THE STATUS OF PCBs[1]

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I welcome this opportunity to review the major developments in the area of polychlorinated biphenyls (PCBs) and to discuss their current status with respect to food. The subject appears to be of more than ordinary interest not only to the FDA but to other federal agencies and to you in state and local food regulatory control work as well. In fact, the problem of PCBs is one we share with public health and environmental control officials in all countries of the world. Like DDT, PCBs do not recognize any national boundaries.

The polychlorinated biphenyls (PCBs) comprise a family of organic chemicals of quite remarkable chemical and physical properties. PCBs are manufactured commercially under the tradename Aroclor by the Monsanto Chemical Company, the sole manufacturer in the U.S. They were first produced commercially in 1929. The chlorine content of individual useful products varies from about 20-70% by weight; those up to about 54% are liquids and those above 54% are solids. The PCBs are extraordinarily stable and chemically inert, have a high dielectric constant and a high boiling point, are non-flammable and very resistant to decomposition by heat.

Industry rapidly capitalized on the unique properties of PCBs and began using them for a variety of purposes: insulating fluids in electrical transformers and capacitors, heat exchange fluids, hydraulic fluids, paints, plasticizers, printing inks, fire retardants, carbonless copy paper, and numerous other uses where electrical nonconductance, non-flammability and heat resistance properties are useful.

The PCBs are highly persistent in the environment; they resist both chemical and microbiological degradation. Thus, in 1971 the manufacturer announced that products for use only in closed systems such as electrical transformers and capacitors would be supplied. All others were being discontinued because of the potential for environmental contamination.

While PCBs had been widely used not only in the U.S. but throughout the world for almost 40 years, it was not recognized that there might be an environmental problem until Jensen identi-

[1]Presented at the 76th Annual Conference of the Association of Food and Drug Officials of the United States, Monticello, New York, June 18-24, 1972.

fied PCBs in bird tissue in Sweden in 1966. Analytical methods for routine examination of food were not available at that time. However, in July 1969, FDA furnished its field laboratories with a GLC method employing an electron capture detector for determining PCB residues in food in the presence of DDT, which is a major interfering chemical. Immediately, our FDA laboratories began analyzing food samples for PCBs and in November 1969 the FDA field laboratories were instructed to analyze all raw agricultural commodities sampled in the pesticide program for PCBs.

No PCBs have been found in fresh fruits and vegetables. This finding is indeed significant because thousands of samples have been analyzed. PCBs have, however, been found in a feed by-product from potato processing plants. The source of the contamination could not be identified. Of all foods, PCBs are encountered most frequently in fish; the fish from Lake Michigan, particularly the Coho salmon, usually contain higher levels than other domestic lake or river fish. The incidence of detectable PCB residues is lower in salt water fish (25% as opposed to 66% in fresh water fish, based on rather limited FDA data) and the PCB levels in salt water fish are also lower. Confronted with the problem of a high percentage of fresh water fish containing excessive levels of PCBs, FDA, in February 1970, set an action level of five parts per million in the edible portion of the fish. Incidentally, you will note that the action level for PCBs in fish is the same as our administrative guideline for DDT in fish.

In July 1971, somewhat unexpectedly, one of FDA's routine analyses of a total diet sample for pesticide residues showed a small amount of PCBs in the food composite consisting of grain and cereal products. Further investigation showed that PCBs were present in only one component of the composite, namely, shredded wheat biscuit. The paperboard dividers used to separate the individual biscuits were found to contain a high level of PCBs and presumably contaminated the biscuits. A followup at the paper mill indicated that the dividers had been produced from recycled paper including carbonless copy paper.

These findings, which demonstrate the value of FDA's continuing total diet studies, suggested food packaging made from recycled paper as a potential source of PCB entry into food. Therefore, in the fall of 1971 FDA instituted a special nation-wide survey of foods packaged in paper materials to determine the extent and the degree of this type of contamination.

Both the food and its paper packaging were analyzed. The initial determination was made by GLC using an electron capture detector; the size of the response for the sample was compared with that for a commercial PCB with the most similar GLC pattern (usually Aroclor 1242). Positive findings were confirmed, when deemed necessary, by halogen-specific GLC detection or by rechromatographing after alkali treatment.

Table 1 summarizes the levels of PCBs found in the food and in its packaging for each of 15 food categories. For the packaging of each food sample or series of food samples the PCB levels are shown; with a series, the range of PCBs in the package is followed by a slash mark and the average value of the series. All paper packaging material was classified, as definitely as possible, as being made from recycled or virgin material. If any component of the packaging was recycled, all of the packaging components of that sample were placed under the heading of recycled packaging material. As might be expected PCB levels in virgin packaging material are significantly lower than those in recycled packaging material, and of course, the packaged food also shows this difference. The overall average of PCBs in all packaged food was 0.1 part per million.

In regard to those cases where PCB residues were found in packaging components that appeared to be composed of virgin material, it is possible that some of the packaging may have been incorrectly classified. In addition, it is also likely that virgin packaging may have picked up PCBs from the water in the paper pulping operation, from chemicals or equipment in the paper mill, or from the package manufacturing operation.

In some instances PCBs were present in the packaging, but none were found in the food. This condition could be due to such factors as insufficient time for migration to occur or a relatively impervious packaging component between the food and the paperboard. On the other hand, a few food samples contained PCB residues even though none was found in the packaging.

Table 2 shows the percentages of the food samples and of the packaging samples containing PCBs segregated by the type of paper packaging, i.e., recycled or virgin.

The incidence of PCB residues reported in food samples which were packaged in recycled packaging components was 15.8% of the total samples, while in food packaged in virgin materials this incidence was 3.4% of the total samples. Thus a total of about 19% of all foods sampled contained PCB residues. The incidence of PCBs was highest in the infant cereals category (75%), but only 16 samples in this category were examined. However, it may be significant that 14 of the 16 samples were packaged in recycle paper. The incidence of PCB residues was in the range of 20-40% in the categories of rice, oatmeal, and farina; dried fruit; and prepared mixes.

A review of the individual sample reports showed that when the food contained 0.5 ppm or more PCBs, in all but one case it had been in direct contact with packaging material containing PCBs. This survey indicates that a principal source of PCB residues in foods packaged in paper products is PCBs in the packaging material.

Before leaving the food and food packaging survey, I should like

TABLE 1. LEVELS OF PCB IN FOOD AND IN FOOD PACKAGING MATERIALS

Food Category	Total No. of Samples	No. of Samples	PCB in Food (ppm)	Recycled Packaging Material: PCB in Packaging (ppm) (range/aver.) Paperboard Package	Inner Wrap	Dividers	Other	No. of Samples	PCB in Food (ppm)	Virgin Packaging Material: PCB in Packaging (ppm) (range/aver.) Paperboard Package	Inner Wrap	Dividers	Other
#1 Crackers, Bread Crumbs, etc.	79	3	0.4	4.0-28.6/16.9	—	—	—	1	0.1	12.0	1.0	—	—
		2	0.3	5.2-89.2/47.2	—	—	—	6	0	T-12.0/4.1	0.04/0.1	0	0
		1	0.2	—	—	—	6.0	16	0	0	0	0	0
		4	0.1	1.0-14.0/7.5	0	—	0						
		3	T	4.2-12.5/10.4	0-0.7/0.3	—	0-7.6/3.8						
		36	0	0-64.0/19.9	0-7.3/1.9	—	0-51.0/14.6						
		7	0	0	0	—	0						
#2 Macaroni and Noodle Products	64	2	0.6	180-338/259	—	0	—	1	0.1	0.4	—	—	—
		1	0.2	17.6	—	—	—	7	0	T-10.0/2.2	—	0	0
		2	0.1	19.0	0-13.0/6.5	—	0-7.0/3.5	1	T	0	—	—	—
		3	T	3.9-13.2/7.4	—	—	—	21	0	0	0	0	—
		25	0	2.0-82.0/15.7	0-1.9/0.1	0-5.0/1.7	T-29.0/10.3						
		1	0	0	—	—	—						
#3 Pretzels, chips, etc.	58	1	5.0	0	15.0	75.0	—	2	0.1	0-0.3/0.1	0-0.7/0.3	—	3.0
		1	1.4	20.0	0	39.0	—	13	0	0-4.6/0.4	0-3.3/0.3	0-0.7/0.2	0-4.0/1.0
		1	0.4	12.8	35.0	24.2	—	10	0	0	0	—	—
		1	0.3	0	6.0	23.0	—						
		1	0.2	4.0	—	—	—						
		1	T	72.1	14.3	—	—						
		24	0	0-174/17.3	0-245/14.6	0-23.0/11.2	0-6.2/2.1						
		3	0	0	—	0	—						
#4 Breakfast Cereals, Ready-to-Eat	45	1	3.7	110	8.6	—	—	1	0.2	3.2	0	—	—
		1	1.8	35.0	—	—	—	7	0	T-1.5/0.6	0-1.3/0.3	—	—
		1	1.1	19.0	5.0	—	—	6	0	0	0	—	—
		1	0.6	3.0	—	—	4.0						
		3	0.2	3.2-32.0/20.0	—	—	—						
		1	T	9.4	0	—	—						
		19	0	0-23.0/3.7	1.0	—	—						
		4	0	0	0	—	—						
#5 Prepared Mixes, Dry	60	1	2.7	16.0	9.0	—	—	1	0.3	0	9.5	—	—
		1	1.1	15.0	—	—	—	1	T	T	T	—	—
		1	0.7	18.0	—	—	—	2	0	1.8-5.0/3.4	T	—	—
		2	0.5	14.3-28/21.1	2.1-4.4/3.2	—	—	19	0	0	0	—	0
		1	0.3	10.0	—	—	—						
		2	0.2	4.1-20.9/12.5	6.0	—	—						
		1	0.1	3.0	—	—	—						
		3	T	2.7-12.6/6.4	—	—	—						
		23	0	1.0-31/6.9	0-4.0/0.6	0	0-3.0/1.2						
		2	0	0	—	—	0						
#6 Dried Milk and Dried Milk Products	13	1	0	1.0	7.0	—	—	1	0.2	0	—	—	0.7
								2	0	T	—	—	0-3.0/1.5
								9	0	0	0	—	0
#7 Dessert and pudding mixes	35	2	0.2	4.0-12.2/8.1	—	—	—	1	2.5	119	111	—	—
		1	0.1	T	1.0	—	—	1	0.1	1.0	1.0	—	—
		16	0	0-34.0/8.5	0-9.9/2.6	0	1.0-7.0/3.7	6	0	0-5.0/1.5	0	0	—
		1	0	0	0	—	0	1	0.3	0	0	—	—
								6	0	0	—	0	—
#8 Infant Cereals, Dry	16	1	1.0	165	—	—	11.0	1	0	2.0	—	—	2.0
		1	0.8	6.2	—	—	3.8	1	0	0	—	—	0
		1	0.7	50.2	—	—	3.8						
		2	0.6	18.4-18.8/18.6	—	—	3.8						
		1	0.5	5.0	—	—	16.0						
		1	0.1	20.0	—	—	—						
		5	T	3.2-8.8/6.2	—	—	T-71.0/28.2						
		2	0	1.4-2.7/2.0	—	—	6.4						

#9 Cookies, Ready-to-Eat	59	1	0.9	35.0	15.0	1.1	84.0	2	0.1	1.0-4.0/2.5	3.0	—	—
		1	0.3	26.0	6.0	—	9.0	4	0	0-1.3/0.6	1.0	0.9-2.0/1.4	0.4
		2	0.1	2.0-16.3/9.1	0	—	35.9						
		19	0	0-27.7/8.3	0-3.2/0.9	0-2.0/0.6	0-20.0/3.2	25	0	0	0	0	0
		4	0	0	0	0	0	1	1.7*	0	—	0	0
#10 Refrigerated, unbaked Specialties	34	3	0.1	0-215/71.7	—	—	2.5-177/89.7	2	0	0-4.4/2.2	5.4	—	—
		9	0	1.6-70.0/6.5	0-4.0/1.8	—	0-26.0/7.0	14	0	0	0	—	0
		5	0	0	—	—	—	1	T*	0	0	—	—
#11 Rice, Oatmeal, Farina, etc.	42	1	2.3	57.0	—	—	20.0	1	0.1	0.1	0.1	—	—
		1	1.8	27.0	—	—	—	1	0	1.1	0	—	7.0
		1	1.2	36.0	—	—	5.0	11	0	0	0	—	0
		1	0.9	90.0	—	—	12.0						
		1	0.7	17.0	—	—	—						
		1	0.6	48.0	—	—	—						
		2	0.5	12.0-13.0/12.5	—	—	—						
		3	0.4	5.0-31.0/16.0	—	—	2.0						
		1	0.3	12.0	—	—	—						
		1	0.2	8.6	—	—	—						
		2	0.1	4.0-4.3/4.1	2.0	3.0	—						
		12	0	1.7-37/7.3	1-0-3.0/1.9	1.0	0-8.0/4.0						
		2	0	0	0	—	—						
#12 Chocolate and Cocoa Products	41	1	0.1	6.0	0	—	24.0	2	T	1.0-4.0/2.5	—	—	0
		3	T	8.0-17.0/7.3	0-3.0/1.0	—	—	2	0	1.0-3.0/2.0	0	—	—
		22	0	0-24.0/10.5	0-8.0/0.6	0-17.0/9.6	0-160.0/23.9						
								7	0	0	0	0	0
		2	0	0	0	—	0	1	T*	0	0	0	0
		1	T*	0	0	0	—						
#13 Grated Cheese and Cheese products, Dry	17	6	0	0-46.6/7.2	3.0-11.0/3.5	—	1.0	8	0	0.7.0/3.1	—	—	1.0-2.0/1.5
								3	0	0	0	—	0
#14 Dried Fruits	21	5	0.1	0.1-73/20.2	0-38/12.9	—	0-11/6.5	1	0.1	0	—	—	0.1
		8	0	5.0-30/12.5	0-6.0/1.6	—	1.0-11.0/4.6	2	0	0-1.0/0.5	0.6-1.7/1.1	—	—
		2	0	0	0	—	0	3	0	0	0	—	0
#15 Frozen Fruit Juice	17	1	T	T	—	—	—	9	0	0-75.0/0.3	—	—	—
		2	0	0	—	—	—	5	0	0	0	—	—

NOTES:

A dash (—) indicates that this component of the package was not present in the samples thus designated.

The four instances of PCB found in the food and none found in the package are listed separately and are marked with an asterisk (*)

"T", trace, designates a positive chromatographic showing of PCB but below the quantitation limit.
"Other" packaging material includes outer wrappers, outer cartons, etc.

to emphasize that we must view these data with a great deal of caution. This survey probably reflects samples at least one year old and the industry has furnished us with data on more recent samples, indicating that the corrective action they have taken is already effective: these PCB residue data appear to be significantly lower, both in food and in its paper packaging. We in FDA are hopeful that this apparent trend will continue as the industry moves to eliminate all the likely sources of PCB contamination to the degree possible, observing not only the letter of the proposed PCB regulation in the *Federal Register* of last March but the spirit of that document as well.

TABLE 2. INCIDENCE (%) OF PCBs IN FOOD AND PAPER PACKAGING MATERIALS FDA SURVEY, 1971

		Recycled Packaging		Virgin Packaging	
Food Category	No. of Samples	Food with PCB (%)	Pkg. with PCB (%)	Food with PCB (%)	Pkg. with PCB (%)
1. Crackers, Bread Crumbs, etc.	79	16.4	62.0	1.2	8.8
2. Macaroni and Noodle Products	64	12.5	51.5	3.1	12.5
3. Pretzels, chips, etc.	58	10.3	51.7	3.4	25.8
4. Breakfast cereals, Ready-to-Eat	45	17.7	60.0	2.2	17.7
5. Prepared mixes, Dry	60	20.0	58.3	3.3	6.6
6. Dried milk and dried milk products	13	0	7.6	7.6	23.0
7. Desserts and pudding mixes	35	8.5	54.2	8.5	22.8
8. Infant cereals, dry	16	75.0	87.5	0	6.2
9. Cookies, Ready-to-Eat	59	6.7	38.9	5.0	10.1
10. Refrigerated unbaked specialties	34	8.8	35.2	2.9	5.8
11. Rice, oatmeal, Farina	42	35.7	64.2	2.3	4.7
12. Chocolate and cocoa products	41	12.1	63.4	7.3	9.7
13. Grated cheese and cheese products, dry	17	0	35.2	0	47.0
14. Dried fruits	21	23.8	61.9	4.7	14.2
15. Frozen fruit juices	17	5.8	5.8	0	52.9
Totals	601	15.8	49.2	3.4	17.9

Table 3 shows the results obtained in a national milk survey for PCBs in early 1972 (completed on April 28, 1972). Milk destined for consumption as fluid milk was sampled separately from milk destined for manufacturing use. The sampling was on a random basis to reflect milk production in each of the states. This survey was prompted by a finding of several cases of PCBs in milk. These cases are further discussed below.

The overall percentage of milk containing PCBs was 5.2%, and most of the PCBs were identified as Aroclor 1254. However, the sample is much too small to conclude that there is a real difference

between milk for bottling and milk for manufacturing. It is noteworthy that only one of the total 520 samples showed a residue in excess of 2.5 ppm, the recently proposed temporary tolerance. We are following up in all cases where the level of PCBs is 1.5 ppm or higher in the fat in order to determine the source of PCB contamination.

TABLE 3. FDA MILK SURVEY OF 1972 FOR PCBs

Milk for bottling	
Total No. of samples	360
Samples containing PCB	21, 5.8%
Range of PCB levels (fat basis)	T - 2.8 p.p.m.
Samples containing 0 - 0.5 p.p.m.	10
Samples containing 0.6 - 1.0 p.p.m.	5
Samples containing 1.1 - 2.0	5
Samples containing more than 2.0	1
Milk for manufacturing	
Total No. of samples	160
Samples containing PCB	6, 3.8%
Range of PCB levels (fat basis)	T - 1.8 p.m.m.
Overall % of milk containing PCB	5.2%

Table 4 shows the results of a national survey of animal feed for PCBs, which was completed in early 1972. The incidence of contamination was 4.3%, but the highest level found was only 0.6 ppm. Thus, there appears to be no significant problem with animal feed generally, but we must be alert to industrial accidents.

TABLE 4. FDA SURVEY OF ANIMAL FEED FOR PCBs, 1972

Feed Category	No. of Samples	No. Containing PCB	% Containing PCB	Range of PCB p.p.m.
Beef	281	6	2.1%	T - 0.6
Dairy	161	8	5.0%	T - 0.5
Sheep	42	3	7.0%	T - 0.5
Chicken Layers	77	5	6.5%	T - 0.3
Chicken Broiler	416	16	4.3%	T - 0.5
Turkeys	36	2	5.3%	Trace
Pigs	210	9	4.3%	T - 0.4
Other	49	5	10.2%	T - 0.4
Total	1274	54	4.3%	

Table 5 shows the results of our total diet studies for PCBs for fiscal year (FY) 1970, FY 1971, and one half of FY 1972. These studies cover 74 market baskets representing a total of 888 composites. Sixty of these composites were found to contain PCB residues ranging from a trace to 0.36 ppm. Aproximately half of these 60 samples (27) represented meat, fish, and poultry composite. Most of the remaining positives were the grain and cereal composites

(22). These studies indicate that the dietary intake of PCBs is of a low order. Expressed as mg/kg body weight per day the PCB level during these years was definitely less than 0.0001. As a point of reference, it is noted that the current dietary intake of DDT is about 0.0007 mg/kg body weight per day.

TABLE 5. PCBs IN TOTAL DIET

	Composite	Frequency	Range (p.p.m.)
FY 1970			
30 market baskets	I Dairy Products	1	0.05
	II Meat, Fish and Poultry	3	0.09 - 0.13
	XI Sugars and Adjuncts	1	0.08
FY 1971			
29 market baskets	II Meat, Fish and Poultry	17	T - 0.15
	III Grain and Cereal Products	9	T - 0.36
	VIII Garden Fruits	1	T
	X Oils, Fats and Shortening	1	T
FY 1972			
15 market baskets thus far reported	I Dairy Products	1	T
	II Meat, Fish and Poultry	7	T
	III Grain and Cereal Products	13	T - .035
	IV Potatoes	1	T
	VI Legume Vegetables	1	T
	VII Root Vegetables	1	T
	X Oils, Fats and Shortening	1	.15
	XI Sugar and Adjuncts	2	T

Let's turn our attention now to the major incidents of food contamination with PCBs. As we shall see, most of these have been caused by accidents.

Milk

1. West Virginia Incident. In July 1969, FDA's Baltimore District found PCBs in milk samples collected in the routine food surveillance program. Baltimore District investigated possible routes of contamination, and by February 1970, the investigation pointed to spent transformer fluid used as a vehicle for herbicide sprayed along power rights-of-way in the Martinsburg, West Virignia area. Through this route, PCBs contaminated dairy cattle grazing areas. The dairy farms involved were taken off production by state officials, using an action level of 0.2 ppm (whole milk basis) recommended by FDA.

2. Ohio Incident. In April 1970, the State of Ohio notified FDA's Cincinnati District of unidentifiable residues in milk. FDA identified the residues as PCBs. The State of Ohio and FDA investigated the problem and determined that the dairy farms were using a PCB—containing sealant in silos that migrated to the silage. The State of Ohio banned milk from some producers and destroyed an undetermined amount of milk.

3. Florida-Georgia Incidents. The States of Florida and Georgia reported findings of PCBs in milk to FDA's Atlanta District in August 1970. A PCB-containing sealant in silos was also found to be the source of contamination in this incident. FDA found approximately 11 percent PCB in the silo coating.

Poultry

1. New York State Incident. Analyses indicated PCBs in poultry fat varying from a non-detectable level to 26.8 parts per million. FDA advised the State of New York and USDA on February 1, 1971, that FDA would not object to the distribution of poultry containing less than five parts per million. This level was applicable to the edible tissue on a whole tissue basis or to the separate fat removed during slaughter or processing and intended for use as a food or feed ingredient.

The source of the PCBs in this incident is believed by State officials to have been plastic bakery wrappers. Bakery goods were used as a feed ingredient for the poultry and the plastic wrappers which may have contained high PCB levels were ground with the bakery goods. However, PCBs are not authorized by the food additive regulations for any use in food packaging materials.

2. East Coast Terminal Incident (FDA Actions). The Monsanto Chemical Company informed FDA in July 1971 that large amounts of fish meal might have been contaminated with Aroclor 1242 leaking from a heating system during pasteurization of fish meal at East Coast Terminal, Wilmington, North Carolina. Aroclor 1242 was used as the heat exchange fluid. FDA inspection revealed PCB contamination of the processed fish meal on hand at the firm. An investigation indicated the leak began in April 1971 and continued through July.

The fish meal on the premises was embargoed and the firm initiated a voluntary recall of fish meal processed during the PCB leakage period. Individual fish meal samples examined contained from 14 to 30 parts per million PCBs.

FDA seized three lots of eggs and five shipments of fish feeds with high residues, as well as a shipment of the contaminated fish meal from East Coast Terminal that had not been recalled.

3. East Coast Terminal Incident (USDA Actions).
The Food and Drug Administration immediately informed USDA of the PCB-contaminated fish meal, which had been used in poultry feed. The five parts per million action level for poultry was reaffirmed. The Meat and Poultry Inspection Program, USDA, was also notified by Holly Farms, Wilkesboro, North Carolina (July 1971) that poor hatchability had alerted them to a problem in their poultry operation. The cause was PCBs in the poultry ration arising from the use of contaminated fish meal as a feed ingredient from one supplier in North Carolina.

4. Minnesota Incident.

USDA notified FDA in August 1971 that USDA and Swift and Company had found excessive PCB levels in turkeys.

Investigation indicated that the PCB residues found in the turkeys were caused by the feed, which apparently contained a PCB-contaminated fat ingredient. The suspect fat used by the feed mill was received from a processor in Minnesota. It was found that the fat being manufactured at the time of the investigation contained negligible levels of PCB. The source of the PCB levels found in the turkeys was never definitely established.

5. Oklahoma Incident.

On August 20, 1971, USDA informed FDA of excessive PCB findings in chickens in Mississippi during routine sampling. Investigation revealed that the birds came from a grower in Oklahoma and the feed from a mill also in Oklahoma. FDA analyses of eggs and feeds from these firms showed no PCBs.

6. California Incident. During the past year, USDA examined turkeys after slaughter in warehouse storage in California. PCBs were found in the amount of 1.41 to 28.0 parts per million in the fat tissue. A total of 100,000 pounds of turkeys were detained until testing was completed. The turkeys had originated from flocks raised in four counties in California. The source of the PCBs could not be determined.

Toxicology of PCBs. The following is a brief summary of the toxicology data derived from animal experiments and from human exposure.

Toxicity of polychlorinated biphenyls has been extensively studied in white leghorn chicken, the rat, and the dog, and to a lesser degree in certain other animals. The chicken studies indicate that PCBs result in reduced growth, some reduction of food intake, a decrease in egg production, and a decrease in hatchability of the eggs; the no-effect levels appear to be about 2 ppm for Aroclor 1260.

Chick embryo studies indicate that lethal effects decrease with increases in the chlorine content of PCBs, and that a variety of birth defects can result from PCBs tested in this sensitive system. However, chick embryo studies are not directly relevant to man.

Studies in rats and dogs extending for two years indicate that at 100 ppm in the diet the effects are essentially the same in both species: moderate growth depression and liver enlargement and no indication of carcinogenesis. In the rat there were also lesions of the liver and an effect on two enzyme systems: the hepatic enzymes and serum alkaline phosphates. In a multigeneration reproduction study in rats the primary effect was reduced survival of pups at the 100 ppm level. The basic picture with reference to toxicity was the same for all of the Aroclors studied, although the most highly

chlorinated 1260 appeared to be slightly less toxic than the 1254 or 1242. In summary for the chronic rat and dog studies, as well as the reproduction study in the rat, the no-effect level appeared to be about 10 ppm. Other studies in the rat also indicate that the PCBs are not teratogenic or mutagenic.

Pathologically, monkeys given 1.4 to 16 mg/day PCBs in their diet showed liver cell enlargement, fatty degeneration, and an increase in the smooth endoplasmic reticulum of the liver cells indicating fibrotic changes. Alteration of liver metabolism, changes in hexabarbital sleeping time and other enzymatic related detoxification steps were noted, largely related to induction of hepatic hydroxylating enzymes.

Human intoxication (termed Yusho disease) with Kanachlor 400, a PCB manufactured in Japan with 48% chlorine, but of unknown chemical purity, was noted when a heat exchanger leaked into rice oil which was consumed by Japanese families in 1968. About 1,000 people were eventually affected. Exposure levels to the oil ranged upwards to more than 1400 ml. The oil itself contained PCBs in the range of about 2000-2500 ppm as shown by chemical analysis. When the consumption of the oil was below 180 ml, the Yusho attack rate was zero; but above 180 ml., the incidence and degree of effect increased with the quantity consumed, reaching 100% incidence at about 1400 ml.

The clinical problems associated with the Japanese incident included chloracne, swelling of the eyelids, anorexia, numbness, joint pain, nausea, headache, and muscle weakness. Birth abnormalities were noted in that a few babies were born with decreased birth weights and skin discoloration (cola-colored babies) which later regressed. At present these infants, now three years old, appear normal in every respect. The adults still suffer some of the effects of Yusho. The Japanese at Kyushu University Medical College plan to follow up on the Yusho victims on a yearly basis as long as they can be identified and funds are available. Thus, additional information may be forthcoming.

In a human monitoring survey conducted by the Division of Pesticide Community Studies of EPA, the fatty tissue of 688 people in the states of Michigan, Florida, and Colorado were analyzed. Almost two-thirds showed detectable PCBs ranging from a trace up to more than two ppm. About one-third of the samples showed a trace to 1.0 ppm., and only about 5% of the samples exceeded two ppm. These PCBs were largely Aroclor 1254 but Aroclor 1260 was also well represented.

To summarize what is presently known, the no-effect level in test mammals is approximately 10 ppm in the total diet. Based on this animal data with allowance for a 1,500 g. human dietary food intake, the ADI would permit a 100-fold margin of safety if set at 150 micrograms PCBs per day (0.1 ppm in the total diet). From the observations available to us concerning the Japanese incident, the maximum cumulative exposure that did not result in Yusho was 500 mg PCBs. Thus, both animal and human data emphasize the need to eliminate to the extent possible all residues of PCBs in our food supply.

FDA Plans with Respect to PCB. In light of all the available data including animal feeding studies, the human data from the Japanese Yusho incident, and a history of use in the industry for about 40 years without any deleterious effects in man being reported, the FDA has concluded that there is no immediate hazard to the public health from the low level of environmental contamination leading to residues in food, but that it is prudent to reduce the long term exposure of man. Thus, the *Federal Register* of March 18, 1972 contains a proposal to deal with PCBs.

Table 6 summarizes the major points in the proposal of FDA with respect to PCBs. Comments on the proposal were invited; deadline was July 16, 1972.

TABLE 6. PROPOSED PCB ORDER, MARCH 18, 1972

1. Preamble summarizes the PCB situation
2. PCBs not considered to be an immediate hazard to public health
3. PCB levels in food and animal feed must be reduced to minimize the long term exposure
4. PCBs would be prohibited in food, food-packaging and feed manufacturing plants
5. Would prohibit recycling of paper containing PCBs for food-packaging use
6. Proposed temporary tolerances for unavoidable residues of PCBs

	Parts Per Million
1. Milk (fat basis)	2.5
2. Dairy products (fat basis)	2.5
3. Poultry (fat basis)	5.0
4. Eggs	0.5
5. Finished animal feed	0.5
6. Animal feed components (including fishmeal)	
7. Fish (edible portion)	5.0
8. Infant and junior foods	0.1
9. Food-packaging material	5.0

In conclusion, the *Federal Register* proposal of March 18, 1972 presents a brief, authoritative statement on the status of PCBs with respect to food. For a rather comprehensive discussion of PCBs, I recommend the federal publication entitled *Polychlorinated Biphenyls and the Environment* by the Interdepartmental Task Force on PCBs, Washington, D. C., May 1972. It is available from the National Technical Information Service, U.S. Department of Commerce, Springfield, Virginia 22151 for $6.00 per copy. This report of

approximately 190 pages is the product of a six-month review of PCBs by five federal agencies and undoubtedly provides a better coverage of the subject than any other single publication.

ACKNOWLEDGMENTS

The analyses reported here were made by the chemists in the 17 field district offices of the FDA. The analytical data with respect to food were compiled and evaluated by the Division of Regulatory Guidance and the Division of Product Technology in the Bureau of Foods; and the data with respect to animal feed, by the Bureau of Veterinary Drugs. The assistance of all involved in the rather extensive studies described above is gratefully acknowledged.

Sandwich Shops	Mobile Food Vending Vehicles
Sandwich Preparation Places	Food Vending Machine Commissaries
Clubs	Retail Bakeries
Organizations	Delicatessens, except in grocery stores
Hamburger Stands	Food Vending Machines
Hot Dog Stands	Interstate and Intrastate Carrier Food Services
Lunch Bars	Dairy Bars
Lunch Counters	Ice Cream Stands
Lunch Rooms	Frozen Custard Stands
Luncheonettes	Taverns
Short Order Restaurants	Grills
Tea Rooms	Cocktail Bars
School Food Service Areas	Night Clubs
College Food Services	Hotel and Temporary Residences
Church Food Services	Migrant Camp Kitchens
Oyster and Clam Bars	Ice Manufacturing Places
Fish Fry Places	Industrial Food Service Facilities
Refreshment Stands	Institutional Food Services
Soda Fountains	Hospital and Nursing Food Services
Carnivals, Circuses, Exhibitions and Festivals	Baby Formula Preparation
Carry-out Restaurants	Fairs
Fast Food Places	Caterers

There is existing, licensing and inspection by Agriculture and Markets in respect to dairy products in some of the above establishments which are subject to future consideration. Also, new legislation affects frozen desserts operation at service food establishments. This legislation is to be considered along with milk and milk products in future separate meetings.

It is also agreed that the Department of Agriculture and Markets has responsibility over wholesale operations and food manufacturing. These include:

Candy Plants	Nut Roasting and Packaging
Frozen Food Plants	Spice and Condiment Plants
Food Warehouses (packaged)	Potato and Vegetable Processing and Packaging
Fruit and Vegetable Brokers	Food Stores
Frozen Food Warehouses	Packaged Meat Processors
Canning Factories	Baby Food Manufacturing

VOLUME 37 NO. 1

ASSOCIATION OF FOOD & DRUG OFFICIALS OF THE UNITED STATES

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77TH ANNUAL CONFERENCE
17-21 JUNE 1973
RAPID CITY, SOUTH DAKOTA

Edited and Published By:
THE EDITORIAL COMMITTEE

EDITORIAL OFFICE: Orlen J. Wiemann, P. O. Box 20306, Denver, Colorado 80220

BUSINESS OFFICE: Evan Wright, Secretary-Treasurer, P. O. Box 1494, Topeka, Kansas 66603

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