is indefensable as testimony by Dr. Duke indicates a factor of 100,000 for the oyster and Dr. Veith's testimony states that river system data indicate potential accumulation factors of up to 200,000.

E. We do not think it practical to write standards on a case-by-case basis for to do so would be to have no "standard" at all as well as be inordinately expensive. Dr. Mount's comments on "sensitive species" (Ex. 94 at 15) supports this position. He states "repeated allegations are raised in the objector's affidavits stating that sensitive life stages such as salmonid eggs or Daphnia should not

MONS 041805

DRAFT

be used to establish standards because these particular forms are not present in all waters ----. It seems a safe assumption to make, that as additional species are tested, some of them are going to be more resistant than those that have already been tested and some are going to be less sensitive ---- it is highly probable that in any given water, species of greater sensitivity than those tested occur. Therefore it would appear that the use of the most sensitive species tested, to establish acceptable levels [rather than a case-by-case approach] may not be overly conservative"-----.

F. We agree that ambiguity did exist relative to whether water quality criteria are based upon aquatic bioassay data or consideration of bioconcentrations levels that will provide protection for consumers of aquatic life. As can be seen in sections II and IV above that problem has been clarified.

G. We think that the allegation about inaccurate toxicity information and non-typical fish is too imprecise to respond to, but we do have confidence

MONS 041806

DRAFT

in the veracity of toxicity data upon which the * 422
standards are based. * 422

II. We believe that ambient levels upon which standards 424
are based should be established at levels that will 425
support the type of desired aquatic life or protect * 426
the health of consumers of any aquatic species * 426
rather than at some convenient level for ease of * 427
monitoring. 427

I. We think that some objectors have been more 429
concerned with attempting to prove that technology 430
does not exist rather than with taking the positive 430
approach of directing their engineering talent to 431
the design of necessary treatment technology. 431
432