CURRENT TOXICOLOGY STATUS OF PCBs

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September 29, 1971

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As a general principle it can be said that almost any substance or chemical can induce some toxic response in man if the exposure level is high enough for a short period of time. Substances that are highly toxic may cause no demonstrable harm if the exposure dose is at a low level.

If one were to classify the acute toxicity of PCBs, in terms of whether or not it is of high, moderate, or minimal toxicity, all available evidence indicates that PCBs are classifiable as being of moderate toxicity. By comparison DDT has a higher acute toxicity than does PCB and it happens that from the viewpoint of worker safety DDT is one of the safest pesticides to use.

Rats experience growth depression and increase in liver size when dosed with 1,000 ppm (parts per million) PCBs in the diet. Pathologically, monkeys given high doses of PCBs in their diet for over a month showed liver cell enlargement and fatty degeneration. Alterations of liver metabolism and other enzymatic related detoxification steps were noted, largely related to induction of hepatic hydroxylating enzymes.

At levels around 100 ppm in the diet, adverse reproductive effects with decreased litter size and survival have been noted in rats with increases noted in liver and thyroid weights.

Human intoxication with Kanachlor 400, a PCB manufactured in Japan with 48% chlorine, but unknown chemical characteristics as to the purity, was noted when a heat exchanger leaked into rice oil which was consumed by Japanese families in 1968. About 600

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people were eventually affected. Exposure levels to the oil were calculated to approximate 15,000 milligrams/day. The oil itself was apparently contaminated at levels of 2,000-3,000 ppm PCBs, (average of about 2,000 ppm) as derived from the known organic chlorine content of rice oil related to the known organic chlorine content of Kanachlor 400. Earlier English summaries of the Japanese reports stating that the level of PCBs was at 200 ppm are erroneous.

From these observations available to us concerning Yusho, while the lowest reported figures estimate a minimal positive effect level at 3 milligrams PCBs per day over several months, the average doses associated with significant disease in these Japanese were much higher and were in the range of 30 milligrams/day.

The clinical problems associated with Japanese Yusho incident included chloracne, impaired vision, systemic gastro intestinal sysmptoms with jaundice, edema, and abdominal pain. A few babies were born with decreased birth weights and skin discoloration which later regressed. Transplacental transmission of PCBs were noted by the presence of residues in fetal tissue.

Animal and human data both point to 150 to 300 MICROgrams/day as being in the range of safety as far as a temporary dietary intake over the relatively short period of time that we as a society will be forced to tolerate the presence of these chemicals in our food supply.

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Since 2,000 milligrams was reported to be the total dose causing an effect in the Japanese, then 200 milligram total dosage PCBs can probably be tolerated over a protracted period of time without significant adverse effect.

It would take 22 months of daily ingestion of 300 MICROgrams of PCBs to arrive at a total ingestion of 200 milligrams. On a shorter term basis, the highest amount of PCBs temporarily permitted by the FDA in any food under our jurisdiction is 5 ppm (other FDA action levels for PCBs in certain foods are lower). This theoretically would permit an adult to eat about 1/2 pound of food contaminated with PCBs at 5 ppm each and every day for a period of six months, but human exposures to food contaminated to this extent are infrequent and sporadic. To our knowledge we are not aware of any foods contaminated at significant levels on a regular and consistent basis. If such a food were identified, a much lower action level would be taken to prevent unwarranted long term exposures.

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Foods Analyzed by FDA for PCB

November 1969 - Thru June 1971

Since November 1969, the FDA has analyzed all raw agricultural commodities sampled in the pesticide program for PCB's. More than 15,000 samples have been collected and analyzed for PCB's in this program. As of June 1971, a total of 479 samples of raw agricultural commodities have been reported to contain PCB's; 200 of these samples were follow-up samples of suspected lots because of previous analyses. See tables 1 and 2. PCB's were encountered most frequently in fish in approximately 300 of the 479 samples;

The FDA total diet studies for 60 market baskets representing a total of 720 composite samples during FY-70 and FY-71 show 22 composite samples to contain PCB residues ranging from a trace to 0.36 p.p.m. Seventeen of these samples represented the meat, fish, and poultry composite. Other positive findings were in the dairy and the grain and ceral composites. Table 4 (last three items) shows the amount of PCB's in individual items of the total diet and indicates the source in three cases to be the packaging material.

We have also analyzed a number of other paperboard packaging materials and the food packaged in such materials. See tables 3 and 4.

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POSITIVE ANALYSES OF RANDOM FOOD SAMPLES
November 1969 through June 1971
(15,000 Samples Analyzed --all prior to
East Coast Terminal Fish Meal Incident)
Number Positive Samples (Range-ppm) Average ppm

Table 1

Examining District	Fish	Fish By Product	Cheese[a]	Milk[a]	Shell Eggs	Potato By Product	Oysters	Misc.	Total Positive All Products
Los Angeles	23(0.1-2.60).62	5(0.2-5.0)2.10		6(0.15-0.30).19	1(0.03).03				35
Minneapolis	2(.12-35.29)17.70								2
New Orleans	23(T-1.70)0.4[d]							Milled Rice 1(0.20)	24
New York	3(0.21-4.78)2.49								3
San Francisco					1(0.50).50				1
Seattle	1(0.40).40					8(0.10-4.20)1.16		Straw 1(0.30) Wheat 1(0.32)	11
Kansas City	19(0.60-13.30)3.41								19
Atlanta	1(0.53).53[e]		1(T)	2(0.94-0.97).96				Silage 1(0.82) Silo Coating 1(11.3)	6
Baltimore				22(T-12.58)2.69	5(T-T).00		12(T-T).00	Crabmeat 1(0.24)	40
Boston	1(6.08)6.08								1
Buffalo	19(T-13.00)3.26[d]	1(T).00							20
Chicago				1(0.23)0.23					1
Cincinnati	55(0.04-4.70)1.77			4(0.22-0.24).24					59
Denver						2(0.15-1.12).64			2
Detroit	49(0.25-15.5)2.96			4(0.49-1.86)1.27				Cat Food 1(6.49) Duck 1(0.70)	55
Dallas									0
Total Positive	196	6	1	39	7	10	12	8	279

ppm fat basis [d]T-Trade; not incl. in ave. [e]marine species

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Table 2

POSITIVE FOLLOW-UP INVESTIGATIONAL SAMPLES
collected because of suspected PCB Residues
November 1969 through June 1971
Number Positive Samples (Range-ppm) Average.ppm

Examining District	Fish	Fish By Product	Cheese[a]	Milk[a]	Shell Eggs	Potato By Product	Oysters	Misc.	Total Positive All Products
os Angeles	31(0.1-6.0)1.54		43 (.03-1.0).30[c]						74
inneapolis	58(T-9.37)1.97[d]								58
ew Orleans	4(0.26-2.0)1.03							Boiled Oyster 1(0.23)	5
ew York								Frog Legs 1(0.09)	1
an Francisco									0
eattle	1(1.98)1.98					2(1.39-1.73)1.56			3
ansas City	1(8.39)8.39								1
tlanta	2(0.43-1.23).83[e]			2(6.60-22.80)14.7					4
altimore	5(T-T).00			13(0.57-9.96)4.03	10(T-.01).01			Apple Pomace 1(T)	29
oston									0
uffalo	3(1.51-2.29)1.95								3
hicago				6(0.14-0.24).19					6
incinnati	3(1.00-1.50)1.27								3
enver	3(0.32-0.77).54[e]								3
etroit	10(0.73-4.70)2.47								10
allas									0
otal ositive	121	0	43	21	10	2	0	3	200

ppm fat basis [c]import [d]trace;not incl. in ave. [e]marine species

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FDA CINCINNATI DISTRICT OFFICE PACKAGING INVESTIGATION

AUGUST 1971

TABLE 3

PCB's in PAPERBOARD

Sample No.	Grade or Use Term	Description	Product Use	PCB 1242 in ppm
INV 010-604E	Gardner Board	Four layer all bleached paperboard from re-cycled paper	Hamburger box	73
	Sulfate Board	Single stock board made from virgin sulfate pulp	Baked food Pizza	1.7 4.7
	Food Packaging	Paperboard with a bleached liner from selected grades of waste selected on basis of no odor or taste	Box for crackers Corn Bread box Gelatin box Rice box Pecan Bars box	433 40 29 44 29
	Chip Board	Paper with one-half to one-third mixed paper in filler. Mixed paper is identified as clean, dry waste paper. May contain over 10% box cuttings and news or news stock such as magazines and catalogues	Shredded Wheat dividers	46

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TABLE 4

PCB's in FOOD PACKAGES and FOOD PRODUCTS

Sample No.	Sample	Arochlor 1242 in ppm Food product	Box or carton	Other
	Carton dividers			5.3 (divider)
	Cartons for Shredded Wheat		18	
062-065E	"		12	
027-695E	Shredded Wheat in cardboard cartons	0.5	14	11 (divider)
013-123E	"	0.5 0.1 ck	18 8 ck	6.4 (divider) 6.2 ck
INV 008-756E	"	0.3 0.3 1.0 1.9 0.9	15-30	
INV 062-260E	"	None 1.5	17	(Re-analyzed after holding 6 weeks)
INV 008-756E	Bread crumbs in cylinder type cartons	None	20	

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TABLE 4

Sample No.	Sample	Arochlor 1242 in ppm Food product	Box or carton	Other
INV 008-757 E	Cookies in cellophane package with cardboard dividers	none	none	none
INV 096-802E	Cookies in cardboard box with cellophane inner wrapper	none	33	none (inner wrapper)
INV 061-880E	Crackers packaged and un-packaged in cardboard cartons	none	8.3 empty 10 packed	none
010-909E	Crackers in 2 lb. boxes	none	132	185 (inner plastic bag) 6.1 (waxed paper)
010-910E	Crackers in 1 lb. boxes	none	99	45 (inner plastic bag) 5.1 (waxed paper)
008-759E	Spaghetti in cardboard package	none	16	
008-760E	"	none	14	—
INV 016-206E	Cartons for Spaghetti dinner		17 12 ck	
INV 016-208E	Cartons for Spaghetti dinner		13 13 ck	
INV 016-207E	Cartons for Noodle and Cheese Dinner		21 15 ck	— — —
010-928E	Confectioner's Powdered Sugar	none	17	none (inner wrapper)

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TABLE 4

Sample No.	Sample	Arochlor 1242 in ppm Food product	Box or carton	Other
INV 016-209E	Cartons for Noodle with Chicken Dinner		5.8 3.6 ck	
002-805E	Spaghetti Dinner	None	14	
002-808E	"	3.0 1.6 ck 2.1 ck	1144	
002-806E	Noodles Dinner	0.4	6.3	
002-807E	"	0.3	17	
002-804E	Macaroni Dinner	none	8.1	
055-234E	Hot Roll Mix	none	27	none (inner wrapper)
055-235E	"	none	19	none (inner wrapper)
063-745E	"	none	104	none (inner wrapper)
093-586E	"	none	88	none (inner wrapper)
000-685E	"	none	32	none (inner wrapper)
INV 000-437E	Cartons for White Hominy Grits		16 20 ck	
INV 000-438E	"		22 17 ck	
INV 000-439E	"		39 29 ck	
INV 000-440E	"		26 27 ck	

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TABLE 4

Sample No.	Sample	Arochlor 1242 in ppm Food product	Box or carton	Other
016-752E	Quick Grits	0.6 0.4 ck	21	
INV 039-981E	Pudding and Pie Filling	none	none	none (inner wrapper)
010-926E	Dark Brown Cane Sugar	none	23	none (inner wrapper)
010-927E	Light Brown Cane Sugar	none	18	35 (inner wrapper)
INV 077-951E	Cereal Six Pack-601 oz. cardboard boxes of various cereals	1.1 (composite)	47	(Note: Check analyses run on the individua cereals)
	Mixed (2)	1.0, 1.1	30	29 (box $\bar{c}$ removed printing)
	Oatmeal (2)	1.6, 1.6	32	28 (box $\bar{c}$ removed printing)
	High Protein (1)	1.9	45	
	Rice (1)	0.8	29	
Boston Total Diet Basket April/May '71	Shredded Wheat	24	70	497 (divider)
Minneapolis Total Diet Basket April/May '71	Corn Meal	0.8		
	Pancake Mix	trace *		
	Wheat Cereal	trace*		
Kansas City Total Diet Basket June/Jyly '71	Corn Meal	0.2 *	12	
	Pancake Mix	0.1 *	6.7	
	Rice grain	trace *		
	Puffed Rice	trace *		
	Hot wheat cereal	trace *		
	Wheaties	trace *		
	Corn Flakes	trace *		
	Wheat Bread	trace *		

* Calc. as 1242; may be a mixture

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Sample No.	Sample	Mfgr.	Arochlor 1242 in ppm Food Product	Box or Carton	Other
Baltimore Total Diet Basket June/July 1971	Oats		2.4(2.5	111(122)	
	Grits		0.5(0.4)	23(22)	
	Cake Mix		0.5(0.3)	4.2(3.6)	
	Pancake Mix		0.3(0.1		
	Corn Flakes		None		
	Shredded Wheat		None		
	Puffed Rice		None		
	Whole Wheat Bread		None		
INV 021-321E	High Protein Baby Cereal		Trace	19	
INV 077-950E	High Protein Baby Cereal		Trace	3.4	

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FOOD AND DRUG ADMINISTRATION

September 29, 1971

1966	Soren Jensen reported PCB in Swedish fish and wildlife.
1967	G. Widmarck published "IUPAC Commission of Methods of Pesticides Analysis: Possible Interference by Chlorinated Biphenyls."
	This article began FDA methods development program to separate polychlorinated biphenyls from chlorinated pesticides encountered in regulatory analysis.
Feb. 24, 1969	Dr. Robert W. Risebrough widely quoted from San Francisco Chronicle Story warning of PCB in eco-system.
March 7, 1969	Associate Commissioner for Science and Deputy Associate Commissioner for Compliance asked Bureau of Science to evaluate foods sampled for pesticides for evidence of PCB. None was indicated except in some fish from the great lakes.
March 10-14, 1969	District pesticide experts were given all of the analytical information concerning PCB and told to be aware of the possibility of its presence in foods. (Pesticide Analytical Workshop 3-10/14-69.
June & July 1969	PCB was identified as a contaminant of many fish analyzed as part of Injunctive proceedings against the City Smoke Fish Co. of Detroit, Michigan. These fish also contained DDT above 5 parts/million.
	The firm was enjoined by U. S. District Court.
July 1, 1969	Eleven page Bulletin was issued to all field districts regarding PCB in fish and outlining instruction how to separate PCB from chlorinated pesticides. Information on any results of apparent PCB findings or unidentified organohalogen residues was to be reported.
Sept. 13, 1969	Baltimore District Office reported PCB in West Virginia Milk. This series of samples was traced to use of Aroclor Oil as solvent for pesticide spray. Grade A milk shippers involved were taken off production by the State.

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Dec. 16, 1969	Regulatory Action at 0.2 ppm (whole milk basis) was established.
Jan. 6, 1970	PCB analysis included in Total Diet Study.
Feb. 3, 1970	Regulatory Action at 5 ppm in edible flesh of fish established.
Mar. 24, 1970	State of Ohio advised FDA they had a problem in milk resulting from Arochlor containing silo sealant. State was told FDA would initiate Federal seizure at 0.2 ppm (whole milk). State handled the problem and dumped an unknown quantity of milk.
Aug. 7, 1970	Fish near effluent Annison Plant Monsanto found to contain PCB. Results were reported to State (these were recreational fish).
Nov. 10, 1970	Formal program for PCB in raw agricultural commodites issued. To date 15,000 samples analyzed with 279 "random" PCB results reported.
Jan. 29, 1970	New York State Poultry. Feed ration contained ground bread cartons and wrappers. PCB in feed may have orginated from this source but is not confirmed at this time. Investigation continuing.
	Action level 5 ppm PCB in poultry established.
July 16, 1971	Leakage of heat exchange of fluid caused contamination of pasteurized fish meal which in turn was fed as a ration to chickens and catfish.
Aug. 1971	Action level 0.5 ppm established for eggs. 5 ppm reaffirmed for poultry.
Aug. 9, 1971	PCB reported in turkeys in Minnesota. FDA investigation could not determine that feed or its constituents was cause. Investigation continuing.
Aug. 11, 1971	Seizure recommendation 75,000 eggs Norfolk, Va. (follow-up Wilmington Terminal). Grain and cereal composite of total diet study found to contain PCB at 0.4 parts/million level. Packaging for shredded wheat component was source of the contamination. Packaging Survey initiated by home district CIN-DO. Highest level 433 ppm found in greyboard.

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Aug. 12, 1971 — Cargill Inc., Pensacola, Fla. Heat exchange leak of Therminal 55. Not PCB related. 1.6 ppm PCB may be enviornmentally in fish meal. Investigation continuing.

Aug. 23, 1971 — National Bi-Products, Mason City, Ill. Meat scrap meal may have been contaminated at 1 ppm level. Material was recalled.

Sep. 1, 1971 — Meeting of Interagency Group with Commissioner to become familiar with and organize to solve many of environmental problems associated with Aroclors.

Sep. 3, 1971 — Conference with American Paper Institute to find out what information they could give about recycling. It was reported NCR had discontinued PCB in copy paper as of June 1, 1971.

Sep. 8, 1971 — Meeting with Monsanto Chemical Company. - Company told FDA PCB would be limited to essential closed system uses with no use in food or feed plants.

Sep. 14, 1971 — Meeting with Food Manufacturers to inform them of PCB risks in greyboard packaging.

Sep. 14, 1971 — Compliance Program issued to Regional and Field Offices to survey 15 food commodity categories for PCB.

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