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Session VII:

APPROACHES TO CONTROL

John L. Buckley, Ph.D.
Session Chairman

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INTRODUCTORY REMARKS

John L. Buckley, Ph.D.

I would like to call to order the final morning of our conference here and I would like to tell you also that I have won an additional brass ring. I will be chairman of the session this morning, not because I planned it that way, but because Dr. Jim Brydon, who had agreed to serve in this capacity and did his best to get here, could not make it. He left Ottawa late yesterday afternoon, having appeared before the Treasury Board in the morning and the Senate in the afternoon, and he made it as far as Toronto, where apparently there were electrical difficulties and so Jim will about this time be turning around to go back to Ottawa instead of coming here.

I would like to explain to you what I have in mind in the way we are going to try and operate. It is not all that difficult or complex. It rather follows the statement in the program. We will have a series of speakers, each of whom has prepared remarks and that will be followed by discussion among the speakers and in response to comments or questions from the floor.

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A REVIEW OF FEDERAL AND STATE GOVERNMENT ROLES IN CONTROLLING IMPACTS OF PCB's ON THE ENVIRONMENT

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Abstract

Polychlorinated biphenyls (PCB's) have found extensive application in a large number of industrial products since they were first commercially used in the 1930's. Presently their use in the United States appears to be principally restricted to closed electrical systems, such as capacitors and transformers, though several tens of millions of pounds are used each year as an insulating fluid in these products. Numerous studies now clearly indicate the contamination of PCB's in the environment. Residues of PCB's are detected in many different aquatic and animal species. They are found in high concentrations in river bottoms, and in samples of commercial and sport fish collected from the Great Lakes region and in several rivers in the East Coast. They are found in amounts greater than the Food and Drug Administration's tolerance limit of 5 ppm.

The roles of the Federal and State governments in controlling the manufacture and use of PCB's are examined. It is concluded that, in most cases, little or no regulatory activities have been initiated by government agencies in recent years to address the problem, in spite of the heightened concern over the potential threat of PCB's on the environment and to public health. Only in the past few months have several Midwestern States bordering the Great Lakes and the State of New York taken measures to control the discharge of PCB's from known sources.

To cope with the problem, several recommendations have been urged, which include: the complete phaseout of the manufacture and use of PCB's, a ban on their import and export, the development of a consumption inventory, an accelerated program of monitoring and surveillance, a moratorium on river bottom dredging, promulgation of the PCB toxic effluent standard, a significant lowering of present FDA tolerance limit on PCB's, and Congressional passage of the Toxic Substances Control Act.

INTRODUCTION

Polychlorinated biphenyls (PCB's) were first introduced into commercial use over 45 years ago, and for a long time they were considered to be relatively nontoxic substances. Their potential threat to the environment was not recognized until 1966, when the Swedish scientist, S. Jensen, observed the presence of PCB's in fish and wildlife samples while analyzing for chlorinated hydrocarbon pesticide residues (refs. 1,2). Since that initial discovery, PCB's have been detected in numerous aquatic and animal species, and have been noted in high concentrations in industrial waste discharges, river bottom sediments, food packaging materials, and in food products, such as poultry, fish, and dairy products.

A large variety of industrial applications have been found for PCB's, since they are endowed with a number of desirable chemical and physical properties. They are chemically stable, nonflammable, and essentially nonsoluble in water. They also possess a high dielectric constant and are relatively viscous materials with a low volatility. Thus, they are used as heat-exchange fluids and as a dielectric medium in electrical capacitors and transformers. They have been used as hydraulic and lubricating fluids, and are used in gas turbines and vacuum pumps. In the past, they were extensively used as plasticizers in plastic products, as coatings in textile products, and in paints and varnishes. They were also used as sealants, as extenders in pesticides, and as an ingredient in caulking compounds, adhesives, printing inks, and carbonless duplicating paper (refs. 3,4,5).

In 1971, over 106 million pounds of PCB's were produced in the industrial countries of the world, with a third or nearly 40 million pounds being manufactured in the United States (ref. 4). During the late 1950's and into the 1960's, U.S. domestic sales of PCB's increased nearly threefold, reaching a peak of approximately 72 million pounds in 1970 (ref. 5). Prior to 1970, about 60 percent of U.S. domestic sales was for closed electrical systems, such as capacitors and transformers. Another 25 percent was used as plasticizers and in the production of carbonless duplicating paper (ref. 5). Since September, 1970, when Monsanto Company, the sole manufacturer of PCB's in the United States, restricted its sale of PCB's to closed electrical systems, the U.S. consumption has been reduced considerably. It is important to note, however, that these reductions occurred mainly with the use of PCB's as plasticizers, and as hydraulic and lubricating fluids and other miscellaneous uses. The bulk of PCB's, as mentioned above, had been used in electrical systems, and it is still being used almost exclusively by

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manufacturers of large power and small ballast capacitors, and electrical transformers, as the preferred dielectric fluid.

ENVIRONMENTAL CONTAMINATION OF PCB's

Residues of PCB's in environmental samples have now been reported in numerous studies conducted during the past 10 years. They have been analyzed in wildlife and fish samples in Holland, Germany, and in the Baltic Sea (refs. 6,7). Off the coast of Scotland, PCB residues were found in several marine species, the contamination presumably having arisen from sewage wastes being dumped into the open sea (ref. 8).

Unlike the almost ubiquitous presence of chlorinated hydrocarbon pesticides in the environment, PCB residues are generally found in areas associated with high industrial and urban activity. Little or no detectable amounts of PCB's were found in wildlife sampled in remote, nonpopulated areas, such as the Gulf of California and Cape Crozier, Antarctica (ref. 9). Similarly, rivers and lakes without known industrial discharges are generally found to be uncontaminated with PCB's, such as has been shown for several watersheds and small lakes in the upper Midwest and in Canada (refs. 10,11). On the other hand, PCB's in increased amounts are detected in the Eastern and Western coastal regions in highly urbanized areas, such as the Chesapeake Bay, San Fransisco Bay, and the Puget Sound, or in regions where industrial discharges are known to occur, such as Escambia Bay, Florida, and the Hudson River (refs. 9,12,13,14).

Studies on plankton species in the marine environment have shown them to contain detectable amounts of PCB's. Zooplankton sampled off the Eastern continental shelf area were observed to contain PCB levels ranging between 0.07 and 3 ppm (ref. 15). Plankton species collected in the Gulf of Mexico and the Gulf of St. Lawrence have been found to contain PCB residues as high as 1 ppm and 3 ppm, respectively (refs. 16,17).

Tuna caught off the Atlantic seaboard are shown to contain PCB's with levels of 0.36 to 1.5 ppm (ref. 18). Considerably high concentrations of PCB's are noted in several predatory birds, with values from 30 to 900 ppm in the livers of heron, 65 ppm (wet weight) in peregrine falcons, 190 ppm (whole body weight) in white-tailed eagles, to 93-470 ppm (wet weight) in the livers of cormorants (ref. 8, 9, 19, 20). Similarly, a number of studies have shown relatively high levels of PCB's in the eggs of wild birds, ranging from 1 to 44 ppm (refs. 18, 19, 21).

An important impact of PCB's on the environment has been contamination of sport and commercial fisheries in the Great Lakes region. Levels of PCB's in lake trout and coho salmon from Lake Michigan show an alarmingly increasing trend since 1972, in the average range of 10 to 25 ppm, well above the present Food and Drug Administration's maximum allowable concentration of 5 ppm for fish and shellfish (see figure 1) (ref. 22). On the other hand, DDT levels for the same species of fish show a decreasing trend since 1970, when DDT consumption in the United States was curtailed (figure 1). It is rather discouraging to note that even with the restriction of domestic sales of PCB's to closed electrical systems since the early 1970's there has been no corresponding decrease in PCB levels in commercially important fish species.

Fish samples collected by the Wisconsin Department of Natural Resources last year showed extensive contamination of several species of fish in Lake Michigan (ref. 23). These include chinook salmon, coho salmon, brown trout, tiger trout, lake trout, whitefish and carp. Generally, the residue levels ranged well above 5 ppm, with lake trout (up to 43.8 ppm) and carp (up to 51.6 ppm) showing the highest concentration values. In the Upper Fox River fish sampled at one station earlier this year by the Department showed high concentration of PCB's in white suckers (32.7 ppm), carp (21.4 to 45.8 ppm, average 35.9 ppm) and northern pike (average 15.4 ppm). Samples analyzed by the Department in 1973 showed similar residues of PCB's in a number of fish species in several reaches of the Mississippi River. These data are summarized in table 1.

An interagency Task-Force on PCB's, formed of Federal and several State agencies of Minnesota and Wisconsin, sampled fish in the Mississippi River during the early summer of this year and found similar levels of PCB's in several fish species: carp (up to 33 ppm), walleye (up to 9.8 ppm), white bass (up to 4.3 ppm). Generally, PCB values were found at higher levels in samples collected south of the Minneapolis-St. Paul metropolitan area (ref. 24). More surprising is the detection of PCB residues in lake trout sampled last year in Lake Superior by the Great Lakes Environmental Contaminants Survey (GLECS), which showed residue levels ranging between 0.5 and 12.7 ppm in the Siscowet (fat) variety of trout. The lean trout variety had lower PCB residues, though the larger size fish often had residue levels close to or above 5 ppm (ref. 25).

The Division of Fish and Game of the Commonwealth of Massachusetts has in the past occassionally sampled PCB levels in fish in several rivers and streams in the State (ref. 26) and high levels have been detected in several species. White sucker samples collected in 1971 in the Housatonic River showed mean PCB levels of 15.10 and 69.30 ppm at two sampling stations near the General Electric plant in Pittsfield, Massachusetts, which

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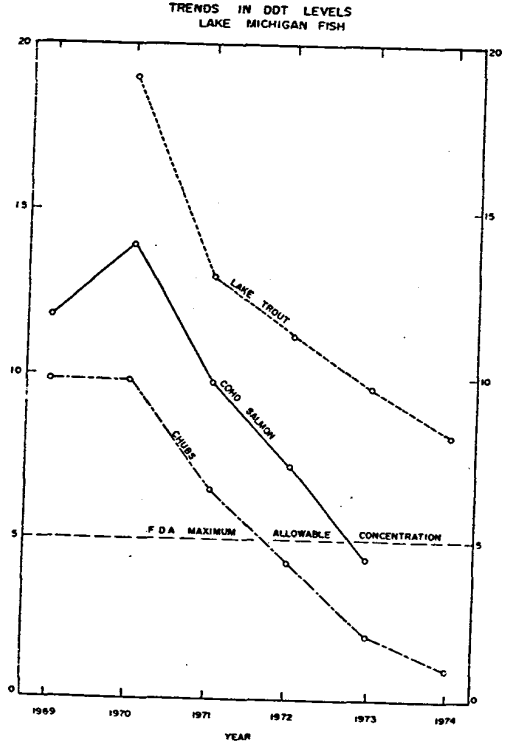

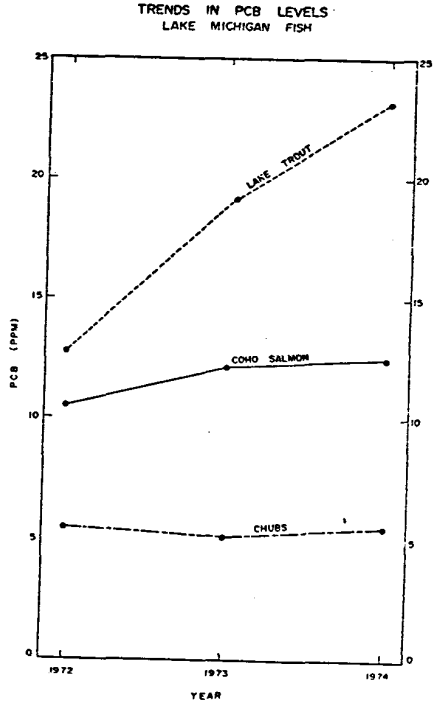

Figure 1. PCB and DDT trends in Lake Michigan fish (ref. 22).

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Table 1. PCB's residue in fish species in Mississippi River, 1973 (ref. 23)

Species	Station	PCB(ppm)	PCB average
Walleye	Lake Pepin	11.9 - 31.4	21.9
	Prescott	7.21 - 11.1	9.04
	Wabasha	3.84 - 9.00	5.85
	Trempealeau	3.16 - 6.34	4.98
Largemouth bass	Lake Pepin	1.65 - 10.5	4.90
	Trempealeau	1.74 - 5.92	2.94
	La Crosse	1.49 - 4.24	2.62
Northern redhorse	Lake Pepin	3.45 - 8.53	5.94
	Prescott	1.01 - 16.2	5.71
Carp	Lake Pepin	5.49 - 11.2	7.69
	Prescott	0.57 - 20.44	8.36
	Wabasha	4.31 - 10.5	7.83
	La Crosse	1.95 - 4.05	2.94

manufactures electrical transformers. Though it was determined by the State agency that the contamination of the fish was due to discharge of PCB's from the General Electric plant, there has been no further monitoring of the Housatonic River since 1971, and there is no indication whether abatement procedures used by the plant were effective. From the data collected by the agency, it is also clear that in 1972 there was extensive contamination of a large variety of fish species in nearly all the rivers that were sampled in the State, with mean PCB residue levels ranging between 1.11 and 197.0 ppm (see table 2).

To date, the most contaminated fish sampled in this country are found in the upper reaches of the Hudson River, near and below two General Electric capacitor plants in the Fort Edward-Hudson Falls area. Earlier sampling by the Federal EPA last year had shown yellow perch and shiner minnows to contain average PCB residues of 17 and 78 ppm, respectively, with one rock bass sample containing 350 ppm (ref. 27). It appears that the two General Electric plants had been discharging approximately 30 pounds of PCB's per day into the river, though in recent months there appears to have been a reduction of daily discharges to less than 10 pounds. The most recent fish samples collected by the New York State Department of Environmental Conservation confirm the earlier findings. The composite PCB averages of fish caught near the plant show typical values well above 20 ppm, with one American eel sample yielding residue values of 403.4 ppm of Aroclor 1016/1242 (ref. 28). These findings are partially summarized in table 3.

At the same time, the New York State Department of Environmental Conservation sampling of fish species of recreational and commercial importance in the lower Hudson also shows high residues of PCB (ref. 28). Striped bass caught near the Albany area showed total PCB residue values ranging between 11.08 and 89.76 ppm. PCB residues in fish caught in the lower reaches of the river have higher concentrations of Aroclor 1254, indicating long-range transport of the previously used higher chlorinated mixture of PCB discharged by industrial activities in the past. Striped bass sampled near the West Point and Tappan Zee area of the Hudson River (50 miles north of New York City and several hundred miles south of the Fort Edward-Hudson Falls area) show total PCB residues ranging between 1.16 and 7.54 ppm. Similarly, a sample of American shad in the Poughkeepsie area showed PCB residue levels of 9.0 ppm.

Of equal concern is the accumulation of PCB in sediments of the river bottoms. PCB's, like most chlorinated hydrocarbons, are highly insoluble in water and tend to settle on river sediment quite readily, being adsorbed on silt and fine particles in river bottoms (ref. 12).

Data collected by the United States Geological Survey (USGS) on the Hudson River during the years 1973-74 show the presence of PCB's in the water and in the bottom sediments of the river (ref. 29). Values ranging between 0.3 and 3.0 ppb PCB have been reported in water samples collected at several stations on the Hudson River. These include locations near Poughkeepsie, Waterford, Chelsea, and Rhinebeck.

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Table 2. Mean PCB concentration (ppm, dry weight) in fish collected in Massachusetts rivers and streams (ref. 26)

Stream and station	Town	No. and species	Aroclor (ppm)	Rank 1972	Rank 1971
		Aroclor 1248			
Millers	Athol	1 White sucker	197.0	1	[a]
Deerfield	Deerfield	5 Fallfish	23.8	2	5
Merrimack #1	Tyngsboro	5 Pumpkinseed	19.1	3	-
Connecticut	Northampton	5 Fallfish	17.7	4	6
Merrimack #2	Haverhill	3 Alewives 1 Eel 1 Banded killifish	13.3	5	4
Chicopee	Ludlow	5 Pumpkinseed	13.3	6	2
Westfield	Westfield	5 Pumpkinseed	11.9	7	3
Blackstone	Millville	5 White sucker	10.1	8	1
Little	Westfield	5 Golden shiner	9.41	9	7
Ware	Thorndike	5 Pumpkinseed	3.32	10	-
		Aroclor 1260			
Blackstone	Millville	5 White sucker	21.3		
		Aroclor 1254			
Charles #2	Cambridge	5 Pumpkinseed	8.3	1	1
Concord	Concord	5 Bluegill	5.96	2	2
Taunton	Taunton	5 Bluegill	3.13	3	3
Quaboag	Palmer	5 Redbreast sunfish	1.11	4	-

[a]No fish could be collected in previous years.

On the other hand, PCB concentrations analyzed from the bottom sediments of the river showed considerably higher values characteristic of the insoluble nature of PCB's. The USGS data are summarized in table 4.

More recently, the U.S. EPA conducted water and sediment analysis for PCB's in the vicinity of Fort Edward, near the GE plant. Water samples collected immediately south of the GE outfalls had PCB values of 2.2 to 3.1 ppb. The sediments contained 540,000 to 2,980,000 ppb (540 to 2,980 ppm) PCB, with 6,600 ppb being detected several miles downstream of the discharge pipes (ref. 27).

These very high concentrations of PCB's in the sediments of the Hudson River for which dredging is proposed are particularly troubling in light of the fact that the highest concentrations are likely to exist in the deep navigation channel. PCB is associated more with finer grain particles than with particles of larger mean grain-size diameters. This was clearly observed in extensive studies carried out in a study conducted by the State of Maryland Department of Natural Resources in conjunction with Westinghouse Electric Company in the Chester River (ref. 12). The study concluded as follows:

> Laboratory and field studies by other workers as well as the present study have indicated that the relatively water-insoluble chlorinated hydrocarbons readily adsorb to the surfaces of suspended clay minerals, and, in turbid waters, are found mainly attached to the suspended

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Table 3. Composite PCB residue in fish species sampled near the Fort Edward-Hudson Falls area of the Hudson River (ref. 28)

Species	Station	PCB, ppm (Aroclor 1242/1016)
Rock bass	Fort Edward	27.35
Walleye	Fort Edward	104.21, 81.12, 9.88
	5 miles below GE	157.27
Yellow perch	Fort Edward	61.10,236.4, 128.3
	5 miles below GE	84.13, 35.5, 88
White sucker	Fort Edward	82.9, 8.8
	5 miles below GE	51.39, 29.7, 36.03, 78.0, 57.5
	Stillwater	10.3, 154.3
	Waterford	20.3, 36.0
Brown bullhead	5 miles below GE	73.24, 85.30
Largemouth bass	Stillwater	24.85, 14.31, 8.99
Smallmouth bass	Waterford	27.0, 36.0

Table 4. PCB's concentration in Hudson River sediments, USGS (ref. 29)

Date	Station	PCB in sediments (ppb)
7/74	Chelsea	3,200
9/74	Chelsea	1,800
7/74	Poughkeepsie	11,000
9/74	Poughkeepsie	3,600
7/74	Waterford	13,000
9/74	Waterford	640
8/75	Roger's Island, south of Glen Falls	18,000
7/74	Winebrook Hills	0.1

particulate matter. In the Chester River Study, *the inverse correlation between mean grain-size diameter of the sediments and chlorinated hydrocarbons content* [including PCB] *suggest that a major route of transport of these compounds into the Chester River is attached to the suspended sediments* that sweep into the lower river from Chesapeake Bay. The sediments are distributed in the bed of the Chester River in accordance to their grain size and the local current velocity regimes. The fine-grain materials (silts and clays) are thrown into suspension in the shallow, shoreline areas by wind-driven and tidal currents. *These materials tend to collect in the deeper channels of the river, and, as is suggested by the core data, the fine-grain sediment areas in the deeper channels and submerged terraces probably represent the major "sinks" for chlorinated hydrocarbons* in the Chester River. (Emphasis added.)

The above observation of the transport and adsorption properties of several chlorinated hydrocarbons, including PCB's, has been further confirmed by a recently completed study in the Upper Chesapeake Bay area (ref. 30). Thus, it has been abundantly demonstrated

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that not only are PCB's adsorbed on fine-grain particulates, but they are also found in highest concentrations in the deeper channels of the river, where the channels act as "sinks" for the insoluble hydrocarbons. Thus, the very areas where dredging operations are being proposed are the most contaminated.

TOXICITY OF PCB's–A BRIEF APPRAISAL

Effects on Aquatic Species

PCB's, as a class of compounds, are extremely persistent and nonbiodegradable substances, and tend to bioaccumulate in the aquatic environment by factors of a few thousand-to several hundred-thousand-fold. PCB's (Aroclor 1254) have been shown to concentrate over 20,000 times the water levels in crustacea, 10,000-to 50,000-fold in certain estuarine fish species, to as much as 200,000-fold with fathead minnows (Aroclor 1242 and 1254) (ref. 31).

The most serious effect of PCB's on aquatic species is their ability to interfere in reproductive process and hatchability of fish eggs. It appears that the thresholds for whole salmon egg mortality is about 0.5 ppb (ref. 32). Similarly, the production and hatchability of fathead minnow eggs was adversely affected by 0.9 ppb of Aroclor 1254 (ref. 33). Pinfish and spot were unable to survive at 5 ppb of Aroclor 1254 (ref. 34) and many aquatic invertebrates were clearly affected at concentration ranges of 1 to 10 ppb PCB, including blue crabs, pink shrimp, and oyster (ref. 14). Studies by Hansen and his colleagues at EPA's Gulf Breeze Environmental Research Laboratory have indicated comparable mortality to several aquatic species exposed to Aroclor 1016 (ref. 35). These findings show that acute 96-hour LC_{50}'s (or EC_{50}'s) for oyster, brown shrimp, and grass shrimp were 10.2 ppb, 10.5 ppb and 12.5 ppb, respectively. It thus appears that the substitution of the lower chlorinated homolog mixture, Aroclor 1016 (chlorine content, 41%), does not diminish the impact of PCB's on the aquatic environment. Based on the high lethality of PCB's to marine and freshwater aquatic species, the National Academy of Sciences-National Academy of Engineering Committee made the following recommendation:

> Aquatic life should be protected where the maximum concentration of total PCB in unfiltered water does not exceed 0.002 microgram per liter [0.002 ppb] at any time or place, and the residues in the general body tissues of any aquatic organism do not exceed 0.5 microgram per gram [0.5 ppm] (ref. 31).

Effects on Humans and Animals

The toxicity of PCB to humans has been clearly demonstrated. In 1968 a severe form of skin disease was diagnosed in Japanese families that consumed rice oil contaminated with Kanachlor 400 (PCB with 48 percent chlorine content) (refs. 36,37). A total of 1,057 poisoning cases have been recorded to date in Japan (ref. 38). The disease is characterized by swelling of the upper eyelids, visual impariment, acne-like formations, and heightened pigmentation of the skin (ref. 36). Patients with this disease also exhibited neurological disorders and showed signs of hearing loss. Several babies born of women patients had many of the symptoms of the disease, which indicated a placental transport of PCB, and most fetuses were born smaller than the national average. Another disturbing feature of this disease was the observation that most patients recovered very slowly, which suggested that PCB was retained in the human body over a very long period (ref. 38).

It should be noted here that human contamination with PCB's is not isolated. PCB's have been detected in human adipose tissue in such widespread occurrence that over 40 percent of the U.S. population contains 1 part per million (ppm) or more (ref. 39).

A number of studies have conclusively shown the effect of PCB's on the reproduction of several animal species. At 100 ppm in the diet of experimental rats, PCB (Aroclor 1242 and 1254) caused a reduction in the number of offspring that were born (ref. 36). Similarly, in another study, dietary levels of as little as 20 ppm of Aroclor 1254 caused a decreased number of litters to be born to female rats (ref. 36). In a reproduction study carried out with minks, dietary levels of less than 1 ppm of PCB's caused a marked depression on the ability of minks to reproduce (ref. 40).

The effects of PCB on the reproduction of pheasants and chickens have also been demonstrated. Aroclor 1254 has a noticeable effect on both the production and hatchability of pheasant eggs (ref. 41). With chickens, dietary levels of as little as 10 ppm of Aroclor 1242 and 100 ppm of Aroclor 1254 caused thinning of eggshells, reduced egg production, and reduced hatchability (ref. 42). In this context, it is important to note that homologs of PCB with lower chlorine content may have a greater effect on reproduction than biphenyls with higher chlorine content. In a recent review article on the toxicology of PCB, Dr. Renate Kimbrough of the Center for Disease Control in Atlanta, Georgia, stated:

> The results obtained from the reproduction studies in birds particularly seem to indicate that

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the lower chlorinated biphenyls affect reproduction more than the higher chlorinated biphenyls, and it is very important to determine whether the lower chlorinated biphenyls that have been suggested as replacements for presently employed chlorinated biphenyls have an effect on reproduction (ref. 36).

In an extensive series of studies carried out by Dr. James Allen and his colleagues at the University of Wisconsin Medical School, PCB's fed in the diet of rhesus monkeys caused significant effects that mimicked both the symptoms of known human toxicity and reproduction failures in experimental animals. When female rhesus monkeys were given 25 ppm of Aroclor 1248 for a period of 2 months, severe symptoms of facial swelling and skin eruptions were manifested (ref. 43). At lower dietary levels of 5 ppm and 2.5 ppm (Aroclor 1248), similar clinical symptoms were observed after a few months, and more significantly, these low levels of PCB caused marked effect on reproduction. After three matings with male monkeys, only 12.5 percent of the 5 ppm PCB dietary group and 37.5 percent of the 2.5 ppm group were pregnant as compared to 90 percent pregnancies with a comparable control group (ref. 44). At the same time, fetuses that were born were significantly smaller in size and continued to ingest high PCB levels from the nursed milk of their mothers (ref. 45). These effects at low PCB levels are particularly important to note, since the present Food and Drug Administration tolerance limit for PCB residue in fish and shellfish is 5 ppm (ref. 46), and were based on an assumption of a higher no-effect level.

Of serious concern is a recent study conducted by a group of research investigators at the Center for Disease Control, Atlanta, Georgia, the U.S. Environmental Protection Agency, the National Cancer Institute, and the Johns Hopkins University School of Medicine (ref. 47). They observed that when Sherman strain female rats were fed 100 ppm of PCB (Aroclor 1260) for about 21 months, 26 of 184 of the experimental animals examined had malignant liver tumors (hepatocellular carcinoma), whereas only 1 of 173 control animals had the same disease. At the same time, 146 of the experimental and none of the control animals had tumorous lesions (neoplastic nodules) in the liver.

Other toxic effects of PCB that have been reported in the scientific literature include: (1) increase in the biological activity of certain hydroxylating enzymes in the liver and increased activity in the rat; (2) induction of liver porphyria in several animal species; (3) interference with the immune defense mechanisms of rabbits; (4) neurological disorders in rats; (5) increased PCB residue in fatty tissues, serum, and milk; and (6) teratogenic effect in the chick embryo (refs. 48, 49).

IMPACT ON RECREATIONAL AND COMMERCIAL FISHERIES

One of the most illustrative examples of the impacts of PCB contamination on the environment is an examination of its effect on sport and commercial fisheries on the Hudson River. The Hudson River is a productive breeding ground for fish, not only for resident species such as white perch, but also for migratory oceanic species like striped bass, shad, and herring. The shortnose sturgeon, which has been classified as an endangered species, is also an inhabitant of the Hudson River (ref. 50).

Striped bass are the most economically important of the fish that spawn in the Hudson since the species supports a major recreational and commercial fishery. For that reason, too, it is a species of particular concern because of the high levels of public consumption of Hudson River striped bass and the economic dependence of commercial fishermen on the species.

The weight in 1970 of the striped bass commercial catch in the New England Region plus New York State (including the Hudson River) was 2,780,000 pounds (ref. 51). The weight in 1970 of the striped bass sport catch in the North Atlantic (which includes New York State) was 45,844,000 pounds (ref. 52). Hudson-spawned striped bass are a major component of the Atlantic stock. Though estimates have varied, there is no doubt that the contribution is substantial. The staff of the Nuclear Regulatory Commission (ref. 53) has taken the position that:

1. The Hudson River stock is the major source of striped bass caught in the Hudson River, the western half of Long Island Sound, and the New York Bight (Barnegat Inlet, N.J., to Moriches Inlet, N.Y.). In this "Inner Zone" of influence the NRC staff estimates that more than 50 percent of the sports and commercial landings are made up of Hudson-spawned striped bass and uses a figure of 90 percent for its own estimates (ref. 53).

2. In the "Outer Zone" of influence, extending from Maine to Cape May County, N.J. (less the Inner Zone), Hudson-spawned striped bass constitute somewhere between 10 and 50 percent of the sports and commercial fishery.

The average annual commercial catch of striped bass for the years 1961-1969 in the Inner Zone was 268,200 pounds (ref. 53). Using the NRC's 90 percent figure,

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241,400 pounds represent the average annual commercial catch in the Inner Zone attributable to Hudson River striped bass. The average annual commercial catch in the Outer Zone is 1,969,000 (ref. 53), 50 percent of which is 984,500 pounds. The annual total for commercial catch of Hudson River striped bass is therefore estimated to be about 1,200,000 pounds.

In 1970, a pound of striped bass would bring a commercial fisherman $.26/lb on the average. The retail price would be, at a minimum, three times that amount. Striped bass is now selling at $1/lb in New York. Using this retail value of $1/lb, the value of commercial catch of Hudson River striped bass appears to be in the range of $1.2 million per year.

In 1970, the striped bass sports catch exceeded the commercial catch in the North Atlantic (which includes New York State) by a factor of 16.5 (ref. 53). Assuming an annual commercial catch of 1,200,000 pounds of Hudson River striped bass, one can extrapolate to a sports catch of 21,200,000 pounds. This amount represents a little less than 50 percent of the 45,844,000 1970 sports catch of striped bass in the North Atlantic and, therefore, is, if anything, an underestimation of the Hudson River sports catch. In sum, something on the order of 22,000,000 pounds of Hudson River striped bass are probably consumed each year, if we combine these commercial and sports catch figures. Moreover, the problem is even more serious than the above information would indicate. The striped bass is a migratory fish with stock from various sources (e.g., the Chesapeake, Delaware, and Hudson) intermingling. Since there is no way to distinguish origin of a striped bass, the entire North Atlantic stock may be contaminated.

An indication of the magnitude of the total Great Lakes fishery problem from PCB contamination can best be seen by evaluating the value of sport and commercial fisheries for the State of Michigan. The sport fisheries in the Great Lakes are comprised of coho and chinook salmon, steelhead, brown and lake trout. This fishery is known collectively as the salmon fishery. This is the fishery most substantially effected by PCB contamination.

Value of sport fishery in Michigan is determined by multiplying the number of angler days by $15 per day. In the Great Lakes contiguous with the State of Michigan in 1974, there were 3.1 million angler days devoted to the anadromous and Great Lakes fishery. The total value of this sports fishery is estimated at $46.5 million. Another determination is a total value of the fishery to resident and nonresident fishermen. Michigan has determined this to be $24 to $30 million—a somewhat lesser figure but still quite substantial. The value of the total Great Lakes sport fishery would be substantially larger when data from other States are included (ref. 54).

The commercial fishery in the Great Lakes has been on recent decline due to overfishing, so the value is substantially less than the sport fishery. In 1974, the number of pounds caught totalled 14,524,079, with an estimated value of $3,814,840.

The commercial species most affected by PCB contamination has been observed to be chubs. These fish are caught commercially in Lake Michigan and Lake Superior. Their 1974 catch and value are recorded in table 5.

As the above table indicates, chubs represent approximately 32 percent and 54 percent of the commercial fishery, respectively, in these two lakes. Any significant decrease in the availability of chub population to the commercial fishery will have a negative impact on the fish-related economy of the region. It is possible that a decreased chub population would eliminate commercial fishery from the Great Lakes altogether.

FEDERAL AND STATE GOVERNMENT ROLES

Since the early 70's, when it was increasingly realized that widespread contamination of PCB's had occurred in this country, a number of events highlight the role that the Federal and State governments have taken, or have failed to take, in addressing this problem. A Federal Interdepartmental Task Force was convened in 1972, which concluded that because of the highly persistent nature of PCB's and their bioaccumulation in the food chain, they posed a serious threat to human health. They recommend restricting the use of PCB's to closed electrical systems, such as electrical transformers and capacitors (ref. 56). However, as mentioned before, Monsanto Company had begun restricting its domestic sales for such exclusive purposes since the fall of 1970, and it is not clear what the Task Force's recommendations issued in May, 1972, had to do with the voluntary move made earlier by the company as has been suggested in recent remarks by an official of a Federal agency (ref. 57).

In July, 1973, the Federal Food and Drug Administration established tolerance limitation in a variety of food products as follows (table 6):

Toxicity data obtained during the past year that show severe reproductive failure in low concentrations of PCB in primates (5 and 2.5 ppm), and the recent demonstration of carcinogenicity with Sherman strain rats (refs. 44,47), clearly indicate the need to substantially revise the present FDA tolerance limitations of PCB's in foods. This in turn will have the effect of completely changing the definition of "unacceptable" levels of PCB's in fish and poultry, to be at times almost all

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Table 5. 1974 commercial fish catch and value in Lakes Michigan and Superior (ref. 55)

	Chubs Catch (lbs)	Value ($)	Total Fish Catch (lbs)	Value ($)
Lake Michigan	1,154,067	780,793	10,924,961	2,496,208
Lake Superior	1,011,234	464,499	1,529,736	826,592

Table 6. FDA tolerances for PCB in food and food packaging (ppm) (ref. 46)

Product	Tolerance level (ppm)
Milk[a]	2.5
Dairy product[a]	2.5
Poultry[a]	5.0
Fish and shellfish[b]	5.0
Eggs	0.5
Infant and junior food	0.2
Complete and finished animal feed	0.2
Animal feed components	2.0
Paper food-packaging material	10.0

[a]On fat basis.

[b]Edible portion.

inclusive of many species that inhabit the polluted lakes, streams, or feedlots, in this country.

In spite of the deficiencies of the present tolerance standards, the FDA has in recent months taken seizure action against several fish shipments earmarked for commercial markets in Lake Michigan, since they exceeded the present 5 ppm guideline (ref. 61). Similarly, the FDA seized a shipment of carp this summer in Lake Pepin on the Mississippi River (ref. 58). In view of a recent legal decision that clearly allows the FDA to define pesticide residues in foods as an indirect food additive, the FDA is expected to enforce its guidelines more forcefully in the future. FDA officials in the Great Lakes region have warned that chubs, coho salmon, and lake trout may be disallowed in interstate commerce, since they continue to contain high residue levels of PCB's (ref. 61). It is apparent that with a more thorough monitoring and surveillance program, nearly all species of fish in the Great Lakes region and in several rivers in the East coast area will be essentially unavailable for human consumption for many years to come.

One of the great ironies of the present situation is that *over 3 years ago* the Federal Water Pollution Control Act (FWPCA) directed the Federal Government, specifically the Environmental Protection Agency (EPA) to take swift action to reduce the discharge of PCB's and other toxic water pollutants to safe levels. The fact that today there is no meaningful national program to regulate PCB discharges is a result of the Federal Government's disappointing failure to carry out the FWPCA as Congress wrote it or, for that matter, to take any other strong regulatory action.

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The Congressional authors of the FWPCA believed that the "hazards posed by toxic substances" made their effective regulation "especially urgent" (ref. 59). Accordingly, they established in the act a "national policy that the discharge of toxic pollutants in toxic amounts be prohibited" (ref. 60) and added to the act a far-reaching special provision, Section 307(a), to insure that this goal was fully implemented. If Section 307 (a)'s mandatory deadlines had been met, toxic pollutant effluent standards covering PCB's and other toxic pollutants would have been promulgated by EPA roughly 2 years ago and complied with by dischargers about 1 year ago. Yet, to date EPA has failed to promulgate a single standard under this provision.

State officials have also expressed dismay over the EPA's failure to promulgate toxic substances effluent standards. John Hesse of the Michigan Department of Natural Resources in recent comments at a regional convention, stated:

> I want to mention that the delay in this standard [effluent standard for PCB] has weakened the states attack on industrial sources and is long over-due. (ref. 61)

It is instructive to review the events leading to the current situation. Section 307(a) of the act requires EPA to first develop a list of toxic water pollutants. For the substances on this list EPA must subsequently develop and enforce strict effluent standards, standards which must protect the users of the waters with an "ample margin of safety" (ref. 60). EPA began inauspiciously by failing to meet FWPCA's January 12, 1973, deadline for publication of the list of toxic pollutants. When 4 months later the list had still not been published, the Natural Resources Defense Council brought suit challenging EPA's default. That suit ended on June 19, 1973, when the U.S. District Court ordered EPA to publish the list "on or before August 31, 1973" (ref. 62). The list published by EPA as a result of this court directive, though inadequate in many respects, did include PCB's along with eight other pollutants.

Section 307(a) also requires that prior to promulgating final standards for substances it has listed, EPA must first propose such standards for public comment and then hold a formal hearing on them. Standards for the nine substances, PCB's included, were in fact proposed by EPA on December 27, 1973. The required hearing began a month later and continued through May, 1974. Under Section 307(a) EPA is mandated to promulgate final standards not later than 6 months after publication of proposed standards, or "immediately" if EPA chooses to modify the proposed standards as a result of the hearings (ref. 60). Yet, despite this requirement, 2 years have elapsed without the promulgation by EPA of a single standard under Section 307(a).

This failure to develop final standards is being challenged in a law suit brought in the District of Columbia (ref. 63). The NRDC and the Environmental Defense Fund (EDF), plaintiffs in the suit, are claiming that the EPA's omission is contrary to FWPCA's requirements and are seeking a ruling establishing court-ordered deadlines for final EPA action on toxic pollutant effluent standards. In affidavits filed in this law suit, EPA has stated that the record of the original hearing "could not justify or support the promulgation of either the originally proposed standards or any specific modification thereof" (ref. 64). In support of this conclusion, EPA claims that the evidence at the hearing was inadequate to permit the agency to determine "what level of each of the toxic pollutants would provide an ample margin of safety as required by Section 307(a) of the Act." EPA also states that it was unable at the hearings "to either assess or respond to" industry evidence "tending to show" that the proposed standards would have substantial economic repercussions on the regulated industries (ref. 64). Accordingly, EPA now intends to repropose, i.e., to propose new toxic pollutant effluent standards, and to begin the hearing process again. The agency states that under its new schedule it "expects" to propose new standards for PCB's in late February, 1976 (ref. 65). EPA has also informed the parties to the law suit that these new PCB standards, unlike the original standards, will be limited to dischargers who manufacture PCB's or use PCB's in castings, electrical transformers and capacitors.

Behind this record of delay lies a series of complex problems which deserve to be examined in a far more comprehensive manner than we can undertake here. Our own judgment, based on our work in this area over the past 3 years, is that several underlying factors are principally responsible for this failure of Federal regulation. We offer them for further examination and discussion.

First, EPA has not had during this period a strong institutional commitment to doing something about the problem of toxic water pollutants. Partly this is a reflection of the historic concerns of the sanitary engineering profession, concerns which still dominate much of EPA's thinking, and partly it results from the failure of EPA leadership to assign priority attention to this problem during the formative period of the agency's programs. Even as Congress was developing the act, EPA informed the House Public Works Committee that "we do not endorse the provisions of Section 307 relating to toxic substances" (ref. 66). Subsequently, the resources EPA allocated to the toxic pollutant problem were miniscule

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in comparison with the need, and this pattern continued despite the fact that it was repeatedly criticized. As late as March, 1975, EPA's priorities in the water pollution area completely neglected control of toxic pollutants. In a discussion of priorities for fiscal year 1976, EPA failed to mention toxic pollutants in a table listing the agency's first, second, *and even third* priorities for the coming year (ref. 67).

A second factor has been the very large and well financed efforts by the dischargers of toxic pollutants to oppose development of standards under Section 307(a). Approximately 35 major corporations and industry groups challenged EPA's proposed standards in the formal hearing that was held in early 1974. The talents of many of the country's best paid lawyers and scientists were at the disposal of the PCB, mercury, and cyanide dischargers, and it seems almost certain that far more resources were spent picking apart EPA's proposed standards than EPA had used in developing them.

One theme developed by the dischargers at these hearings was the potential economic impact of meeting the proposed standards. Evidence was introduced at the hearings to show that the technology to meet some of the standards was not available or that where it was available it could only be installed at substantial expense. It was also contended that the proposal would force segments of major industries to shut down. EPA, though it has never rigorously investigated these claims, has nevertheless acted on them to the point that concern over economic dislocations has become a major inhibiting factor within the agency, overshadowing any concern with public health and environmental quality. Environmental organizations have urged EPA, unsuccessfully, not to delay standards development on these grounds, pointing out the self-interest in such claims of hardship and also EPA's obligation to implement the act as Congress wrote it. If a discharger believes that a variance from a Section 307(a) standard is justified in light of economic hardship, that plea, environmental groups have urged, should first be addressed to Congress, since Section 307(a) does not now contain a variance provision. But the absence of such a variance provision should not be used to justify inaction, or inadequate action, by EPA.

Because of recent publicity in the media of PCB-contamination in the Great Lakes region and the Hudson River, it is encouraging to note that several States have taken administrative and legislative initiatives to control the discharge of PCB's into lakes and rivers. Earlier this year, the Michigan Natural Resources Commission endorsed the recommendation of the Lake Michigan Toxic Substances Committee, calling for a ban on PCB imports and use in the United States and for a rapid replacement of PCB's in electrical capacitors and transformers (ref. 61). At the same time, a bill has been introduced in the State Legislature to place strict control on the use and sale of PCB's in the State (ref. 61).

In Wisconsin, the Division of Health of the State Department of Natural Resources has issued warnings on consumption of large size lake trout and salmon from Lake Michigan and the upper Mississippi River. The Department also held a hearing in August of this year, with a view to developing a strategy to control the sale and distribution of PCB's within the State (ref. 61). In Minnesota, an Interagency Task Force was established, principally to widen the monitoring of PCB's in fish in several rivers and streams in the State (ref. 24).

In terms of administrative remedies, the strongest action was taken this year in New York State, after it was discovered that two G E plants on the Hudson River appeared to be the major dischargers of PCB's in upper regions of the river. The New York State Department of Environmental Conservation on September 23, 1975, issued an abatement order requiring the G E plants to achieve zero discharge of PCB's by September 30, 1976. Administrative hearings begun on October 6, 1975, are expected to continue for several weeks (ref. 69). At the same time, Commissioner Ogden Reid of the department publicly cautioned consumers against eating striped bass from the Hudson River and salmon caught in Lake Ontario (ref. 70).

On the international front, the Organization for Economic Cooperation and Development (OECD) a few years ago recommended to its member countries, which includes the United States, West Germany, France, United Kingdom, Japan, Italy, and Spain, involved in the production of PCB's, to restrict the commercial use of PCB's to closed systems (ref. 71). Only Japan has taken further strict measures to completely eliminate the use of PCB's in all commercial application, including capacitors and transformers. It also prohibits the import and export of the compound, and since September, 1972, there has been a virtual elimination of almost all applications of PCB's in the country (ref. 57).

CONCLUSION AND RECOMMENDATIONS

On August 29 of this year, NRDC and the Hudson River Fisherman's Association requested the Administrator of EPA to take immediate and decisive action to curtail the discharge of PCB's into the Hudson River, pursuant to § 504 of the Federal Water Pollution Control Act (FWPCA) (ref. 72). Under § 504, the EPA is given authority to seek whatever emergency relief is needed to seek abatement with pollution sources presenting "an imminent and substantial endangerment to

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the health of persons or to the welfare of persons." To date, we have received no indication that the EPA is prepared to take emergency action against PCB dischargers, and with respect to the G E plants on the Hudson River, it has postponed its permit hearings pending the present State of New York proceedings against the company.

At the same time, we are very concerned about the proposal by the U.S. Army Corp of Engineers to undertake extensive maintenance dredging in shipping channels in the Hudson River. We have called upon the Corp of Engineers to hold public hearings before the agency prepares its final environmental impact statement, since in the earlier draft statement the agency had failed to recognize the problem of PCB contamination of sediments in river bottoms (ref. 73).

On behalf of three New York environmental and conservation organizations, we have intervened in the administrative proceedings now being conducted by the New York State Department of Environmental Conservation against the two G E plants in the Fort Edward-Hudson Falls region of the Hudson River. We are in general agreement with the State's abatement order of achieving zero discharge of PCB's by September next year.

Finally, we are at present, along with the Environmental Defense Fund, planning to petition the Federal Food and Drug Administration to lower the current PCB tolerance limits on foods and food products in the United States. This is, as mentioned previously, based on recent long-term data that show considerably lower "effect" levels of PCB's on experimental animals.

We recommend the following courses of action that should be taken by Federal and State agencies to address the problem of PCB's contamination of the environment:

1. A complete phase-out of the manufacture, sale, use and distribution of PCB's in this country, including its use in closed electrical systems;

2. A ban on the import and export of PCB's to and from the United States;

3. Development of a PCB use and consumption inventory, to pinpoint all point and nonpoint discharge of PCB's to the environment;

4. An accelerated program of monitoring and surveillance of PCB's in fish, wildlife, and foods by State and Federal agencies;

5. A moratorium on all dredging of river bottoms, until a complete study is conducted to examine the resuspension of PCB's in river water from such activities;

6. Promulgation by the EPA of the toxic substances effluent standard with respect to PCB's, such that water quality standards in receiving streams be no more than 0.001 ppb;

7. A significant lowering of present FDA tolerance limitation of PCB's in foods to reflect present knowledge of its long term chronic toxicity; and

8. A swift passage of the Toxic Substances Control Act, which is still pending in Congress, to provide additional authority to Federal agencies to cope with the manufacture and use of toxic substances.

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FDA REGULATION OF PCB's IN FOOD

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Abstract

Investigations by the Food and Drug Administration (FDA) during the period of 1969-1971 disclosed that PCB's had become a significant contaminant of the Nation's food supply. Spillage or leakage of PCB's from manufacturing equipment or contact with PCB-containing materials were identified as routes of direct contamination of food and animal feed. The presence of PCB's in the environment was causing the indirect, unavoidable contamination of certain types of food, particularly those of animal origin. In March 1972, the Food and Drug Administration formally proposed regulations to limit bureau exposure to PCB's from these sources of PCB's in the diet (the scientific and legal basis for these regulations, which were finalized in July 1973, are described). Presently, the problem of PCB contamination of foods, except for certain freshwater fish, has substantially diminished. Because of new scientific information on the potential hazards of PCB's on the public health and the continuing presence of high levels of PCB's in certain freshwater fish, the Food and Drug Administration has initiated a review of its temporary tolerance of 5 ppm in fish.

In 1969, the Food and Drug Administration identified the presence of PCB residues in milk from several dairy farms in West Virginia. Eventually, the source of contamination was traced to spent PCB transformer fluid that was used as a vehicle for a herbicide. The herbicide-PCB mixture was sprayed along powerline rights-of-way causing dairy cattle grazing areas to become contaminated. West Virginia officials were advised that FDA would initiate regulatory action against shipments of milk containing 5 ppm or more PCB's on a fat basis. As a result, the involved dairy farms were placed under State embargo until it was demonstrated that milk from these farms contained acceptable levels of the contaminant.

I mention this incident for several reasons. First, it represented the first documented incident in which an industrial use of PCB's directly contaminated food, in this case animal feed, which subsequently caused residues in milk. Second, it represented the first U.S. regulatory action taken because of PCB contamination of food. Third, aside from historical interests, it represented a preview and start of what was to become a complex and serious problem.

Within the next 2 years, seven other major incidents of PCB contamination of food had occurred in the United States. Not only did these so-called "industrial accidents" present a threat to human health, they also resulted in severe economic losses to the milk, egg, poultry, and feed-producing industries. Since the details on these accidents have been reported (ref. 1), I will not describe the circumstances surrounding each. Suffice it to say that by late 1971, it was quite apparent that spillage or leakage of PCB's from manufacturing equipment or contact with PCB-containing materials could, and did, directly contaminate food and feed.

During the same period, FDA and other regulatory agencies began to routinely test foods for the presence of PCB residues. It soon became evident that because of their widespread, uncontrolled industrial uses, PCB's had also become persistent and ubiquitous contaminants in the environment, causing the unavoidable, indirect contamination of certain types of foods.

Although scientific information on their hazards was limited in 1971, there was sufficient data for FDA to conclude that the presence of PCB's in food posed a potentially serious public health problem and that regulatory controls were necessary.

Accordingly, FDA developed and published a notice of proposed rulemaking in March 1972 (ref. 2) to limit human exposure to PCB's by dealing with the direct and indirect sources of PCB's in the diet. On July 6, 1973, a final order on the proposed regulations was issued in the *Federal Register* (ref. 3).

The final regulations included two main provisions:

First, it banned the industrial uses of PCB's in establishments manufacturing, handling, or storing human food, animal feeds, and paper food-packaging materials. This was done to preclude the direct, accidental contamination of these articles. The ban did not apply to the use of PCB-containing electrical transformers and capacitors.

The Federal Food, Drug, and Cosmetic Act provided the statutory authority for invoking these restrictions as part of FDA regulations on Current Good Manufacturing Practices. This preventive approach means that the industrial uses of PCB's in firms subject to FDA jurisdiction would be considered a violation of the law without first having to demonstrate that products from these firms were being contaminated.

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The second provision of the FDA regulations was the establishment of temporary tolerance for unavoidable, indirect PCB contamination of milk and other dairy products, eggs, poultry, baby foods, animal feed and feed ingredients, and fish; also, since 1973, FDA has had in effect an action level for PCB's in paper food-packaging materials (table 1).

Table 1. FDA temporary tolerances for PCB's

Commodity	Temporary tolerance (ppm)
Milk	2.5 (fat basis)
Dairy products	2.5 (fat basis)
Poultry	5.0 (fat basis)
Eggs	0.5
Finished animal feeds	0.2
Animal feed components	2.0
Fish	5.0 (edible portion)
Infant and junior foods	0.2
Paper food-packaging material	10.0[a]

[a]Action level.

Prior to the 1972 issuance of the proposed PCB regulations, FDA used guidelines or informal action levels to control the marketing of foods and feeds with excessive PCB residues.

The authority to establish the tolerances for PCB's in these consumer products is found in section 406 of the Federal Food, Drug, and Cosmetic Act. This section provides that where the addition of a poisonous or deleterious substance to food cannot be avoided, regulations shall be promulgated to set limits on the quantity of the substance permitted. Section 406 contains three criteria for the setting of these limits: (1) the extent to which a limit is necessary for protection of public health, (2) the extent to which the substance cannot be avoided, and (3) the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

In dealing with the problem of unavoidable PCB contamination of foods, FDA's principal objective was to minimize human exposure from dietary sources of PCB's. At the same time, the agency sought to avoid serious disruption of the Nation's food distribution system so as not to deprive the consumer of a significant portion of his food supply. As a result, it was considered necessary to establish separate and different limits for each type of food shown to contain unavoidable residues. Only in this way would overall dietary levels be kept at a minimum and would the public be assured that PCB's, if present in these foods, are generally within safe limits.

Thus, the selection of appropriate tolerance levels for PCB's in the different foods represented a "balancing" between potential harm to the consumer and economic impact. This balancing principle, which is mandated by section 406 of the statute, necessitated the use of subjective judgment regarding available information on the toxicity of PCB's and on the occurrence of PCB's in the food supply. In other words, while they took into account established, acceptable daily intakes, the tolerance levels were not based solely on ADI's, nor can they be explained strictly in terms of ADI's.

Data from FDA total diet studies and surveillance programs for 1969-1972 were also important considerations. These data showed that PCB residues in food were sporadic and that by eating a well-balanced diet, there was only a remote possibility of systematic exposures to PCB's at or above the ADI's over an extended period of time. As a result, FDA concluded that the tolerance levels would provide an adequate margin of safety for the public, provided dietary exposure to PCB's remained sporadic and, in time, would diminish. This approach also allowed FDA to set the tolerance levels high enough to minimize the economic impact that would result from the food and feed industries' compliance with the tolerances.

Since issuance of the FDA regulations, the agency has not encountered the types of "PCB-accidents" involving food or feed that had occurred prior to 1972. Current surveillance data form FDA, the U.S. Department of Agriculture, and others show that with the exception of freshwater fish, the presence of PCB's in those commodities subject to tolerances continue to be random and sporadic, but with an overall substantial decline in their frequency and levels.

This decrease is precisely what FDA intended when

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it promulgated the PCB regulations and, as I just mentioned, served as one of the basic premises for the temporary tolerances.

FDA attributes the present situation to several factors:

1. Voluntary restrictions instituted by industry with respect to the industrial uses of PCB's. This has resulted in less potential for PCB contamination of the environment and subsequent transfer to food.
2. Regulatory actions initiated by FDA, USDA, and State agencies when excessive levels of PCB's in food were encountered. This has had a salutary effect on industry practices.
3. Efforts of the food and feed industries to conform to Current Good Manufacturing Practices and to market only those products that comply with the tolerances.

I wish to emphasize, however, that the present situation does not mean that FDA considers PCB's to be no longer a problem. Since occasional shipments of food exceeding tolerance have been encountered during the past 2 years, there is still a need to monitor foods for PCB residues and to have regulations governing the presence of PCB's in the food supply. Furthermore, and certainly of a more serious nature, is the continued problem of PCB's in fish as a result of continued industrial discharges of the chemical into lakes and rivers. Needless to say, reports of PCB levels in freshwater fish from certain waters at 5 to 10 times higher than the FDA tolerance of 5 ppm are reasons for concern, particularly since there is little, if any, scientific disagreement that the regular and consistent consumption of fish at these levels may pose a potentially serious threat to the consumer.

Because of this concern, FDA recently began evaluating the adequacy of its current tolerance for PCB's in fish. This evaluation includes a review of all recently reported studies on the toxicity of PCB's, as well as a review of available data on the current PCB levels in fish and the economic impact that would result from a lowering of the 5 ppm tolerance.

If the decision is made to lower the tolerance, a proposed amendment to the existing regulation will be published in the *Federal Register* along with a detailed explanation of the basis for the proposal. Through this rulemaking procedure, public comment will be solicited and fully considered by FDA before final action is taken and implemented.

Obviously, a lowering of the tolerance by FDA will not in itself solve the many problems of pollution of the environment with PCB's. Nor will it guarantee that fish available for consumption will comply with the tolerance since only fish involved in interstate commerce are subject to FDA's jurisdiction. Thus, FDA enforcement of a lower tolerance will not necessarily result in additional protection for each and every consumer. Furthermore, even if warnings and advisories are issued by FDA and State officials, there is no assurance that sports fishermen and, perhaps others, would abide by these warnings.

The same may also be said for foods other than fish since, as long as the chemical is being used in a manner that causes its introduction into the environment, the potential for the indirect contamination of the food supply surely exists.

For these reasons, the Food and Drug Administration urges and will support the Environmental Protection Agency and State agencies in the initiation of controls aimed at the industrial uses and particularly the disposal of PCB's in order to curtail and eliminate further pollution of the environment and the contamination of foods with PCB's.

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PROGRAMS AND AUTHORITIES OF THE ENVIRONMENTAL PROTECTION AGENCY

Walter C. Barber*

Abstract

The Environmental Protection Agency operates under many constraints. Its research and regulatory functions are influenced by Congress, court action, and public opinion. The time and energy required to produce even a simple regulatory action is substantial. And what appears to be a large EPA staff is actually small when the number of toxic substances and contaminant point sources to be controlled are considered. When creating regulations, EPA must attempt to make them reasonable and enforceable; the regulations then must of necessity be limited.

EPA's role with respect to the Federal Water Pollution Control Act and the Clean Air Act is herein explained. Recommendations are made that could improve the Federal/State Point Source Regulatory Program: public awareness could be increased among people who use PCB's as to their handling and disposal; there is potential for joint industry/government voluntary labelling and disposal control for PCB's; EPA could focus attention on electric utilities, the major user of PCB's; and finally, local water quality management programs funded under the Federal Pollution Control Act could be redirected so that they give PCB control greater emphasis.

The purpose of my talk is not to tell you again what either EPA has or has not done to control PCB's or to tell you what we are going to do. Quite frankly, I do not know what we are going to do beyond what you have heard explained in terms of increased monitoring, research, establishing a 307(a) toxic effluent limitation, and establishing permit limitations for known dischargers of PCB's.

Rather, what I thought I would do today is briefly to review EPA's programs and authorities. I will try to give you a feel for the context of our decisionmaking and the limitations on it so that the non-EPA people here have a better feel for what they can rely on the Federal Government to do in the future and what things they probably ought to think about doing at the State or even, perhaps more importantly, at the local level.

Perhaps the overriding concern is that Federal regulation in the environment (or anywhere else) requires a clear understanding of the consequences of regulatory action. The law requires it, the public expects it, and we are making every effort to do it. As a result, the regulatory process is not as responsive and rapid as we might like it to be Dr. Ahmed made some pointed comments about EPA progress in regulating under the Federal Water Pollution Control Act. These comments were factually correct, but I think there are probably some reasons for these things happening, generic reasons associated with Federal regulation that we should keep in mind. I do not know that there is a way, even if all the people in the Environmental Protection Agency were replaced, to change substantially the approach to environmental regulation at the Federal level.

It is important for non-Federal people to remember that the Federal Government is no more than a collection of people. The people who are going to regulate PCB's are in this room or have been in this room over this 3-day period. So when we say that EPA or the Federal Government should do something, in essence we are saying that the people sitting here, who know no more or less about PCB's than you do, should do something.

The Environmental Protection Agency is not a very large organization when you think about the scope of the problems that Congress has asked it to deal with. EPA is asked to regulate tens of thousands of stationary-point sources of air and water pollution, tens of thousands of pesticides that are being used in the environment, and tens and even hundreds of thousands of drinking water supplies. We have programs on radiation noise, solid waste, and toxic substances. In addition, we have what is considered to be the largest Federal Public Works program in our Municipal Construction Grants effort. We also have a substantial research and development program. There is no army of people to implement these programs. There are fewer than 10,000 people in the Agency with only a couple of hundred in the Regional Office here. When they are divided among the various programs and the number of sources to be controlled, and the time and energy that goes into taking even some of the most simplistic regulatory enforcement steps is considered, it seems unlikely that EPA will be able to revolutionize regulation or enforcement in the area of PCB's.

Mr. Train has made it clear that he is going to accord a high priority to PCB control, and hopefully, we are going to do substantially better than we have. However, we do not have hundreds of Federal bureaucrats to

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locate and control all the sources of the PCB's that are going into municipal sewers, being dumped on the ground, and running off into streams and rivers. It is important to remember that our resource allocations frequently are driven by things that we cannot control. We come under tremendous pressures from the public, the courts, and from the Congress to do or take action in various areas. A year ago, municipal construction grants received a great deal of attention—we were not spending the construction grants money fast enough or building enough municipal treatment works. With regard to regulations, our friends at NRDC have served a very valuable public service by encouraging us to overcome our bureaucratic inertia and to move faster in some areas. But in fact our efforts to accelerate the regulatory process have often resulted in the courts remanding our decisions, doubling the work, with little or no environmental benefit.

The Federal Water Pollution Control Act, for those of you who have not had an opportunity to read it, is extremely long and complex and has a number of provisions that would bear on the PCB pollution problem. They overlap, I won't say that they conflict, but they have the potential to conflict in some cases. The act is very demanding in terms of the things which the Federal Government must consider in the process of developing its regulations. When we do not consider them, the courts require us to go back and do so.

We are caught somewhat in the middle. I see the legislative history and the nature of environmental laws, Federal Water and Pollution Control Act, and Clean Air Act as essentially having established the purpose of Federal involvement to be a reinforcement for State programs, with the State having the basic responsibility. The Federal role is to establish national standards, provide some financial and technical assistance, and to act where a State government is unable or unwilling to enforce the regulations.

Because of the way the acts are written, there are some things that EPA can do well. There are other things that the State and local governments can do much better, and there are still other things that the public can do. The strength of the environmental program is clearly with the public, and then with the State and local governments and must flow up rather than down.

Regulation, either for the control of toxic substances, of which PCB's are an example, or for the control of biochemical oxygen demand, will not be meaningful and will not have any real impact on the environment unless reasonable limitations are applied. I do not know what these reasonable limitations are for PCB's—they may be zero. The reasonableness of a regulation is determined by technology, economics, and enforceability. Based on what I have heard over the past 2½ days, there are serious questions as to the enforceability of regulatory actions which go beyond the 20 principal users.

EPA's legislative authorities and its principal areas of effectiveness focus on major point sources and discharges. With PCB's we do not have very many major point source discharges. Although at least some of those point sources seem to be creating problems, it is not clear to me, based on some of the numbers that were presented, particularly for the Los Angeles area, that controlling point sources is going to solve even a major part of this problem.

We will regulate these point sources, and hopefully we will be able to enforce those regulations so that the contribution from the major point sources will be diminished, if not eliminated. Based on quantities of PCB's in existence in the environment, we can say that those that have been produced over the last 30 years have not degraded those that have been imported. It seems somewhat questionable to me, if not unlikely, that that control of major point sources of PCB's is going to solve the fishery problem in the Great Lakes.

Let me take about 2 minutes to run through the Federal Water Pollution Control Act and the Clean Air Act, just to tell you where we are with regard to controlling PCB's. Under the Federal Water Pollution Control Act, the Federal government can establish water quality criteria, which we have done. This was done before the current act was passed. We have proposed revisions, and those final revisions have been printed and are creeping their way through the bureaucracy and toward the *Federal Register*. I expect that they will be published in final form in the next several months. This is a fairly substantial document and includes what we recommend in terms of ambient water quality, which is adequate to protect biological populations. The States in turn have to set the standards based in part on these criteria and in part on their own judgments of the local conditions.

Establishment of the standards does not solve any problems because it does not eliminate any discharges. Other sections of the act are designed to reduce discharges to achieve the standards. Section 304 provides for us to establish technology-based limitations and effluent guidelines upon which we base our industrial permits. Section 307, the toxic substance part, has turned out, at least in our minds, to be a very difficult section of the act to implement. Perhaps it will not be as difficult to implement for PCB's as it is for some of the other toxic substances and we are moving forward on it, although belatedly.

Section 307(b) calls for pretreatment and is significant because a substantial portion of the PCB's reaching

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our waterways are discharged from municipal treatment works and not from direct discharges on the part of industry. The pretreatment standards are going to present enforcement problems because it is difficult for municipalities and essentially impossible for the Federal Government to trace down every discharger of toxic pollutants to municipal sewer systems. We do not know whether the discharger is throwing pollutants down a manhole under the cover of darkness, whether he is discharging regularly through drainage in a building, or whether the pollutants are run off through combined sewers from a nonpoint source.

Section 311, the hazardous substances section of the act, is designed to protect from spills of hazardous substances. We have had some spills of PCB's, however, it seems clear to me that, unless someone has been hiding a lot of spills, the quantities of PCB's that are in the Great Lakes are several orders of magnitude larger than anything you could attribute to spills into the water. Spills on the land could be another question. However, once again, a few hundred Federal bureaucrats are not going to be able to chase a million capacitors or transformers and find out whether someone is releasing PCB's on the ground.

The section 402 permit program provides for effluent limitations for direct discharges to navigable waters. In addition, we have the emergency power provisions of section 504, which were alluded to by Dr. Ahmed. Quite frankly, I do not know what the criteria are for employing the emergency powers or what Mr. Train proposes to do in response to the petition.

The Clean Air Act might become a significant part of the effort to control PCB's if the numbers for the Los Angeles basin are accurate and representative. With this act, we are in a more difficult position in my opinion than we are with the Federal Water Pollution Control Act. The Clean Air Act is based on ambient standards, as opposed to technology-based effluent or emission limitations. It is unlikely that we could establish, monitor, and enforce an ambient standard for PCB's unless, by some fortuitous happening, most of the PCB's emitted into the air are coming from a few discreet point sources.

We can establish new source performance standards for air emissions, which are in fact technology standards, but I do not believe that new air emission sources are going to be the key to the PCB problem.

The hazardous air pollutant section in 112 of the Clean Air Act provides for emission limitations which are adequate to protect the public health with an adequate margin of safety. I have seen nothing in the information presented that alluded to the health effects of airborne PCB's. It seems to be more a question of the airborne PCB's washing into the rivers. I think that we would have a difficult time employing section 112.

I would like to run through what I personally think might be attractive supplements to the Federal/State Point Source Regulatory program. Based on what I have heard over the last few days, I believe that a substantially increased level of public awareness is necessary among the people who use PCB's. Working principally with labor and the management of industries using PCB's, we must try to improve the level of awareness about proper handling and disposal.

I see potential for a joint industry/government voluntary labeling and disposal control program, which would be substantially more restrictive than what we have now. Given the magnitude of the problem, it would appear that both the industry and the affected labor unions might be sympathetic in trying something along those lines to avoid the problems caused by unknowledgeable dumping of PCB's.

It seems to me that we have a major resource in our electric utilities, who apparently use the predominant share of PCB's in closed electrical systems. Electric utilities are fairly sensitive to public concern, and I would think that the electric utilities as a group or perhaps even individually might be sympathetic to mounting a significant labeling and waste-handling campaign, which they would subject to some public scrutiny.

Lastly, we are spending substantial sums of money on funding local water quality management agencies under section 208 of the Federal Pollution Control Act. It seems to me that, with what is likely to be millions of dollars available in the Great Lakes basin for water quality management, the people who live here might be well served by having the 208 agency work on the PCB problem in addition to BOD reduction, waste load allocations, and sediment laws. If in fact the PCB's remain the dominant concern in the Great Lakes basin, then maybe the 208 agency could help track down the apparent myriad of small discharge sources, to educate dischargers, and to help put controls on them.

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U.S. FEDERAL AGENCY ROLES AND ACTIONS: THE DEPARTMENT OF THE INTERIOR

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Abstract

The Department of the Interior warns that its assessment of the impact of polychlorinated biphenyls upon national fish and wildlife resources, as determined by the National Pesticide Monitoring Program, reveals environmental hazards. The evaluation of data from the monitoring program has demonstrated a serious detrimental impact by PCB's upon national fish and wildlife resources and restoration programs. The Department of the Interior recommends immediate toxic substances legislation for control of domestic and imported sources of toxic substances.

During the past 2 days numerous reports have been given describing the uses and sources of PCB's, their occurrence in various components of the environment, and their real or potential threats to the health of our natural resources. The documentation of the widespread contamination of our environment by this group of compounds demands that we elevate our recognition of PCB's from a local concern to a national and global level. We must immediately respond to the dangers posed by PCB's; they represent an ubiquitous degenerative influence on our national health and well-being.

The reasons for this concern are simply stated: Our food and water supplies are contaminated; our health is threatened; and we are faced with "environmental stress" about which we know comparatively little!

The PCB problem is a national problem that the U.S. Fish and Wildlife Service has identified in both research studies and in the National Pesticide Monitoring Program. As earlier papers pointed out, PCB residues were found in all of the fish samples from 100 stations located in major river systems throughout the United States, and in almost all the bird samples taken since 1970.

I am deeply shocked by the pervasiveness of PCB's; they are literally everywhere. And I am very troubled by the exceedingly high levels found in fish from all our drainage systems; and I do not mean just the Hudson and the entire Great Lakes' system, but the Merrimac and Connecticut Rivers of the Atlantic Coast, the Mississippi, Missouri, and Ohio Rivers of the Midwest, the Columbia River system in the Northwest, the Sacramento in the West, Rio Grande River and other Gulf Coast streams, and even the Yukon in Alaska!

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Fish are not alone in absorbing sizeable quantities of PCB's. The birds we are monitoring are equally susceptible. Waterfowl carry the highest residues in the Atlantic flyway, followed in descending order by the Mississippi, Pacific, and Central flyways. Further, all starlings collected since 1970 contain PCB residues.

It is one thing to trot out all these scientific facts and figures identifying quantitative residues in various terrestrial and aquatic organisms; it is quite another to assess the broad impact of PCB's upon our environment and natural resources. What are the effects of pesticides, heavy metals, and hazardous substances such as PCB's and what do they mean to our fish and wildlife habitat?

Cleansed of all the details, the facts, simply stated, are that we are in trouble. My department has spent millions of dollars, and is programming millions more in these times of fiscal austerity, on programs aimed at reinvigorating our wildlife resources, and protecting and restoring numerous threatened and endangered species.

The omnipresence of PCB residues in our environment looms as a very dark cloud casting an ominous shadow upon all of our fish and wildlife resource programs which depend on environmental quality and healthy habitats. In particular, PCB's pose an immediate threat to our efforts to preserve and protect threatened and endangered species. Under present conditions PCB's may very well pull the rug out from beneath us by destroying marginal species in spite of our best efforts for preservation.

Consider the Atlantic salmon, a species we are striving to reintroduce into our northeastern rivers. Atlantic salmon egg mortality has been associated with a threshold concentration of about 0.5 ppm of PCB. Our scientists tell me that this threshold concentration in the eggs would be equivalent to residual PCB levels in whole fish of 2.5 to 5.0 ppm, comparable to unhealthy levels found in many species throughout the United States.

I cannot justify a salmon restoration program in any northeastern river system where the fish will be subjected to PCB residues. Other recent tests show that rainbow trout eggs containing as little as 2.7 ppm of the PCB, identified as Aroclor 1242, and 90 ppb of DDT complex caused 75 percent mortality—and about 60 to 70 percent of the surviving fry were deformed.

Another test demonstrated that fish bioaccumulated more than 40,000 times the concentration of PCB in the water. I think the fish are telling us something. They are stating unequivocally that our rivers and streams are sick. We should not need a clarion call to realize that our

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rivers and lakes—the very lifelines of our environment—are in mortal danger.

I am aware that it took many years of research before we could identify the effects of DDT, dieldrin, and other organochlorine pesticides in birds and mammals. We know that the reproductive success of bald eagles has been greatly reduced in Maine and along the shores of Lake Michigan where high residues of DDE, dieldrin and PCB are present in eagle eggs.

Similarly, the once abundant osprey population of Long Island Sound has suffered a near total decline as a result of chemical toxicants. Although our extensive work on PCB-fed ducks revealed little reproductive loss or eggshell thinning at environmental levels of PCB, I hope we don't have to repeatedly demonstrate the differences in susceptibility among wildlife species before we establish the imminence of a hazard requiring drastic national action. Remember that while we found quail and pheasant resistent to DDE thinning of eggshells, mallard and black ducks, american kestrels, screech owls, and brown pelicans were all highly susceptible. It pains me to remind you that the ban on DDT was not imposed until long after its threat to wildlife was proved, and action was taken only when studies showed the potential hazard to human health.

I suggest that we cease to quibble over scientific niceties and respond to the ailing resources around us. In this day and age, we should not need to be told that if the health of our natural resources is impaired, then human health is next around the corner en route to the sick bay.

We are meeting on the shore of one of a series of lakes that represents the world's greatest single freshwater resource; appropriately, they are called the Great Lakes. But how do we measure their greatness? Their immense area and volume are sufficient to characterize them as "great." They can also be considered "great" because of their esthetic and recreational value. Perhaps we could even classify them as "great" based on the amount of municipal and industrial waste they hold.

The list of attributes for these lakes is long and varied but regardless of the criteria used, the conclusion remains the same—the lakes and everything contained therein truly constitute a "great" resource.

The lakes' fisheries are particularly important both as utilizable and renewable resources and as indicators of the health of our Great Lakes. I am convinced that fish and wildlife are the true barometers of the quality of our environment. In my capacity as the steward of fish and wildlife for the Department of the Interior, and as a commissioner on the Great Lakes Fishery Commission, I have an overwhelming concern for the protection and management of Great Lakes Fishery resources.

During this century, the fisheries of the Great Lakes have suffered from heavy fishing, relentless predation by the parasitic sea lamprey, the influx of other nonnative species like the alewife, and the diminished quality of habitat as a result of waste disposal, uncontrolled shoreline development, and numerous other water polluting activities.

In recent years, however, we have taken significant steps at great financial cost to stop the decline of Great Lakes fisheries and to restore them to their former productivity. As a first step in this restoration, we undertook the control of the parasitic sea lamprey. Our cooperative efforts with the States, Provinces, and the Canadian Government achieved success in all the Great Lakes except Lake Ontario, where intensive control programs are now underway.

After 17 years and 33 million dollars, the sea lamprey, with a continued sustained control effort, no longer represents a major threat to the fisheries of the upper Great Lakes. The dissolution of the lamprey threat has allowed a successful State and Federal restocking program involving more than 150 million lake trout, splake, coho salmon, chinook salmon, atlantic salmon, and kokanee. Additional millions of rainbow, brook, and brown trout have also been stocked.

These stocked salmonids have fed heavily on the plentiful alewife and have rapidly grown to trophy size. The resulting sport fishery of these salmonids, when combined with the existing sport fisheries on other species, currently contributes approximately 350 million dollars annually to the Great Lakes States and the Province of Ontario.

All our efforts are for naught if these fish cannot be harvested—and we now face this stark possibility. A significant portion of these fish contain PCB residues in excess of the current 5.0 ppm action level established by FDA. As a result, warnings have been issued about the consumption of large lake trout and salmon from Lake Michigan. To varying degrees a similar PCB problem exists in Lakes Superior, Huron, and Ontario.

Although contamination by PCB's is particularly evident in salmonids, the problem is also present in commercial species such as carp, chubs, smelt, and alewives. Carp from Lake Michigan have already encountered marketability problems because of PCB's, and chubs appear to be at or just below the 5.0 ppm action level.

But if the current level were lowered to 1 or 2 ppm, then virtually all species would be restricted and essentially the entire Great Lakes' fishery would be curtailed. The current guidelines of 5.0 ppm has already tabled any serious consideration of commercially utilizing the salmonid populations in the near future. PCB's present a major problem in the future maintenance and growth of

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commerical fisheries. These fisheries today have a dock-side value of about $19 million annually and a total economic contribution to the United States and Canada of possibly $95 million annually when processing, shipping, and retailing are included.

We must now consider the expenditure of millions of dollars for controlling sea lamprey and stocking salmonids in the Great Lakes in the light of continued contamination of the fish stocks with unacceptable levels of PCB's. There are overriding reasons in favor of continuing our program. These include aspects of biology, economics, and ecology. The lake trout restoration program exemplifies these considerations. More than 17 years were required to restore lake trout to its present abundance in Lakes Superior and Michigan. If we stop our current programs, it is almost certain that the sea lamprey would reestablish itself and the salmonid populations and the fisheries dependent upon them would collapse, thus wiping out the past Federal investment of many years and millions of dollars and a Great Lakes economy worth several hundred million dollars. Although we know considerably more now than we did 17 years ago about lamprey control and salmonid stocking programs, it would still require at least 10 years to recontrol the lamprey and rebuild the lake trout stocks.

Why so long? The reason is a simple biological one—it takes 7 years for a lake trout to mature to an adult, spawning fish. There are few overnight solutions to natural resource restoration projects. Obviously, the quickest and most economical solution to the problem is to eliminate PCB's from the environment. With PCB's in the lakes, the entire program of restoring self-sustaining stocks of lake trout in the Great Lakes, or in fact all salmonids, is in serious jeopardy. And yet if we cannot eat these fish, I cannot justify spending millions of dollars contributed by the American taxpayer.

We cannot wish this problem away. Nothing short of immediate drastic action will enable us to raise anything better than lakes full of eunuchized fish. With the present preponderance of PCB's, the lifespan of the Great Lakes fishery will be limited to a single generation. The Great Lakes are a virtual "sink" for PCB's! It takes more than 50 years for water to turn over in Lake Michigan; there is no fast flushing action by mighty rivers or ocean energies to mitigate the lakes' absorbance of toxicants. Moreover, with more than one-third of the United States population and an even greater proportion of the Canadian population living near the lake shores, tons upon tons of PCB-infested materials are daily deposited into the Great Lakes receptacle. Transformer fluids, plastic bottles, hydraulic fluids, carbonless paper, ink, and other PCB-loaded wastes all find their way into the lakes, where the percentages of PCB's amalgamate malignantly. As soon as the food chain absorbs these wastes, the poison is off and running.

The tiny invertebrate fingernail clam has demonstrated an inordinate capacity to concentrate poisonous PCB residues and pesticides and heavy metals, which may ultimately spell the extinction of one of America's favorite waterfowl, the canvasback, which feeds voraciously on the clam. The clam was once common in the Detroit River and Lake St. Clair, habitats that used to attract major flights of canvasbacks.

The dieoff of fingernail clams on the Illinois River in 1956 spelled the end of that favorite spot for the canvasback. The canvasback represents a valuable waterfowl resource struggling against many odds as a declining species, but I foresee little succor for a population which winters and breeds in areas heavily infested with PCB's.

No dollar values can be assigned to endangered species, and even our society of technological whizzes cannot rejuvenate a species when its sole environmental niche is so totally contaminated with toxicants. The complete disappearance of Atlantic salmon from Lake Ontario during the early part of this century and blue pike from Lake Erie in the early 1960's have served as classic examples of man's impact on Great Lakes fishes and their environment. Currently we appear to be losing certain species, such as cisco and chubs, that are native inhabitants of the deepwater portions of Lakes Superior, Michigan, and Huron. Even restoration of self-sustaining populations of lake trout is in doubt in Lake Michigan because of an apparent lack of natural reproduction in the lake.

Possible reasons for these species' decline are numerous and complex. Although we have yet to pinpoint the interaction of dynamic ingredients, our scientists are certain that toxic substances such as PCB's are playing an important role. The potential effects of PCB residues in excess of 20 ppm in adult, spawning lake trout cannot be ignored.

I think I have gone far enough in detailing the problems that we face with this contaminant in the protection and management of Great Lakes fishery resources. The potential impact of PCB's on the future management of the lakes' multimillion dollar sport and commercial fisheries is tremendous, especially if the FDA lowers its guidelines, or if average PCB concentrations in fish increase.

Past attempts to control point sources of PCB's into the environment have failed to bring about any measurable reduction in the contamination of Great Lakes fishes. DDT levels in Lake Michigan fishes and mercury levels in Lake St. Clair fishes, however, have declined from between 50 and 87 percent in the past 4 to 5 years as a result of controls on their use. Why haven't PCB

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levels responded similarly? Do they behave so differently from DDT and mercury in the environment that we cannot reasonably expect to have observed some decline by this time? We will never know unless the flow of PCB's to the environment is stopped. I remind you that it was commonly thought that decades might elapse before DDT and mercury would decline to satisfactory levels in the great Lakes. It appears highly probable that the primary cause for the failure of PCB's to decline in Lake Michigan fish is that their sources have not been curtailed to any significant degree.

To sum up, the insidious character of PCB's is now self-evident and presents a very serious problem to all of us. These pollutants affect the very core of State and Federal fisheries restoration programs throughout the United States. Here in the Great Lakes, PCB's have the potential of severely damaging multimillion dollar sport and commercial fishing industries. We urgently need an effective program of control capable of rapidly eliminating the release of PCB's into the Great Lakes and our other national watersheds. Because of my deep concern with the problem, I support the recommendation of the Lake Michigan Toxic Substances Committee for a "national ban on all domestic and imported PCB's destined for use other than in transformers and capacitors, and [recommend] that the critical or essential use of PCB's in transformers and capacitors be immediately and critically reviewed in light of current potential replacement products."

There must be at the same time an immediate and intensive evaluation of proposed replacement products to determine their suitability for industrial use and the hazards associated with their potential loss to the environment. For the immediate range, our goal must be the elimination of all sources of PCB's in the environment within 3 years; for the long haul, however, we must vigorously pursue legislation that will preclude new "PCB's" from being discharged into the environment.

I have addressed you on my professional concerns as they apply to fish and wildlife. Now let me speak to you as a citizen. I have demonstrated that the Fish and Wildlife Service's pesticide monitoring program acts as a bellwether for measuring the future environmental impacts of toxic substances upon mankind. I reiterate that one-third of the population of the United States lives within the drainage area of the Great Lakes. The domestic water supplies for many millions of people are drawn from these Great Lakes—the same lakes whose fish populations are so contaminated with chemical toxicants that they are unfit for human consumption even under the present, outdated FDA regulations.

We are all aware that EPA is considering the establishment of PCB limits for water quality in the vicinity of 1 ppt (trillion), which is truly startling when we realize some of the lakes may already exceed 10 ppts right now. The passage of an effective toxic substances act and the complete control of PCB importation are imperative to the health of the American people. A piecemeal approach to toxic substances control would only delay and hamper our efforts to stringently regulate the occurrence of poisons in our environment.

Philosophically, we must consider man's role in his environment. Thoreau urged that we "probe the earth to see where our main roots run." The health of our fish and wildlife acts as a pulse indicator for human health. As this conference has shown, all medical and environmental gauges indicate this pulse to be unsteady and irregular. The irony of our position today is that our left hand is spending millions of dollars and thousands of man-years to establish a crucial resource while our right hand renders each new growth of this resource malignant. Our new resource will not only self-destruct but will place the human population in mortal danger.

As a final thought, let me stress that we should consider all alternatives. Since drastic action is needed, we should not be afraid to step back from industrial efficiency if we can step forward to environmental health.

Quite frankly, I am thoroughly disgusted by the gnashing of teeth, wailing, and rubbing of hands. To the agencies which have the enforcement responsibilities, a word on behalf of the bewildered but concerned American people—GET ON WITH IT!

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U.S. FEDERAL AGENCY ROLES AND ACTIONS: NATIONAL INSTITUTE OF OCCUPATIONAL SAFETY AND HEALTH

Richard A. Rhoden, Ph.D.*

Abstract

NIOSH activities regarding PCB's have included: (1) the issuance of a background information document on PCB's for the occupational health community; (2) the decision to develop recommended workplace standards to be forwarded to the Department of Labor; and (3) plans for conducting retrospective mortality studies of workplaces where PCB's are processed. NIOSH is equipped to perform onsite retrospective mortality studies of workplaces, but as yet no facilities handling PCB's have requested an analysis.

To date NIOSH activity in regard to PCB's has consisted of three undertakings. On the 3rd of this month, our Office of Occupational Health Surveillance and Biometrics issued a PCB background information document. Its purpose was to inform the occupational health community of current knowledge concerning industrial uses and the toxicity of PCB's. I have a few copies of that document with me and others may be obtained by writing to our Rockville, Maryland, offices. (I might add right here that NIOSH would welcome any technical input from members of the audience with regard to case studies, hygiene surveys, workplace levels, and so forth.)

In a second action of NIOSH, it has been decided that criteria for our recommended workplace standards will be developed and forwarded to the Department of Labor Occupational Safety and Health Administration with formal development efforts to commence in March of next year. This will be an in-house effort, in contrast to the case with many of our criteria development efforts. It is anticipated that the final finished document will be transmitted to OSHA in late 1976 or early 1977. The Center for Disease Control has kindly made Dr. Kimbrough available to aid us in this effort.

At present, U.S. workplace standards for PCB's consist of environmental limits, time-weighted averages of .5 mg/m^3 for Aroclor 1254 and 1 mg/m^3 for Aroclor 1242, with skin notations. NIOSH is acutely aware of its responsibility to insure that its recommended workplace practices will not result in increased contamination of the general environment.

The NIOSH division of field studies and clinical investigations will conduct a retrospective mortality study of an as yet unselected workplace where PCB's are processed or handled. A cross sectional medical surveillance of current workers at that facility is a possibility. Such surveillance would be conducted by the medical investigations branch of that division.

To our knowledge, no such studies have yet been undertaken. A complete industrial hygiene survey will also be conducted at the selected facility, including personal air sampling, and checks of breathing zones of workers, housekeeping, and other work practice monitoring. The environmental investigations branch will conduct the personal hygiene survey.

The mortality study to which I referred will be conducted by the biometry branch. Mr. David Brown, an epidemiologist with that branch, is here and is ready and willing to discuss the protocol with interested people. The mortality study will consist of first, cohort selection—that is, determination that the selected facility has existed for at least 25 to 30 years so that sufficient time has elapsed for cancer induction and so forth. Next is cohort size determination; the cohort must be large enough to insure detection of low-incidence events. And there will be a personnel record evaluation; the personnel records must be comprehensive enough to permit followup and determination of employee work history.

Once a facility is selected for study, personnel records will be microfilmed and encoded into a data bank. The followup to determine the vital status of the cohort is then undertaken. That is, cause of death and so forth and the findings are analyzed using modified life tables in order to determine any excess mortalities and the specifics thereof.

Attempts are then made to correlate the mortality experience with workplace exposure levels, as ascertained from work history data. Section 20A7B of the Occupational Safety and Health Act of 1970 authorizes the Department of Health, Education, and Welfare to make inspections and question employers and employees as provided in section 8 of the act in order to carry out its functions and responsibilities.

The field investigations are conducted hopefully in the spirit of government, management, and labor cooperation. Section 20A6 of the Occupational Safety and Health Act of 1970 charges the Department of Health, Education, and Welfare with the responsibility for evaluating the potential toxicity of the materials used or

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found in the workplace. That is upon receipt of written request by employers and employee representatives.

NIOSH is the agency which provides these onsite toxicity determinations. I found upon checking with the responsible NIOSH division that no such requests have been received to date from any facility that can be identified as a PCB facility. I have a few health hazard evaluation forms with me and I also have a few NIOSH mailing list forms and with that I'll close. Thank you.

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PROPOSED CANADIAN REGULATORY MEASURES FOR PCB'S

Maurice F. Millson, Ph.D.*

Abstract

A systematic approach to the development of regulations intended to reduce environmental levels of PCB's involves three aspects: the nature of the problem, the ways of reducing the severity of the problem, and the recognition of those ways in formulating the regulations. Six regulatory packages are outlined. The Canadian legislative base on which to impose these packages is indicated, along with preparatory steps underway in anticipation of the coming into force of the Environmental Contaminants Act.

The contrast between the purposes for which DDT and PCB's have been used leads to the conclusion that presently measured PCB residue levels in the environment should not be expected to decrease, in response to Monsanto's imposed decrease in usage, at a rate comparable to that at which DDT residues have decreased.

The title given in the program is a bit optimistic. It sounds as if we made up our minds to pass information out, whereas in fact we are here to gather evidence in order to decide exactly what regulations we need. I shall deal only with an approach to regulations intended to affect the situation in the open environment, not regulations of food or other direct threats to humans. In this presentation I plan to follow a systematic objective approach to development of regulations, and it involves three aspects: the nature of the problem, the ways of reducing the severity of the problem, and how to recognize those ways in formulating practical regulations.

From the regulatory point of view, the nature of the problem is that there are dangers posed to living things by the presence of PCB's in their environment and levels do not seem to be decreasing. The dangers are a combination of the inherent toxicity of various PCB's and the exposure of susceptible species to those PCB's. Since we cannot change the toxicity of the types of PCB's, we can reduce the severity of the problem only by reducing the exposure.

Exposure incurred by PCB's in the environment is a little different from normal exposure. I think Dr. Kimbrough touched on this. For humans, one talks of exposure in terms of intake, whereas in the environment we normally talk in terms of the residues of PCB's in an organism or in a sediment. And it is those residues that we need to reduce as far as the environment itself is concerned. As a consequence, that would affect the intake of humans. We can reduce the residue levels by restricting the permitted range of uses of PCB's, by restricting losses of PCB's into the environment from any permitted uses, or by restricting the proportion of persistent homologs in the PCB's that get into the environment.

This brings us to the third aspect: how to recognize, it in the formulation of alternate regulations, the three ways of reducing the residue levels. I have put together six alternative regulatory packages of increasing severity with regard to those three ways.

The first package prohibits all uses other than in transformers and capacitors, and couples that with controls on disposal of industrial sizes of capacitors and transformers, the PCB's in them, and manufacturing wastes in making them.

The second package prohibits all uses other than transformers and capacitors. It puts a restriction on the higher chlorinated PCB's, meaning more than four chlorines, in capacitors and puts controls on disposal of industrial material.

The third package prohibits all uses other than transformers and capacitors. It restricts higher chlorinated PCB's in any capacitors, with an additional restriction on the medium chlorinated PCB's (more than three chlorines) in small capacitors because of their disposal. There are controls on disposal of industrial materials, recognizing that small capacitors are inherently unregulatable as far as disposal is concerned.

The fourth package prohibits all uses other than transformers and large capacitors, with a restriction on the higher chlorinated PCB's (more than four chlorines) in the capacitors, and has the disposal controls. This package would remove PCB's from small disposable capacitors.

The fifth package prohibits all uses other than for transformers and capacitors, and places a restriction on any PCB's with more than four chlorines. That would wipe out Aroclor 1254. It would probably not entirely wipe out the use in transformers; I think Westinghouse has always used a brand of 1242 for certain transformers.

The sixth package is total prohibition of PCB's. To any of those six there could be slight modifications. We might have to permit the use of PCB's in research; if we're going to allow them at all then we should allow

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their use in research, otherwise we'll never know any more about them.

We could permit their use as a chemical intermediate. Somebody may have reason to use 4,4'-dichlorobiphenyl for conversion to something else. And with sufficient restrictions on the conversion efficiencies and the disposal of waste, it might be possible to allow them to do that. We could add an extra restriction on the concentration of the chlorinated dibenzofuran in any fluid in which it appears to be a problem or in any fluid in which it's possible to remove it or prevent it from being there in the first place.

We are currently involved in examining the evidence on which to decide what package of regulations should be recommended to those who make the final decision. How we could legally impose the chosen set? We have the traditional fields of pollution control: waste water, air pollution, solid waste disposal, and just as in the United States, in Canada there is much legislation. We have 10 provinces, all with different laws and regulations. We have the Federal Government. Between them they could cover the whole range if everyone used its authority to pass, impose, and enforce the laws that are available.

It is generally recognized, as you already heard from EPA's point of view, that those sort of laws are not adequate for the proper control of PCB's. That does not mean they are not useful in conjunction with other legislation on products.

Canada almost has a law on products—the proposed Environmental Contaminants Act. It is Bill C25 at the moment and whenever a civil servant speaks of a bill he has to be careful to say he means the proposed act, because if one talks of the act, the legislature gets rather upset that you are taking it for granted. The reason that Jim Brydon is not here today is that yesterday he had to appear at a Senate committee hearing, and my understanding from phoning back this morning is that the committee passed the bill. Now whether it passed it with one amendment I am not sure. It passed the bill, which means it will go to third reading in the Senate next Tuesday, and then all it requires is the signature of, or Royal Assent from, the Governor General or whoever is acting for him. At that point it is on the statutes books but not in force. It comes into force on a date to be fixed by proclamation. When that will be I do not know. Various people are pressing for an early proclamation; certain others feel you need time to get organized before you proclaim the act, otherwise you can get into serious problems with handling paper.

In addition to that possibility of controlling products, the provinces have constitutional power, if they care to use it, to pass laws to control in detail all industrial activities within their boundaries. They can tell industry it must do this and it may not do that. They can control them in detail. They recognize that the regulation of products is better done at the national level in order to avoid fragmenting the markets and ending up with 10 different classes of laws. The Contaminants Act implicitly recognizes provincial power and requires the Federal Government to consult the provincial governments before putting in any regulations, in fact, before publishing the proposed regulations. The consultation is to determine whether any particular province prefers to deal with the problem itself. I do not imagine that any province would want that option for PCB's, or else they would have handled it already.

How to apply the new act when it becomes available to the six packages? It contains an information gathering power, which gives us the right to demand all kinds of information if there is reason to believe a significant danger exists. Those involved with a nominated substance must identify themselves, and on request must identify what their involvement is.

The act contains three powers of prohibition. Because of the nature of its constitution base, it may only prohibit. It may not regulate in a management sense merely because we feel it better that way.

The activities that can be prohibited are those liable to injure health or the environment. With respect to something such as PCB's, this could involve prohibition of willful release into the environment and prohibition of import, manufacture, processing, sale, or use for prescribed uses. Another prohibition is that on incorporation of a substance into a product beyond a certain specified concentration or proportion.

I should point out the possible strange regulations on proportions of chlorine in PCB's. If we wish to regulate them, it would not be by naming allowable proportions of specified substances by product, but by naming classes of substances and prohibiting them for certain uses. We can name substances or classes of substances with some limitation on the type of class. These classifications are nowhere near as broad as some of those in the draft U.S. toxic substances bills.

If we combine the three powers of prohibition in the new act with the conventional pollution control powers of the federal and provincial governments, you can see that we could put in any of those six packages on PCB's. In regard to what we actually intend to do, there is no secret that the earliest regulation that would be put forward would be very simply a restriction to no PCB use other than for transformers and capacitors, with the possible exception of research and maybe chemical intermediates.

In effect that would initially confirm Monsanto's

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1971 curtailment of sales. And it would not disrupt the market for electrical uses at the moment. It would disrupt whatever other markets there are that we do not have a handle on. We know some people are using PCB's. We don't know where they got them from. We have suspicions about who might be using them. Our information gathering power could be used, when in force, to find out who is using them. To go beyond the curtailment to transformers and capacitors, I cannot tell you what we shall do because we have not made up our minds. We would have to consult other government agencies or the Federal agencies. We would certainly have to discuss the action with electrical equipment manufacturers as to timing if or when we go beyond that one step.

To go to regulations on composition of fluids by prohibiting higher chlorinated PCB's, and certain chlorinated dibenzofurans, we would have to be able to specify analytical procedures. The procedure would have to be developed and would have to stand up to international comparisons; you do not do that overnight. People do not agree, for good scientific reasons, particularly on the chlorinated dibenzofurans as to exactly what are you measuring when you go through different procedures.

We have put together a good deal of information on the situation in Canada because we would have to be prepared to state the basis for a regulation. By we I mean a task force from the National Health & Welfare and Environment Departments, and the environment, health, and agriculture ministries of the province of Ontario. (Ontario controls the whole northern shore of the Great Lakes other than Michigan.) Several members of the task force are at this meeting; when we get back we shall debate our impressions of the data reported here, the opinions reported here, what we already know. We were not all of the same opinion the last time we met as to exactly what the evidence justified. We came here with open minds, but I doubt whether we shall reassemble all with one opinion. We shall be better informed, maybe a bit wiser, and a bit more scared about difficulties.

I cannot describe the Contaminants Act to you in a few minutes. It does require publication of any proposed restriction after it's been discussed with the provinces and before it comes into force. It provides for the creation of a board of review if a notice of objection is lodged. For this reason we would have to be prepared to submit to a board the evidence on which we claim to have become satisfied that the substance constitutes a significant danger to health or the environment. That is the basis of the act—the Governor-in-Council, meaning the Federal cabinet, has to be satisfied that a significant danger exists. This means that we would have to convince other departments whose interests are in promoting economic development and so on, that the danger is enough that the Federal Government as a whole should become involved. That would prevent arbitrary and capricious decisions.

We have come here partly to find evidence on the more perplexing points, in particular, the degree of persistence in the environment of the different PCB's. When they appear, one does not know for sure whether it is because they just came into that location or because they are persistent, or even which ones do persist.

On a personal level, everyone is worried that the Monsanto restrictions of 1973, '71, and '72 have not caused a significant decrease of levels of PCB's; that is, there has been no significant decrease in the levels of the persistent PCB's—1254, 1260.

I do not expect to see the persistent PCB's decrease in the 1970's in the biological accumulators, the fish and birds, and in sediments, which are nonbiological accumulators. If you look back to DDT, use dropped off from about 1963 around the Great Lakes and more or less ceased about 1968, '69, and '70. Five years later, after argument, people accepted the fact that DDT and DDE were decreasing.

All the DDT ever manufactured was intended to be spread into the environment within 1 to 2 years of its manufacture. Five years after stopping its production and use, a decrease in the environmental level has been shown. Almost all the PCB's ever made were intended to be kept somewhere because they were long-life products, and so they have not yet reached the open environment, let alone begun to show decreasing levels. One member of our task force, as a matter of fact, happens to analyze from time to time his invoices, and the carbonless copy paper invoice is still in use. It has not been manufactured for 3 years. So not only has it not yet appeared to go out of company files into the disposal system; it is not yet even in the company files—it is in the stock of unused paper.

What I do expect to decrease, if only we had the evidence, are the so-called less persistent PCB's—the 1242's or call them what you will. No one seems to have evidence or data on 1242 types in biota or sediments going back 5 years. Most people do not have any evidence for it at all, because either it is not there or they have not looked or the system cannot pick it up. There is some hope that one group in the Wildlife Service may be able to go back to some of its samples and determine the trichloro, tetrachloro levels over the last 3 years, and certainly over the next 3 years it can obtain samples and follow the trend if it exists. If that one does not decrease by 1980 or before, we have a bigger problem than anybody thinks.

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PCB's IN FOODS: A LOOK AT FEDERAL GOVERNMENT RESPONSIBILITIES

Joseph Highland, Ph.D.*

Abstract

Our growing concern over the continued contamination of food supplies by polychlorinated biphenyls (PCB's) reflects an ever increasing knowledge of the extreme health hazards posed by these compounds. PCB's are both subacutely and chronically toxic, and have recently been shown to cause severe chronic effects at dietary intakes as low as 2.5 ppm in nonhuman primates (refs. 1-4). To date, a no-effect level for PCB's in nonhuman primates has not been established.

Federal sampling and surveillance programs have continually demonstrated the presence of PCB's in our food supply. Not only have the existing temporary tolerances for PCB's established by the FDA been insufficient to protect the public health, but recent evidence also indicates they must now be considered both obsolete and inappropriate. A new regulatory posture is needed which takes into account recent evidence of chronic effects caused by low level dietary intakes of PCB's and, more importantly, new evidence (ref. 5) substantiating the carcinogenicity of these compounds.

Such a regulatory approach is mandated by the FDA's responsibilities under the Food, Drug, and Cosmetic Act. It must involve the establishment of a zero tolerance level for PCB's in food to be achieved by means of a phased reduction to zero (using appropriately set temporary tolerances) determined by the levels of PCB's presently found in the environment. Such temporary tolerances must be sufficient to minimize the risks to public health and must be based on a level of risk which has been assessed using appropriate statistical models to account for the potential carcinogenic risk posed by any given residue level.

Appropriate regulatory action is long overdue. PCB contamination of food clearly poses a potential health hazard. The longer action is delayed, the longer society will involuntarily be required to endure such health hazards.

THE NEED TO REGULATE

The need to regulate the levels of PCB's in the food supply is brought about by our knowledge of the health hazards posed by the ingestion of these compounds.

Are PCB's Toxic?

PCB's are considered to have a low acute toxicity (ref. 6). In adult rats, the oral LD_{50} ranges from 4-10 g per kg body weight. In weaning rats, an oral LD_{50} for Aroclor† 1254 of 1,295 mg per kg body weight and 1,315 mg per kg for Aroclor 1269 have been reported (ref. 7). However, a low acute toxicity does not mean the absence of health hazards. On the contrary, PCB's are subacutely and chronically toxic at relatively low dose levels (ref. 8).

The chemical nature of PCB's in part may help explain why they are subacutely and chronically toxic rather than being acutely toxic. They have a low solubility in water but are highly soluble in fat (ref. 9). Therefore, they tend to accumulate and concentrate in the body's fat stores rather than being rapidly metabolized and excreted. It appears that the metabolism and excretion of PCB's, especially of those Aroclors with high chlorine content, are even slower than for some of the most persistent pesticides, such as dieldrin and DDT (ref. 6). Thus, after ingestion, PCB's persist in the body for long periods of time and thereby may elicit chronic effects.

Bioaccumulation of PCB's in Tissue

From both animal and human data we know that PCB's accumulate in adipose tissue. Animals continuously fed PCB's show a steady buildup of these compounds in their tissues; to date, no known upper limit for PCB storage has been found. Steady-state levels of dietary PCB's were reported for certain but not all tissues in rats fed 100 ppm Aroclors 1248, 1254, and 1262 for approximately 10 months (ref. 8). Once these levels were reached, they appeared to remain relatively stable for a long while even after dietary exposure to PCB's ceased. Rats fed PCB's for 58 days showed levels in their adipose tissue 5 times greater than their daily dietary intake (ref. 10). When the dietary exposure was for 240 days rather than 58 days, levels of 10 times dietary intake were noted. If PCB feeding was curtailed after 58 days and the levels in tissue measured after 71 days on a PCB-free diet, adipose tissue still showed 80 percent of the highest

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†The term Aroclor is Monsanto's trade name for the PCB's it produces. Monsanto is the sole U.S. producer of PCB's. The last two digits of the four-digit number indicate the percent chlorination of the product (e.g., Aroclor 1260 contains 60% chlorination). Other trade names for PCB's manufactured outside the United States include: Kenaclor (Japan), and Clophen, Flenclor, Phenoclor, and Sorol (Europe).

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level previously measured while the levels in the brain showed no decrease but remained relatively constant.

As noted above, significant levels of PCB's have been found in the adipose tissues of humans as well. It is estimated that levels of 1 ppm PCB or more exist in 30 to 45 percent of the general U.S. population (refs. 11,12). In a few cases, levels as high as 200 and 600 ppm have been reported. Moreover, as the PCB's continue to be consumed, the composition of the residues stored in the body no longer directly reflect what has been ingested (refs. 10,13-15). This is due to differences in the body's retention of various PCB homologs. The more highly chlorinated homologs, which tend to be more chronically toxic, are retained longer. Therefore, the toxicity of the PCB's stored in tissues may actually increase and the mobilization and metabolism of a given amount of stored PCB can produce a more severe toxic effect than the ingestion of an equivalent amount (by weight) of a commercially produced PCB mixture.

Toxicity of PCB Metabolites

It is not only the direct toxic effects of PCB's with which we must be concerned, but also the effects of their metabolites as well. Many times metabolites are more toxic than the parent compound. In fact, in the case of the PCB metabolite 5-hydroxy-2,4,3',4'-tetrachlorobiphenyl, this has been shown to be the case (ref. 8).

The nature of PCB metabolites not only warns us of possible increased toxicological risks, but also of the types of toxicological responses that may be expected. The metabolism of PCB's by monkeys (primates like man) occurs by way of the formation of an epoxide intermediate (ref. 16). Aromatic hydrocarbons such as PCB's, metabolized via this intermediate, often produce cancer, birth defects, mutation, and cell death in experimental animals (ref. 17).

The Toxicity of PCB's in Humans

In response to PCB poisoning several adverse effects have also been observed in man. In 1968 over 1,000 Japanese experienced PCB poisoning after consuming rice oil contaminated with Kanechlor 400 (refs. 18,19). In addition to causing headaches, swelling of eyelids, temporary loss of vision, and many other symptoms, PCB's stored in the adipose tissue of pregnant women were passed through the placental wall and into their fetuses. As a result, 9 of the 10 live-born babies had unusually greyish, darkened skin, and most were born underweight. The importance of these observations cannot be underestimated, especially in light of very recent findings reported by Allen and coworkers on the effects of low-level exposure of nonhuman primates to PCB's (refs. 1-4). The effects seen in these monkey studies are similar in appearance and persistence to the symptoms of the human poisoning already discussed. Moreover, these symptoms were documented at levels of dietary intake of as low as 2.5 ppm. To date, a no-effect level for PCB's in monkeys has not been established.

Carcinogenicity of PCB's

Although carcinogenicity in primates in response to the dietary intake of PCB's has not yet been observed, it has been reported for both mice and rats (refs. 5,8). The World Health Organization has reported that Kanechlor 500 and Aroclor 1254 are carcinogenic in mice and induce both benign and malignant liver cell tumors following oral ingestion. Most recently, a team of research investigators from the Center for Disease Control, Atlanta, Georgia, the U.S. Environmental Protection Agency, the National Cancer Institute and Johns Hopkins University School of Medicine reported that 26 of 184 experimental animals (rats) fed 100 ppm of Aroclor 1260 for approximately 21 months developed hepatocellular carcinomas. Only 1 out of 173 control animals developed this lesion in the same period of time. Moreover, 146 of the experimental animals but none of the controls had tumorous lesions (neoplastic nodules) of the liver.

Appropriate regulatory action with regard to the presence of PCB's in food must take into account the following factors among others: the bioconcentration of these compounds in human tissues; the selective nature of this process which can lead to more severe toxic effects than those expected from the ingestion of the original PCB mixtures; the toxicity of the PCB metabolites; the severe chronic effects observed in nonhuman primates from dietary ingestion of low levels of PCB's; and the demonstrated carcinogenicity of PCB's in two animal species.

PCB's IN FOOD

The first evidence that food supplies had become contaminated with PCB's was reported in 1966, when fish from various Swedish waters were shown to contain PCB's (ref. 20). Since then, PCB's have been identified as contaminants in food supplies around the world. They have been found in pike taken from a lake in Finland, mollusks and marine fish from Scottish waters, a wide variety of fish caught in the St. John River system, wildlife in California, and in trout and salmon taken from Lake Michigan (refs. 8,21). More recent findings indicate that contamination by PCB's continues to be widespread. Within the last few months, striped bass caught in the Hudson River have been found to contain as much as 90 ppm PCB's, while pike caught in the Baltic Sea were shown to contain 0.31 ppm PCB in their muscle

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and up to 190 ppm in their ovaries (refs. 22,23). Moreover, plankton from the Baltic Sea, upon which many fish feed, contained levels of 25 ppm PCB in their fat (ref. 24).

Federal Sampling and Surveillance Programs for Chemical Residues in Food

The Federal government currently conducts three separate programs in which the contamination of foods by PCB's is measured. These programs include: the FDA Pesticide Surveillance Program, the FDA Total Diet Program, and the USDA Surveillance Program.

The FDA Pesticide Surveillance Program, which began in 1968, was developed to gather information on the levels of pesticides (including PCB's) in foods and animal feeds based on a statistical sampling program designed to cover specific geographical regions of the United States. The program is intended to assure the safety of the human food supply by screening and removing shipments of foods containing PCB's or pesticides in excess of established tolerances. Commodities covered under this testing program include dairy products, eggs, fish, animal feeds, fruits, vegetables, and processed foods.

In the FDA Total Diet Program, the levels of pesticides, PCB's, and trace heavy metals in the diet are measured. Bimonthly, a diet approximating that which would be consumed in a 2-week period by a hypothetical 15- to 20-year-old male is collected at retail stores in five regions around the United States. The foods are cooked or prepared in the appropriate manner and then divided into 12 basic food composite classes. These include meat, fish, poultry, leafy vegetables, etc. Each composite is then analyzed for contaminants.

The USDA Surveillance Program consists of periodic sampling and analysis of meats and poultry from chemical contaminants including PCB's. Samples are taken from federally inspected slaughterhouses.

The Levels of PCB's Found in Food

A summary of the findings, with respect to PCB's, of the survey and surveillance programs described above are listed in tables 1 through 3. It represents a compilation of data gathered from Federal sources (refs. 8,20,25).

Although the data are incomplete, it is clear that PCB's continue to contaminate our food. Results of the pesticide surveillance program appear to indicate an increase in the extent of contamination, while those of the USDA surveillance program indicate a decrease. This apparent conflict may be explained by the fact that different foods are sampled in these programs and it is quite possible that contamination of some foods has decreased while increasing for others.

The apparent decrease in the levels of PCB's reported in the FDA total diet survey between FY 73 and the first half of FY 74 must be viewed with caution. During the first half of FY 74, the average PCB levels for milk and other dairy products, for eggs and egg products, and for animal feed ingredients were equal to or greater than those reported for FY 73. Then why the apparent decrease? In large part this reflects an apparent decrease in the numbers of fish that were found to be contaminated with PCB's. In FY 73, 62.2 percent of the fish samples examined contained PCB's in the range of trace amounts to 123 ppm. In the first half of FY 74 only 35.3 percent of the samples checked were contaminated and the levels found ranged from trace amounts to 9.70 ppm. However, the fish data reported for FY 73 included mostly freshwater fish, where the contamination with PCB's has been shown to be the greatest, while during the first half of FY 74 the FDA samples consisted mainly of marine fish. Since the samples are not comparable, the apparent decrease observed is more probably a reflection of the difference between PCB contamination of freshwater and marine fish than an indication of a decline in PCB's in fish generally.

In addition to these observations, numerous specific incidents of PCB contamination of food have been reported by the FDA and USDA. A summary of these has been compiled by Wessel (ref. 20). A few examples follow. In 1970, the Campbell Soup Company detected high levels of PCB's (26.8 ppm on a fat basis) in chickens grown in New York State. As a result, 140,450 chickens were destroyed. In July of 1971 Monsanto Chemical Company informed the Food and Drug Administration that large amounts of fish meal might have been contaminated with PCB's during pasteurization from a leak in the heating system at their East Coast Terminal in Wilmington, North Carolina. An investigation by the FDA revealed that the leak had begun in April of 1971 and had continued through July 1971. Contamination of the fish meal was verified, and as a result, over 123,000 pounds of egg products and 88,000 chickens were destroyed. That same year, the FDA was notified that high levels of PCB's (20 ppm) had been found in Swift and Company turkeys. As a result, approximately 1 million birds were kept from market. These incidents and the results of the Federal surveillance programs demonstrate that the contamination of food by PCB's is not a new phenomenon. It is a continuing problem, which has resulted in part from the continued indiscriminate discharge of PCB's into the environment, and one which

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Table 1. FDA total diet survey

Year	Number of composite food samples	Percent contaminated	Levels of contamination
68-71	900	6%	trace--0.36 ppm
FY 73	360	6%	trace--6.0 ppm
FY 74	360	4%	trace--0.05 ppm

Table 2. FDA pesticide surveillance program

Year	Number of samples	Percent contaminated	Levels of contamination
68-71	15,000	3.2%	"detectable" (fish, specifically: 1-10 ppm)
FY 73	7,882	4.0%	"detectable"
FY 74	1,723	5.4%	"detectable"

Table 3. USDA surveillance program

Year	Number of samples	Percent contaminated	Levels of contamination
71	4,175	4%	trace--15 ppm
FY 73 (poultry only)	1,037	2.6%	trace--4 ppm
FY 74 (poultry only)	574	<1%	1.25 ppm

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must be eliminated because of the severe health hazards posed by these compounds.

THE ESTABLISHMENT OF TOLERANCES

Existing Tolerances

In partial recognition of the health hazards posed by PCB's, the FDA proposed the following temporary tolerances (in ppm) for the levels of PCB's which would be permitted to contaminate food:

1.	Milk (fat basis)	2.5
2.	Dairy products (fat basis)	2.5
3.	Poultry (fat basis)	5.0
4.	Eggs	0.5
5.	Complete and finished animal feeds	0.2
6.	Animal feed components	2.0
7.	Fish and shellfish (edible portion)	5.0
8.	Infant and junior food	0.2
9.	Paper food-packaging material	10.0

The FDA contends that these tolerances are sufficient to protect the public health. However, careful consideration of the available evidence indicates clearly that this conclusion is unwarranted and unsupported by the facts.

The Toxicological Basis for Calculation of The "Acceptable Dietary Intake" of PCB's

The FDA has calculated what is termed an "acceptable daily dietary intake" for PCB's. Even if the validity of such a concept is assumed, the basis for establishing such a level must be evaluated in order to determine whether the temporary tolerances that have been promulgated sufficiently limit PCB intake. In this connection the FDA's final environmental impact statement for rulemaking on PCB's (ref. 26) indicated that both animal and human toxicological data were used to establish an allowable dietary intake.

According to data avilable at that time, long-term animal studies showed no-effect levels in dogs and rats of 10 ppm for Aroclors 1242, 1254, and 1260. Employing the standard 100-to-1 safety factor, a no-effect level for man based on data derived from dogs was calculated to be 2.5 μg/kg body weight/day. From the data on rats, a 3 μg per kg body weight figure was obtained. Therefore, the allowable level of PCB ingestion in man was figured to be 0.175 mg per day for a 70-kg individual. However, according to Dr. H. Blumenthal, Acting Director, Division of Toxicology, Bureau of Foods, FDA (ref. 8), in the time since these calculations were made, there have been two important observations concerning PCB's which alter our understanding. These observations make the allowable daily intake previously calculated obsolete.

First, the recent studies cited earlier in this paper dealing with experiments on nonhuman primates were reported, indicating that the rat and dog are relatively insensitive to many of the toxic effects of PCB's. As stated previously, a no-effect level for PCB's has not yet been determined for monkeys. Second, recent work by Allen (ref. 1) indicates that the use of gross observations of toxicity are not reliable in the study of PCB's. Allen observed that routine toxicological evaluations of rats fed 100 ppm Aroclor 1248 for 1 year revealed no abnormalities in growth, mortality, and hematology. However, more sophisticated tests showed that these rates had drastically altered fat and cholesterol metabolism as well as changes in liver size and structure. Therefore, even if one were willing to accept an allowable human daily dose for PCB's calculated from animal toxicological data, one would have to question seriously the basis for the FDA's 1972 calculations.

The human toxicological data used to determine the allowable daily dose came from the accident at Yusho described earlier in this paper. The reasoning put forth by the FDA (ref. 26) was as follows:

> Since 2,000 mg was reported to be the average total dose causing an effect in the Japanese, it is possible that 200 mg total dosage PCBs (applying a safety factor of 10 to 1 as above) may be tolerated over a much more protracted period of time without overt adverse effect if daily exposure is held to minimal levels. This would permit ingestion of 4 μg per kg body weight per day in a 70-kg man. Since the lowest total dose producing an effect in man in the Japanese incident was 500 mg, a similar analysis leads to an allowable protracted ingestion of 1 μg per kg body weight per day as derived from a 70-kg man.

On the basis of these data, the FDA arrived at an allowable dose of PCB's (for a 70-kg man) of between 70-280 μg/day, although the significance of these calculations is very questionable. Particularly suspect are the estimates that had to be made of actual doses received by the Japanese, as well as the arbitrary assumption that a safety factor of 10-to-1 is sufficient to determine a safe level of intake for a "protracted period of time." In addition, the calculations fail to consider the potential long-term effects caused by stored PCB residues. Recent evidence from controlled feeding experiments of nonhuman primates which demonstrated severe chronic effects from low-level intakes of PCB's raises the question of whether similar effects might also be seen in man under the appropriate conditions.

The "Acceptable Daily Dietary Intake" Can Readily Be Exceeded

The FDA's acceptable daily PCB intake of 75-210 μg/day for a 70-kg man seems questionable at best. As

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Dr. J. Wessel, Scientific Coordinator, FDA, has pointed out (ref. 20), "it is quite clear that the acceptable daily PCB intake of 75-210 μg/day could easily be exceeded by an adult consuming some of the heavily contaminated foods in his diet." Table 4 below, taken directly from the testimony of Dr. Wessel (ref. 20), illustrates this point clearly.

As Dr. Wessel concludes, "Even when PCBs are present at the tolerance level, it would be possible for an adult, with normal dietary habits, to exceed 175 μg of PCB per day." Adults with "normal dietary habits" are not the only people unprotected. Perhaps at even greater risk are those large groups within the population, such as sport fisherman or people on special diets, who consume above-average quantities of PCB-contaminated foods, or nursing babies who ingest PCB's in their mothers' contaminated milk and who, for biochemical reasons, have a very limited capacity to metabolize foreign chemicals such as PCB's. Dr. A. Kolbye, Jr., Associate Director for Science, Bureau of Foods, FDA (ref. 27), and Dr. H. Blumenthal, Acting Director, Division of Toxicology, Bureau of Foods, FDA (ref. 8), are clearly correct when they say respectively: "Infants or young children could also readily exceed the tolerable daily exposure," and "Thus, the best evidence indicates that children would be more susceptible to the poisoning caused by unmetabolized PCBs, since they have not developed effective ways of eliminating them from the body."

The Need for Reevaluation of PCB Tolerances Is Apparent

The FDA's temporary tolerances for PCB's in food are both inadequate and inappropriate. They fail to protect the populace even if one accepts the concept of an acceptable daily dose, because the dose calculated in 1972 is now obsolete in light of more recent findings. More importantly, however, the appropriateness of any "acceptable daily dose" for PCB's is highly questionable

Table 4. Relative contribution to acceptable daily intake (175 μg/g by foods subject to PCB temporary tolerances)

Type of food	Serving of food	Temporary tolerance (ppm)	Equivalent amount PCB in food	Relative contribution to ADI
Milk	800 ml (3.5 cups)	2.5 (fat basis) 0.1 (whole product)	80 μg	46%
Cheese	100 g (3.5 oz)	2.5 (fat basis) 0.6 (whole basis, assuming 25% fat)	60 μg	35%
Poultry	200 g (7 oz)	5.0 (fat basis) 0.5 (whole basis, assuming 10% fat)	100 μg	58%
Eggs	100 g (2 eggs)	0.5	50 μg	29%
Fish	200 g (7 oz)	5.0	1000 μg	580%
Packaged food	100-200 g (3.5-7.0 oz)	10 ppm (packaging)	10-60 μg[a]	6-35%

[a]Based on 1971 FDA Survey that 10 ppm PCB in packaging can result in migration of 0.1-0.6 ppm PCB to packaged food.

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in light of the evidence demonstrating in experimental animals the carcinogenicity of these compounds. Since there is, at the present time, no scientific evidence that any level of intake of a carcinogen is safe, the entire concept of an acceptable daily dose for a carcinogen such as PCB is self-contradictory and scientifically unsupportable. A new regulatory posture is therefore needed.

A PROPOSAL FOR APPROPRIATE REGULATION

Responsibility Under the Law

The FDA's responsibility and obligation to protect the public health against hazardous substances in the food supply were established by Congress in the Food, Drug, and Cosmetic Act. Section 409 of the act embodies in the Delaney Amendment the explicit Congressional policy to prohibit all carcinogenic additives in food. Since "food additive" has recently been judicially interpreted to include any substance whose use can reasonably be expected to result, directly or indirectly, in its becoming a component of food,* the policy underlying the Delaney Clause is applicable to PCB's in food. In addition, Section 406 of the act authorizes the establishment of tolerances for poisonous and deleterious substances in food. An appropriate regulatory policy with respect to the contamination of food by PCB's must therefore take cognizance of these expressions of legislative intent.

A Regulatory Approach Consistent With the Health Hazards Involved

Consistent with the foregoing expressions of Congressional policy and with the evidence that PCB's are both ubiquitous in the food supply and carcinogenic in laboratory animals, the FDA should and indeed must establish a zero tolerance for the levels of PCB's permitted in food. New FDA regulations pertaining to PCB's must start with the premise that elimination of PCB's from the food supply is the ultimate goal. This does not mean that all food supplies currently contaminated with PCB's must be immediately condemned and confiscated. Such an effort would be impracticable and irresponsible. It does mean, however, that within a reasonable period of time, PCB contamination of food supplies will no longer be tolerated. In the interim, a temporary tolerance, sufficient to minimize the risks to public health, must be established, and then progressively reduced to zero. Such a regulatory posture would also require the EPA to carry out, in a reasonable and appropriate manner, its responsibilities with respect to environmental contamination by PCB's and to stop the indiscriminate discharge of PCB's into the environment.

The method used to establish temporary tolerances for PCB's is very important. PCB's have been shown to be carcinogenic in two species of laboratory animals. In light of this evidence, it is clear that the routinely applied 100-to-1 safety factor for toxic substances is completely inappropriate. The FDA has already indicated (ref. 27) its intention to adopt the Mantel-Bryan method (refs. 28,29) of statistical analysis to establish the required sensitivity of the testing method in cases where carcinogenic additives or drugs are intentionally added to animal feed or administered directly to animals. The FDA has adopted this position in an attempt to satisfy the intent of Congress as expressed in the Delaney Amendment. Temporary tolerances for PCB's, established using the Mantel-Bryan or other (ref. 30) appropriate statistical procedure, would be consistent with this policy. Any values so obtained could not be considered a "safe" level since neither the Mantel-Bryan procedure nor any similar statistical method is intended to be used to establish "safe" levels of exposure to environmental carcinogens in food. On the contrary, they are used to relate the dose of a carcinogen ingested to the probability of the induction of cancer.

The establishment of temporary tolerances must be viewed in light of the potential carcinogenic hazards posed by PCB's. The rapid reduction to zero of such tolerances is the only reasonable and responsible action that can be taken. Appropriate regulatory action is long overdue. Any additional delay in reducing dietary levels of PCB's can only result in increased exposure of the population to potentially disastrous health risks which neither they nor their elected representatives have undertaken to assume.

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CONCERNS AND RECOMMENDATIONS OF THE NATIONAL MARINE FISHERIES SERVICE REGARDING APPROACHES TO CONTROL THE POLYCHLORINATED BIPHENYLS PROBLEM

Thomas J. Billy*

Abstract

The views of the National Marine Fisheries Service concerning what can and should be done to (1) prevent PCB's from further polluting the environment, (2) protect consumers and limit human exposure, and (3) avoid unnecessary adverse publicity having a severe economic impact upon the fishing industry are described. Specific environmental, consumer, and fishing industry concerns are discussed and recommendations made in light of these concerns.

INTRODUCTION

On the occasion of this conference, the National Marine Fisheries Service (NMFS) would like to express its views concerning what can or should be done to (1) reduce the amounts of PCB's reaching the environment, (2) limit human exposure, and (3) avoid unnecessary adverse publicity.

In earlier sessions, we have heard presentations on:

1. Health effects and human exposure, including the available toxicological information.
2. The uses, sources, and identification of PCB's.
3. Discussion on the environmental fate and occurrence, including the ecological effects of exposure.
4. The availability and economics of substitutes.
5. The impact that the PCB pollution problem has already had on people and their livelihoods.

During this session of the conference, presentations have been made on what can be done to reduce the amounts of PCB's reaching the environment and to limit human exposure. Federal and State roles and responsibilities have been described and the recent Canadian regulatory measures have been presented.

With this information and data base and with the approaches and responsibilities for control outlined in this session, I would like to express our concerns and recommendations, as the Federal Agency with the primary responsibility for the management and utilization of our Nation's marine fishery resources.

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AREAS OF CONCERN

Our concerns can be put into the following three categories:

1. Aquatic environment,
2. Consumers of fishery products, and
3. Fishing/seafood industry.

Let us take a brief look at each of these areas.

1. *Environmental Concerns*

Effective, comprehensive controls to prevent the pollution of the environment from the manufacture, sale, use, and disposal of PCB's in the United States have not been implemented to date, resulting in the continuing contamination of the ecosystem and the consequent occurrence of PCB residues in a number of fish species and other foods.

2. *Consumer Concerns.*

We believe responsible regulatory action has been taken already to deal with the public health issue, and we fully support the current 5.0 ppm temporary tolerance for PCB's in fishery products. However, our concern is that certain information being presented at this conference and other pressures could result in precipitous further regulatory actions that are not based upon the full and complete information necessary to justify such actions.

No change in the present tolerance should be contemplated until full and proper consideration has been given to:

a. New, conclusive toxicological information.
b. The role of the specific species in the diet.
c. Probable further decreases in PCB levels over an extended period of time.
d. Direct economic impact to the fishing industry as well as the overall economic impact.
e. Alternative government and industry approaches for assuring consumer protection.

Finally, there is concern that some of us in this room may fail to recognize our responsibility to insure that information reaching the public be completely factual, not speculative, and that it be presented fairly so as to prevent unnecessary confusion on the part of consumers and the resultant severe economic impact on the fishing industry.

3. *Seafood Industry Concerns*

There is a lack of recognition by some that an industry depends upon the natural resources which we are

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discussing, and we have imposed a serious problem on them that is not of their making. The seafood industry is concerned about the safety of their products and has been and continues to be willing to take responsible actions to protect public health.

However, NMFS is concerned that the lessons from the past in over-regulating or implementing unnecessary regulatory actions will not be heeded.

RECOMMENDATIONS

In light of these concerns as well as the available information, the National Marine Fisheries Service recommends the following:

1. That Federal and State governments take immediate steps to implement effective controls to prevent the pollution of the environment by PCB's under the many authorities available to them. These controls should consider the manufacture, sale, use, and disposal of PCB's and other similar hazardous substances.
2. That current tolerance for PCB's in seafood should be maintained unless new and complete information warrants consideration of specific actions to selectively deal with specific problems.
3. That release of unnecessary or irresponsible adverse publicity or other actions that will have a direct impact on all seafood sales should be avoided.

In summary, let us not once again lay ourselves open to the criticism of having only single purpose goals. Let us evaluate all risks, costs, and benefits and then take further regulatory actions, based on the greatest net good to society.

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THE ROLE OF THE COAST GUARD IN PCB POLLUTION CONTROL

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Abstract

In order for the Coast Guard to act in protecting the environment, the substance to be controlled must be designated as a harmful or a hazardous polluting substance by EPA. To this date, PCB's have not been officially established as such. Public awareness is also crucial in helping the Coast Guard fulfill its role—handlers must learn that PCB's are hazardous and treat them accordingly, and those who detect spills should report them promptly.

The Coast Guard's role in protecting the environment from PCB pollution is defined in Section 311 of the Federal Water Pollution Control Act of 1972 as amended. That role is to prevent transportation-related spills of oil and hazardous polluting substances from entering the navigable waters of the United States or the contiguous zone, and to enforce the provisions established in Section 311.

In order for the Coast Guard to initiate actions to respond to this role, PCB's must be designated by the Environmental Protection Agency as a harmful or hazardous polluting substance, and a determination made as to the amount that is hazardous. After this is determined, the Coast Guard will address the problem in three basic ways: detection of spills, prevention of spills, and enforcement of statutory sanctions for such spills.

Increased public awareness will help to reduce and mitigate the effects of PCB spills. As soon as the public is aware that PCB's are hazardous, and that special precautions should be taken in their handling and transportation, the number of spills involving PCB's will certainly decline.

Detection is exceedingly difficult because PCB's are a relatively colorless liquid. Oil, on the other hand, is more easily detected although even certain oils present problems for us from time to time. It may be possible that some form of tagging, such as the utilization of dyes, would assist in the detection of PCB spills.

Prevention also ties back into public awareness. If the stevedore handling a transformer containing PCB's on a pier in Seattle had been aware that the transformer contained a hazardous polluting substance, he might have been more cautious while handling that transformer, and the resultant spill might have been averted.

Enforcement is predicated upon an illegal spill being detected and reported to the proper authorities. We must ascertain that a spill took place, establish its cause, and identify the responsible party so that penalty assessments and statutory sanctions can be invoked.

To reduce and mitigate the effects of a spill after it has taken place, we would deal with it in a manner somewhat analagous to the manner in which we deal with oil spills. Response teams capable of dealing with spills of any number of hazardous substances of various magnitudes would assist in the containment and cleanup. Unfortunately, with PCB's these actions are made very difficult by the physical properties of the liquid.

There are some hard questions that need answering immediately. The Coast Guard, EPA, and other agencies will address them as soon as practicable. I would reemphasize, however, the fact that our future actions in regard to PCB's are predicated upon its establishment as a hazardous polluting substance.

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CONSIDERATIONS BY THE DEPARTMENT OF TRANSPORTATION

Alfred W. Grella*

Abstract

The Department of Transportation (DOT) has nine categories for hazardous materials. Packages containing these substances are to be labeled by category and handled accordingly. PCB's are not presently classified as conventional toxic materials and are therefore not regulated under DOT criteria. The department is now considering whether to develop a generic category of "hazardous wastes" and/or similar categories for environmentally hazardous materials, which would possibly include materials such as PCB's.

I have just a few remarks which would point out some of the thinking in DOT, some of the concerns we have, and some reasons why we do not have any regulatory criteria at the present time for transportation requirements for PCB's. It is important at the outset to point out that the current standards and philosophies in regulating hazardous materials in transportation are based on considerations of preventing acute hazards caused by release of hazardous materials from their packaging. This philosophy is common to both the international and the domestic transportation requirements.

Another way of saying this is that we do not regulate materials from a standpoint of the long-term effects from chronic hazards. In transportation hazardous materials are grouped or categorized into approximately nine classifications. The hazardous material may either be listed by name and classification or under a generic heading by classification.

The regulations, for the most part, provide test criteria for persons to test a material to determine its classification, if the material is not already listed. If it is regulated under these criteria, then packaging, marking, and labeling requirements are prescribed, and sometimes carrier stowage requirements are indicated.

For these purposes, the "conventional" poison classification criteria relate to the effects of animal tests against oral, inhalation, and skin-absorbtion criteria. It is clear that the PCB's that we are aware of are not presently regulated as "conventional" toxic materials. Therefore, they are not regulated in transportation under our present DOT criteria.

Previously there has never been a statutory definition of "hazardous materials." Recent legislation, as recent as January of this year, resulted in the Transportation Safety Act of 1974, Public Law 93-633. In section 103, paragraph 2, "hazardous material" is defined as "a substance or material in a quantity and form which may pose an unreasonable risk to health and safety for property when transported in commerce."

Therefore, it appears, for the first time, that we may have some sort of a basis to look at criteria other than the acute hazard, if such action appears appropriate. And the same consideration is coming up more and more when we talk about the generic term, "hazardous wastes." Many hazardous wastes may already be regulated now as hazardous materials. There are also many types of hazardous waste that may not be quite toxic enough or quite corrosive enough or quite flammable enough to be regulated. But they still may be objectionable with respect to release to the environment.

The other area is carcinogenic materials in general, which do not meet the conventional toxicity criteria.

So in these three areas—PCB's, hazardous wastes, and carcinogenic materials, we are starting to take a long look at whether there is a need for some degree of regulation in transportation. The question would then arise: What should that degree of regulation be? Certainly, packaging requirements might have to be addressed and, certainly, considerations for labeling. This will give you some idea of the things we are thinking about. We have not formed any actual, concrete plans. We are following very closely what the other agencies are doing and are maintaining as close contact as possible with those agencies.

The UN Group of Experts on Dangerous Goods, which is the international body that develops regulations for the transport of hazardous materials, has been debating the subject of PCB's and environmental pollutants for several years and has not been able to come to agreement as to whether they should undertake to regulate environmental hazards at all or whether this should be left to the environmental groups.

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OBSERVATIONS ON AND SUMMARY OF SESSION VII

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It has been a very interesting meeting and we have heard a lot of interesting data, opinions, and some rhetoric. I would like to make a few quick points that I think we should all keep in mind, because personally I feel once again we in FDA are the straight men in a bad joke. We are asked to mediate decisions that involve many parameters, not the least of which concerns human safety very directly.

We are asked to interpret data and to come up with limits on human exposure over time. We have previously dealt with environmental contaminants. We have a few that we unfortunately have experience with that are biologically persistent and for which experimental data show that there are varying degrees of carcinogenic potential, at least in animals.

I should like to talk about a guideline for a moment, because a guideline or a tolerance or however you wish to think of it represents a level in a particular food. What is really important in the long run is what the exposure dose is that humans receive and how they receive it.

The major point that I am trying to make is that we feel the average consumer is fairly well protected against the hazards of PCB's. But if one eats food with a high percentage of contaminating residues, and if one eats that particular food commodity frequently, one's exposure dose quite obviously goes up. As far as I can see, the people who in this country bear the greatest potential risk are selected sport fishermen, "sport fisher people," who, if they are catching and retaining and consuming with a high degree of frequency certain species of fish from certain geographic locations, have higher exposures than do the rest of us in this country.

One of the decisions we have to make is what incremental degree of protection will be afforded to the public by a decremental change in our guidelines. But please remember once again that a guideline itself represents a judgment concerning dietary intake, which also represents a judgment about the frequency of food consumption. And it is a little difficult sometimes to draw a bright line in a gray zone and I believe you can expect reasonable people to differ somewhat in their opinions about where that bright line should be drawn.

I would like to say one other thing about a guideline, because it would appear from time to time here and there that there has been some confusion about the meaning of a guideline with reference to cooperative action by various governmental sectors regarding the environment. An FDA guideline involving an environmental contaminant in food is not, and I repeat, is not equivalent to permitting pollution. It does not give license to pollute. Some people seem to have thought in the back of their minds that as long as fish did not exceed such and such a level of PCB's, a certain amount of PCB's entering the aquatic environment was permissible. That thinking is now obsolete.

The ecological criteria as far as I can see, with respect to wildlife, are some of the most sensitive indicators with respect to substances like PCB's, and I think, as was mentioned earlier, we should take note of such data in terms of our overall cooperative efforts to protect the environment.

I think health and environmental education should be undertaken for the public (and in particular for certain people who are concerned with disposal of solid waste) as to what containers are likely to contain PCB's and the proper identification and disposal of transformer fluid, etc.

I would also like to make one note. Let us not unduly focus on the polychlorinated biphenyls. There are other environmentally persistent compounds of concern, and a recent episode has led us to fully appreciate that the polybrominated biphenyls are also of concern. Thank you very much.

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