CURRENT TOXICOLOGY STATUS OF PCBs

Albert C. Kolbye, Jr., M.D., M.P.H., J.D.
Deputy Director, Bureau of Foods
Food and Drug Administration

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MONS 043230

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 Kanechlor 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

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 Kanechlor 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 symptoms 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.

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.

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 then 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 cereal 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.

MONS 043234

You will note in examining these tables of PCB data that no PCB's have been found in fresh fruits or vegetables. This is indeed significent because thousands of samples have been analyzed. However, PCB's have been found in a feed by-product from potato processing plants (source of the PCB's could not be identified).

During the past year, there has been a series of accidents related to fishmeal and other animal feeds, which have resulted in the contamination of food. As of August 30, 1971, 166 samples of eggs had been analyzed as a part of the follow-up investigation of the Wilmington East Coast Terminal fish meal accident. Fifty-five of these contained PCB's in excess of the action level of 0.5 p.p.m. Seizures aggregating about 75,000 eggs have been made. The FDA also seized one shipment of the fish meal and five shipments of a catfish and trout chow manufactured from the contaminated meal. It was then agreed the responsible firms would recall the fishmeal and the fish feed.

The U.S.D.A. has examined the poultry involved in that incident and our two agencies have coordinated their efforts to protect the consumer.

POSITIVE ANALYSES OF RANDOM FOOD SAMPLES
November 1969 through June 1971
(13,000 Samples Analyzed --all prior to
Ernt Count Termin:l 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)2.69								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(6.00)6.00								1
Buffalo	19(T-13.00)3.26[d]	1(T).00							20
Chicago				1(0.23)0.23					1
Cincinnati	35(0.04-4.70)1.77			4(0.22-0.24).24					39
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

[a]ppm fat basis [b]T=Trace; not incl. in ave. [c]marine species

MDNS 043236

Table 2

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

Receiving District	Fish	Fish By Product	Cheese[a]	Milk[a]	Shell Eggs	Potato By Product	Oysters	Misc.	Total Positive All Products
Los Angeles	31(0.1-6.0)1.34		43 (.03-1.0).30[c]						74
Minneapolis	58(T-9.37)1.97[d]								58
New Orleans	4(0.36-2.0)1.03								5
New York								Boiled Oyster 1(0.23)	1
San Francisco								Frog Legs 1(0.09)	0
Seattle	1(1.98)1.98					2(1.39-1.73)1.56			3
Kansas City	1(8.39)8.39								1
Atlanta	2(0.43-1.23).83[c]			2(6.60-22.80)14.7					6
Cincinnati	5(T-T).00			13(0.57-9.96)4.03	10(T-.01).01			Apple Pomace 1(T)	29
Boston									0
Buffalo	3(1.51-2.29)1.95								3
Chicago				6(0.14-0.24).19					6
Cincinnati	3(1.80-1.50)1.27								3
Denver	3(0.32-0.77).54[c]								3
Detroit	10(0.73-4.70)2.67								10
Dallas									0
Total Positive	121	0	43	21	10	2	0	3	200

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

MONS 043237

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 recycled 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

MONS 043238

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	

MONS 043239

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 unpackaged 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)

MONS 043240

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	

MDNS 043241

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 c removed printing)
	Oatmeal (2)	1.6, 1.6	32	28 (box 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

MONS 043242

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	

MDNS 043243