COMMENTS BY THE GENERAL ELECTRIC COMPANY ON

"PROPOSED TOXIC POLLUTANT EFFLUENT STANDARDS

FOR POLYCHLORINATED BIPHENYLS"

(41 FR 30468, July 23, 1976

INTRODUCTION

The General Electric Company is a major manufacturer of electrical capacitors and transformers whose dielectric fluids contain polychlorinated biphenyls (PCBs). Consequently, we have followed diligently the development of the regulatory structure for PCBs, and we submit the following comments regarding the proposed toxic pollutant effluent standards for PCBs published in the Federal Register on July 23, 1976 (41 FR 30468). We hope that our comments will assist the Environmental Protection Agency in promulgating effluent standards for polychlorinated biphenyls (PCBs) that are technically sound, clear and equitable in application, and in compliance with the terms of the Federal Water Pollution Control Act.

Although these comments are directed specifically to the proposed standards for PCBs, they are also relevant to two related issues: (1) the establishment of effluent limitations on PCBs for dischargers not covered by the proposed standards, and (2) the development of effluent limitations and guidelines for the 65 chemicals and chemical classes covered by the same consent agreement* that established a deadline for the proposal of these PCB effluent standards.

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* Approved on June 9 by the U. S. District Court for the District of Columbia, NRDC v. Train, 8 ERC 2120.

In conformity with this agreement, the preamble to the proposed standards states that "in developing the standards proposed herein the Administrator has given careful consideration to each of the factors enumerated in Section 307(a)(2)... In addition, the Administrator has considered the availability of various methods of control and related technology by which discharge of PCBs might be eliminated or reduced." In its initial Notice of Proposed Toxic Pollutant Effluent Standards (41 FR 23576, June 10, 1976) the Agency presents its justification for giving "at least some consideration to ... the availability of control technology in setting standards under Section 307(a)..."

The Agency therefore first examined the available data base in order to arrive at an ambient water criterion and then "examined feasible control technology to ascertain what concentration levels industrial dischargers might be able to achieve in their effluents..."

Recognizing that "translating an ambient water criterion number to an end-of-the-pipe standard is at best an imprecise calculation," the Agency has decided (41 FR 23580) that "in any case where a discharge is allowed, on the spectrum ranging from certain safety (a prohibition) to that uncertain point where harmful effects are caused and safety ends, a logical break point is struck where the very best that control technology can do is required." To deal with those "few cases" where local receiving water conditions may be inadequate to ensure "sufficient dispersion and dilution" of the pollutant, the Agency has proposed a Section 129.7 allowing "the cognizant regulatory authority to impose such more stringent effluent limitations as may be required in order to achieve the ambient water criterion..."

Thus, even though the proposed "ambient water criterion" is not used directly in the derivation of the proposed effluent standards (as it was by the Agency in its earlier proposed rule making, 38 FR 35388 et seq.), it could serve as a basis for some future ad hoc tightening of effluent limitations.

Our comments, therefore, address two main issues:

(1) The scientific approach used by the Agency in arriving at an ambient water criterion for PCBs. We feel that the Agency should distinguish between two major groups of PCBs, and that it has failed to establish a logical, straightforward derivation of its proposed ambient water criterion from the relevant scientific data base.

(2) The technological approach used by the Agency in proposing Section 307(a) standards. We feel that the Agency has gone beyond the scope of the Federal Water Pollution Control Act in requiring the institution of process changes by existing plants within one year of promulgation of standards under Section 307(a). We also suggest improvements for a revised version of the analytical method for PCBs specified by the Agency for reliable determination of compliance or non-compliance.

COMMENTS ON ISSUES

1) The Scientific Approach Used By The Agency

We find two major areas of weakness in the approach used by the Agency in arriving at an ambient water criterion of 0.001 µg/l:

a) The reasoning used by the Agency in deciding (41 FR 30473) that "there appears to be no sound basis for setting different criterion numbers or standards for different isomers."

b) The absence of any logical, straightforward derivation of the proposed ambient water criterion from the relevant scientific data base.

a) Definition of PCBs [Sec. 129.4(f)] Does Not Differentiate Among Isomers and Homologs

There is neither chemical nor biological justification for considering all PCB isomers and homologs to be equivalent in respect to the criteria for toxicity used by EPA in selecting pollutants for the list of toxic pollutants (38 FR 24342).

An interdisciplinary group of life scientists on the staff of GE's Corporate Research and Development Center recently conducted an exhaustive analysis of the available toxicological and environmental literature on PCBs. This analysis disclosed substantial evidence of large differences in toxicity, bioaccumulation, and environmental persistence among different commercial grades of PCBs and among different test species.

For example, large ranges of toxicity have been seen in animal studies that focussed on the nature of the effect produced by similar doses of different Aroclors, including studies conducted by the same group of workers in the same laboratory. Thus, the same group (Kimbrough, Burse et al) that reported that Aroclor 1254 or 1260 in rats could provoke a progression of hepatic changes, beginning with hypertrophy and pyperplasia, and going on to adenofibrosis, neoplastic nodules, and carcinomas (cited under "(4) Carcinogenesis" on p. 30472) also reported parallel studies indicating that none of these toxic manifestations occurred with Aroclor 1242 or 1016. Similarly, the initial liver response to Aroclors 1254 and 1260, i.e. marked induction of drug-metabolizing enzymes, was absent when Aroclor 1016 was used.

The extensive Japanese investigations of the Yusho poisoning episode, particularly the more recent findings summarized by Dr. Kuratsune at the

National Conference on PCBs in November 1975, have disclosed the origin of the huge ranges in toxicity exhibited by different grades and even different specimens of the same grade of PCB. The actual toxic agents in the PCBs have been identified as the polychlorodibenzofurans (PCDFs). Kuratsune showed that it was the PCDFs, not the PCBs, that were chronically accumulated in humans and that it was the levels of PCDF, not those of PCB, that correlated with toxic manifestations in man. It is remarkable that the very first clinical report on PCB poisoning in humans, that of Jones and Alden in 1936, clearly recognized that the toxic action had to come from an impurity; however, the impurity was not actually identified as PCDF until more than 35 years later. Clear-cut correlations of toxicity with PCDF level were reported for chickens by Vos et al in 1970-72.

We reviewed all relevant data in the scientific literature describing chronic PCB toxicity studies on mammals. We then constructed Table 1, in which columns 3, 5, 6, and 7 present our best quantitative estimates or calculations, from these published data, of PCDF concentrations in the PCBs used, of "maximum no-effect" concentrations of PCB in food, of food intake rates, and of "maximum no-effect" dose rates. For comparison, we have included Kuratsune's data on humans. Among the animal studies, we note in particular that the lowest "maximum no-effect" concentrations and "maximum no-effect" dose rates were associated with the highest estimated PCDF concentrations (>> 1 ppm PCDF in PCB). Furthermore, the "no-effect" numbers for hepatic effects in rats are significantly higher for Aroclor 1016 (which was estimated to have no PCDF) than for the higher chlorinated Aroclors (which were estimated to have about 1 ppm PCDF in the PCB used.)

TABLE I. CALCULATION OF MAXIMUM NO-EFFECT DOSE RATE FOR PCB/PCDF COMPOSITIONS

(1) Test Subject	(2) PCB/PCDF Tested	(3) Ppm PCDF in PCB (Estimated)	(4) Major Toxic Effect	(5) Max. no-effect, ppm PCB in food	(6) Intake rate, kg.food/kg. body wt.-day	(7) Maximum No-effect dose rate, mg.PCB/kg. body wt.-day
Human	Kaneclor-400 (heat aged)	10,000[a]	Dermal	(0.5g.)[c]*	(~1000 day)[k]**	~0.007
Monkey (adult)	Aroclor-1248 (shelf aged)	>>1[n]	Dermal	<2.5[d]	0.04	<0.1
Monkey (infant)	Aroclor-1248	~1[b]	Dermal	>300.[e]	0.04	>12.
Mink	Aroclor-1254 (metabolized)	>>1[o]	Hepatic	<0.6[f]	0.05	<0.03
"	Aroclor-1254	~1[b]	"	<5.[g]	"	<0.25
Dog	Aroclor-1260	~1[b]	Hepatic	~10.[h]	0.03	~0.3
	Aroclor-1254	~1[b]	"	<100.	"	<3.
	Aroclor-1242	~1[m]	"	>100.	"	>3.
Rat	Aroclor-1260	~1[b]	Hepatic	~10[i]	0.05	~0.5
	Aroclor-1254	~1[b]	"			
	Aroclor-1242	~1[m]	"			
"	Aroclor-1016	0[b]	"	~100[j]	"	~5.

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Sources

a. Kuratsune, 1976. b. Bowes et al., 1975. c. Kuratsune, 1972. d. Barsotti et al., 1975. e. Abrahamson and Allen, 1973. f. Platanow and Karsted 1973. g. Ringer et al., 1972. h. Keplinger et al., 1971; Calandra, 1975; as interpreted by FDA, 1973. i. Keplinger et al., 1971; Calandra, 1975; Kimbrough et al., 1972; as interpreted by FDA 1973. j. Burse et al., 1974. k. Assumption of FDA, 1973. m. Ax and Hansen, 1975. n. Estimated from progressive increases in toxicity observed in going from early to late (Ref.6) tests. o. Estimated from use of liver, known to concentrate PCDF relative to PCB (Ref.a) as mink food.

* This figure is the maximum no-effect dose in grams of PCB.

** This is FDA's assumption of number of days over which dose is accumulated by humans.

Even more significant was the demonstration by the Japanese group that the particular PCDF's chronically and specifically accumulated by the human liver were the penta- and hexachlorinated homologs. Since the PCDF's were found to arise from the PCBs upon aging, particularly under conditions favoring thermal oxidation of the PCB's, it is evident that the source of the chronically toxic penta- and hexachloro PCDF's must be the corresponding penta- and hexachloro PCBs.

In this connection, it is significant that Aroclor 1016, which is essentially the only Aroclor used by the capcitor industry since 1971, was specifically designed to contain virtually none of these more environmentally persistent and potentially toxic penta- and hexachloro homologs. The widely-quoted Monsanto prospectus indicates a total content of these "higher homologs" as $< 1.1\%$; however, the product quality control limit was set at 0.4%; and the actual material shipped to GE during the past two years has usually contained less than 0.1%. This contrasts with the 100-fold higher level of "higher homologs" found in Aroclor 1242 (typically, around 9%) or the 1000-fold higher level in 1254 or 1260 ($> 70\%$). Thus, there is a clear chemical basis for the strikingly lower toxicity levels actually observed in mammals whose diet contained Aroclor 1016.

Toxicity in fish probably results from a general anesthetic effect of the PCBs themselves rather than PCDF activity in most cases; even so, there are significant differences in chronic toxicity among the various product grades, which appear only partly relatable to differences in bioaccumulation. Reported values for bioaccumulation of Aroclor 1016 in various species and life stages of fish run from 2,500 to 55,000, and are usually 10-20,000. Bioaccumulation of Aroclor 1254 is typically 2-5

fold larger. In continuous flow chronic toxicity tests, reported LC 50 values for various species and life stages of fish cover the range 11-81 ppb for Aroclor 1016 (Hansen, Parrish and Forester, 1974) and about 1-5 ppb for Aroclor 1254 (Nebeker and Puglisi, 1974). There is one report of "significant mortality" in sheepshead minnow fry at 0.1 ppb of Aroclor 1254; the same authors also reported, however, that 100-fold higher levels were required to produce a comparable effect with Aroclor 1016. (Nebeker and Defoe, 1974).

In summary, all available evidence indicates that Aroclor 1016 is 10- to 100-fold less hazardous than the higher PCBs to fish; 100- to 1000-fold less hazardous upon direct exposure to animals, and probably 500- to 5000-fold less hazardous if exposed via the fish bioaccumulation - fish consumption route. Inasmuch as there is no analytical problem in distinguishing among the different degrees of chlorination present in a given PCB sample, it is scientifically justified and practically feasible to establish separate ambient water criteria for PCBs with degrees of chlorination $\leq$ 4 Cl/biphenyl (which represent 65% of current U.S. production) and for PCBs with degrees of chlorination $\geq$ 5 Cl/biphenyl (which are the homologs most persistent in the environment and potentially the most toxic).

We believe that separate criteria for the higher and lower PCBs would be in the public interest for three reasons.

o The development of Aroclor 1016 by Monsanto and its subsequent use by capacitor manufacturers beginning in 1971, represented a major and technically successful effort by industry to reduce to a negligible level the most environmentally persistent components of the dielectric fluid used in capacitors. Failure of the proposed rules to give any

recognition to the differences between the toxicity and persistence of different commercial grades of PCBs would certainly discourage other manufacturers from attempting to remove objectionable impurities from other products in the future.

o A regulation that attempts to discourage the use of one substance on the basis of a gross exaggeration of its toxicity increases the likelihood that it will be replaced by a substitute that may in fact be environmentally less desirable than the original substance.

o Although the proposed effluent standards apply only to manufacturers of PCBs, capacitors, and transformers, the ambient water criterion could be used as a basis for regulating other dischargers, such as paper mills, whose effluents contain Aroclor 1242 because they recycle paper containing that material. A water quality criterion that recognized the more benign nature of Aroclor 1242 compared to higher chlorinated PCBs, which were not used in paper products, would protect aquatic life and still enable the public to enjoy the environmental benefits of recycled paper.

b) Derivation of Proposed Ambient Water Criterion

The criteria that are most defensible, and that best serve the public interest, are those that follow in the most logical and straightforward manner from the demonstrated scientific facts of the situation. The establishment of such criteria requires (1) a thorough, critical evaluation of the available toxicological data, in order to separate the solid, self-consistent facts from the anomalies, extrapolations, and inferences, and (2) a clear statement of the safety factors used in proceeding from any "maximum no-effect dose" thereby established to the proposed criterion. If such safety factors have been generated ad hoc, then the rationale behind them should be indicated.

The preamble to the proposed standards contains a series of categorical statements relating to the reported toxicity, carcinogenesis, and human health effects of PCBs, and to the persistence, mobility degradability, bioaccumulation and biomagnification of PCBs. These statements summarize the highlights of "the extensive data base set forth in the criteria document" (which is referred to in Appendix A), and lead EPA to the conclusion that "a criterion level of 0.001 µg/l would appear to avoid adverse effects to most aquatic organisms..."

However, the only direct connection made by the Agency between the biological data and the proposed criterion is its statement that "This level is based primarily on the bioaccumulation properties of PCBs." But, in fact, the Agency does not develop any such quantitative derivation of the criterion from bioaccumulation data. Instead, it says: "Based upon a bioaccumulation factor of 274,000* a concentration of 0.001 µg/l would result in bioaccumulation to 0.274 ppm in flesh, which is below the dietary levels which have been shown injurious to aquatic birds and mammals who may feed upon them." (underlining added). The Agency goes on to say: "In addition, however, there is evidence that in some waters some fish bioaccumulate at rates roughly ten times this, and in waters where the chronic level generally exceeds 0.001 µg/l, such as Lake Michigan, there is evidence of sublethal toxic effects on fish." None of the foregoing provides any rational basis for choosing 0.001 µg/l as the ambient water criterion.

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* The upper end of the range the Agency says is found "after prolonged esposure in the laboratory."

Even after proposing this ambient water criterion, the Agency proceeds to raise doubts about its adequacy in its statement that "the Agency recognizes the possibility that such water quality level may not provide absolute safety for all organisms in all waters," and "there probably is no numerical concentration level above zero which one can at this time say with great confidence provides an 'ample margin of safety' for all organisms under all circumstances." Furthermore, the Agency goes on to say that "even if every point source discharge were prohibited, PCB concentrations in the water would remain for a long time not only above zero, but in some water bodies, above .001 µg/l. Moreover, since the capability does not exist presently to measure PCB concentrations below 0.001 µg/l with any reasonable degree of reliability, no useful purpose would be served in establishing a criterion number below this."

In essence, the Agency appears to have adopted the position that no level of PCBs in the ambient waters provides an "ample margin of safety," and is setting an actual numerical value at what it believes is the lowest level of analytical detectability. (On this point the Agency appears to be inconsistent, because the analytical method specified for PCBs in Section 129.105 states that "the limit of detection is approximately 1 µg/l for each Aroclor mixture.")

There is no doubt that some PCB/PCDF systems are toxic, that they do bioaccumulate, and that safety factors are required whenever one is attempting to regulate exposure to a toxic agent that is difficult to detect (e.g. PCDF) via the level of a more readily detectable congener or precursor (e.g. PCB). However, regulation should be derived from sound data. Weight

must be given in the regulatory process to the established, self-consistent portions of the data base rather than to values reported by individual observers.

2) Technological Basis for Proposed Effluent Standard.

a) Control Technology Required

We can understand the pragmatic approach of the Administrator in interpreting the language of Section 307(a) to authorize consideration of control technology in setting toxic pollutant effluent standards. However, because Section 307(a) contains no explicit language on control technology, the Administrator should look for guidance in this area to those sections of the Act that do require specific levels of control.

For existing plants, such guidance is provided by Sections 301 and 304, which call for effluent limitations that shall require the application of BPCTA (1977) or BATEA (1983). The present proposal, as it applies to existing plants, is neither BPCTA or BATEA. Instead, it more closely resembles Section 306, which applies to national standards of performance for new sources. Section 306 requires "a standard ... which reflects the greatest degree of effluent reduction ... achievable through application of the best available demonstrated control technology, processes, operating methods, or other alternatives, including where practicable, a standard permitting no discharge of pollutants." Note the striking parallelism between the language of Section 306(a) and the current proposal that "the Administrator is requiring that discharges be prohibited where possible and that other discharge comply with the very best results which available technology can achieve," including specific process changes and operating methods, such as replacing steam jets with mechanical pumps and replacing detergent washing with solvent vapor degreasing (underlining added).

We understand the intent of the law to set more stringent effluent limitations for new plants than for existing plants and to require existing plants to meet more stringent limitations by 1983 (BATEA) than by 1977 (BPCTCA). We also understand that under Section 304 the Administrator is directed to consider process changes in his assessment of BAT, which would be applicable to existing plants. But the timetables set forth in the Act certainly do not authorize the requirement that these proposed rules would impose, namely that existing plants must institute process changes within only one year of promulgation.

In light of the foregoing, the Administrator should amend the proposed standards to make the items listed in the column "type of technology applied" (p. 30475) that relate to process changes* applicable only to new sources. Existing sources should be subject only to requirements involving treatment technologies (e.g. carbon adsorption), not process changes.

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* E.g. "Replace steam jets with mechanical pumps" and "Replace (detergent washing water) with solvent vapor degreasing."

b) Analytical Method Acceptable (Section 129.105)

We have reviewed the method specified in 40 CFR Part 136 for PCBs (NPDES, Appendix A, FR 38, No. 75, Pt. 11) and have compared the procedure and the claims made for it with our own experience in analyzing industrial effluents for PCBs.

We have two comments concerning the use of the EPA method to establish compliance with an effluent standard.

1) The published method fails to specify the details of the procedure to be used in obtaining effluent samples for analysis. In our experience, the scatter among the results of single analyses on successive samples of a given waste stream is far wider than the scatter among successive analyses on aliquot portions of a single sample. Standardization of sampling procedures is essential if results obtained on samples taken at different times are to be meaningfully compared either to each other or to a prescribed effluent standard.

2) Our experience and that of other laboratories offers qualified support to the EPA claim that "the limit of detection is approximately 1 µg/l (1 ppb) for each Aroclor mixture." When blanks are very low, and no interferences are present, and the calibrating standard is qualitatively the same as the sample, this limit is reasonable. The results of a recent ASTM round robin test indicate that the 95% confidence limits at the 1 ppb level ranged from ± 25% to ± 75% of the reported value for a single analysis. In this test the samples used were pure Aroclors in distilled water and one sample of river water. In the real-world sequence of industrial sampling, sample preparation, sampling handling, and analysis, the reliable limit of

detection may range from 1 to 10 ppb, and the 95% confidence limit for a single determination at the 1 ppb level may be ≥ ± 100%.

We believe it is essential that EPA prepare a revised version of its proposed analytical method that will include the following items:

1) A description of acceptable sampling procedures.

2) A description of acceptable methods for removing or correcting for interferences likely to be present in industrial waste water streams. (The present version refers primarily to pesticide-type interferences, which are unlikely to be present in industrial samples).

3) A well-documented statistical analyses of the method as applied to industrial waste samples so that decisions on compliance with the effluent standards as promulgated will be based on a realistic understanding of the confidence limits associated with results reported by dischargers.

Submitted
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