COMPLIANCE PROGRAM EVALUATION

FY 1974 POLYCHLORINATED BIPHENYLS IN PAPER FOOD PACKAGING

MATERIAL SURVEY

(Assignment)

Bureau of Foods

Date: January 24, 1975

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A. Objective:

1. To remove from market domestically produced foods packaged in paper material containing more than 10 ppm PCB (polychlorinated biphenyls).

2. To measure the effectiveness of industrial efforts toward reduction of PCB in paperboard.

B. Background:

In mid-1971, one of FDA's regular analyses of total diet samples showed an unexpected finding of PCB in the grain and cereal products composite. Follow-up investigations disclosed a broad problem of contamination in recycled paper (grayboard) which resulted in migration to food.

Carbonless copy paper containing PCB's was determined to be the major contaminator of recycled paper. This occured even though carbonless copy paper was being produced without PCB's by mid-1971. However, it became clear that unknown amounts of such "PCB copy paper" on the Nation's shelves, as well as the extreme stability of these compounds in the recycling process were causes for immediate concern for the safety of a large amount of the food supply packaged in paper.

In the fall of 1971, FDA launched a national survey. In all, 621 samples were examined for PCBs. The foods and all packaging components (inner, outer, dividers, etc) were examined and paper identified as recycled or virgin to the extent possible. Results showed recycled paper (grayboard) to be the only significant and identifiable source of PCB contamination of the packaged foods examined. Some apparent roduction in migration to food was observed where inner wrappers(barriers) separated the food from the grayboard.

In March, 1972, FDA initially proposed regulations intended to reduce and eventually eliminate paper packaging materials as a source of PCB residues in food. The proposed rules also included a temporary tolerance for PCB in infant and junior foods. {Dept. Health, Education and Welfare, Food and Drug Administration, Polychlorinated Biphenyls, Notice of Proposed Rule Making; Federal Register, Vol. 37 (No. 54), pp. 5705-5707 (March 18, 1972)}. Since then, FDA has issued formal tolerances for a variety of foods, as well as a tolerance of 10 ppm in paper food packaging material.

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The Boxboard Research and Development Association (BRDA) entered into a Cooperative Quality Assurance (CQA) agreement with FDA on February 5, 1974. While the C.Q.A. is too lengthy to describe fully in this evaluation, it essentially involves self-monitoring by the firms affiliated with this trade association, withholding violative products from market, and regularly reporting findings to FDA.

This survey was designed and conducted to remove any encountered violative products from the market and to examine the current state of the art in paperboard production relative to PCB content.

Following are excerpts from the assignment which issued to all FDA Field Offices May 14, 1974. In brief, all 22 FDA Field Units were told to collect 5 samples of recently manufactured domestic foods packaged in direct contact with grayboard, examine the packaging material, and initiate seizure action on samples containing more than 10 ppm in the packaging material.

"The samples will be official and will consist of foods packaged in grayboard (only) one step removed from the food manufacturer, i.e., brokers and/or wholesalers that receive interstate shipments direct from the manufacturer will be used as sample sources. Grayboard is the gray-colored, lightweight cardboard used extensively to package dry foods.

Samples may be collected from the following categories of foods which are packaged in grayboard.

Crackers, Bread Crumbs, etc.
Pretzels, Chips, etc.
Macaroni and Noodle Products
Breakfast Cereals, Ready to Eat
Prepared Mixes, Dry
Infant Cereals, Dry
Rice, Oatmeal, Farina

Restrict sampling to packages that have the food product directly in contact with the grayboard. Do Not Sample foods that have any type of barrier that prevents the food product from contacting the grayboard.

Sample only seizable size lots that were shipped by the manufacturer on or after October 1, 1973. Do Not Sample Older Stock.

For those food products packaged in such a way that the grayboard container is in direct contact with the food, a random sample of twenty-four containers representative of the lot in question will be required for this assay. Collect these 24 containers in duplicate to provide for a reserve portion.

The paperboard packaging material from each of the twenty-four containers shall be removed, processed, and composited so as to obtain a homogeneous mixture for analysis. If paper packaging material is used as a divider inside the container, such material shall be removed, processed, and composited separately for analysis.

Use the method appearing in the JAOAC 56, pp. 957-961 (1973), extraction and cleanup for determination of polychlorinated biphenyls in paper and paperboard, S.J.V. Young , C. Finsterwalder and J.A. Burke.

When both initial analysis and check analysis using the above method result in a determination in excess of 10 ppm, a confirmatory assay is necessary. The residue must be confirmed using techniques such as halogen specific GLC detectors or derivatization at the analyzing district's discretion."

C. *Program Data: Summary and Quality*

One District collected some samples which were actually packaged in virgin paper and the samples were therefore not examined. Some other Districts collected more samples than requested. The overall survey thus involved 115 samples instead of the anticipated 105. *These variances did not adversely affect this survey.*

Table 1 shows findings in the 115 samples examined, by food sample type and by collecting FDA field unit (note that even though foods are named only the packaging material was examined). No attempt is made to show differences between collection points or between food product packages because of the limited number of samples.

Table 2 is a comparison between results in this survey and the recycled food packaging samples in the previous FY 72 survey. Only relevant packaging types from the FY 72 survey are presented in this table since many of the other sample types in that survey were found to be irrelevant to the grayboard question. It can be seen that the majority of samples still contain PCB but the levels have been reduced very significantly.

One out of the 115 samples contained violative PCB but the entire lot had been marketed before results were complete, rendering seizure action impossible in follow-up on that sample.

The variation noted in the criteria among laboratories in reporting zeroes, traces, or finite ppm values at low levels indicates a need for more precise program instructions in this type of survey. However, overall evaluation of this survey was not adversely affected.

D. Data Interpretation

There are two vital questions involved in this survey: (1) What is the current PCB-in-paperboard situation relative to permitted levels and past levels (the FY 72 survey)? (2) Are the industry (BRDA) reports to FDA valid and comparable to actual results found in FDA sampling?

Frequency of PCB occurrence in Grayboard

The rate of PCB detection has declined from 92% (FY 72) to 72% (FY 74) by FDA surveillance.

Average Levels of PCB in Grayboard

By FDA surveillance, there has been a whole order of magnitude reduction in average levels: 15.3 ppm in FY 72 and approximately 1.4 ppm in FY 74.

Preponderance of PCB Levels

Figure I shows good correlation between FDA and BRDA in that well over 80% of samples in FY 74 were below 2.5 ppm. This range would also include the negative findings. It should be mentioned that a negative finding is merely a non-detection with the analytical parameters employed. Therefore, emphasis on the number of samples below 2.5 ppm may have more meaning than the number of negative reportings for study of the low findings.

Infant Cereals

Notwithstanding the vast difference in the number of samples in the FY 72 and FY 74 surveys, results appear to suggest a marked decline in PCB in infant cereal packaging. Rate of incidence declined from nearly 100% to about 29%, and average levels decreased from 5.2 ppm to 1.7 ppm.

Comparison of FDA Findings with BRDA Results

BRDA provided FDA with a summary of 1,992 results from 15 plants representing 7 companies. The 1,992 results each represented composites of 8-hour production periods. These BRDA results were obtained during the second quarter of calendar 1974. Since the FDA survey issued in May 1974 and excluded samples manufactured before October 1, 1973, comparison between BRDA and FDA findings should be quite valid from the standpoint of date of production.

Figure I is a cumulatative distribution chart which superimposes BRDA and FDA results. It can be seen that results are nearly identical.

In the BRDA Cooperative Quality Assurance program, some type of action (additional analyses or removal of production) is taken when the composite findings exceed 7.5 ppm. Since all analytical findings are presented in Figure I, it can be assumed that the marketed production would be even more similar to FDA findings of less than 1% violative.

E. *Conclusions:*

1. *Only 1 of 115 grayboard samples was found to exceed 10 ppm PCB (less than 1% violative) in this survey by FDA.*

2. *PCB is still present in the vast majority of grayboard samples but the average level has declined a whole decade to about 1.4 ppm.*

3. *The Cooperative Quality Control program conducted by BRDA appears to provide results which agree extremely well with FDA findings.*

4. *The continued high rate of PCB occurrence in grayboard, coupled with the occassional high finding necessitate continued monitoring by industry with appropriate checking by FDA.*

5. *Based on the significant decline of this problem since FY 72, it appears that at some time in the future the problem will be reduced to where monitoring may be relaxed unless new health-hazard data are developed.*

6. *This survey relates only to domestic production and provides no information on imported foods in paper packaging.*

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F. Intended Course of Action

The Bureau will:

1. Continue the C.O.A. with BRDA until such time as the rate of occurrence and levels of PCB in grayboard have declined to insignificant levels.

2. Continue FDA monitoring of this subject area in the ongoing total diet studies and pesticide in foods surveillance program by retaining selected food packages until food analysis is complete and shows no PCB. If the food shows PCB, the packages will be analyzed and appropriate regulatory follow-up enacted if results are violative.

3. The Agency is currently performing a survey of imported food packaged in paperboard to determine the PCB content of these packages and to take regulatory action when necessary.

Table 1

SUMMARY OF PCB FINDINGS IN PAPERBOARD FY '74

(Parts Per Million)

	Grits	Cereal (Ready-to-eat)*	Cereal (Other)**	Infant Cereal	Rice	Macaroni (Plain)	Macaroni (Part of Packaged Dinner)	Salt	Corn Starch	Corn Flakes/ Bread Crumbs	Biscuit Mix/ Corn Meal	Pancake/ Waffle Mix	Instant Mashed Potatoes
Boston			2.9, 2.0		2.0	2.3						1.3	
Buffalo			T		6.36	T	3.6			0			
New York			T, 1.32		T			T	2.05				
Newark			2.06, 1.16 2.9			1.56						7.71	
Baltimore		1.39	T		0	2.1				0			
Philadelphia			1.44		2.11	2.23							
Atlanta	T		1.31, 1.33 3.26		.94								
Scottville			T		T 2.86	1.46						.87	
Orlando					T,T,T 0, 0								
Los Angeles			0, 3.0		0	1.0			0	27.4, 8.0	0.1		
San Francisco			0		0, 0.2						1.0, .2		
Detroit			1.0, 2.0		1.0, 2.0	0, 1.0, 1.0	2.0						0
Chicago			0	0	0		0			.5			
Cincinnati				0	1.08	3.51, .19				T			
Minneapolis			1.96, .21	0	.19	T							
Dallas	0		0.0	0, 0	0		0, 0			0			0
New Orleans		0	0, T		0		2.7					0 3.0, .77	
Kansas City			1.3, .0									3.0	1.8
Denver					3.0 1.0		2.0						
Seattle			1.3, 1.0 2.6									.7, 1.2	
San Juan				0.63, 1.12	1.16	.73, 2.70							

* Ready-to-eat cereals include cereals such as Post Grape Nuts mainly consumed as purchased by adding cream or milk.
** Other cereals include oatmeals, farina, etc. which would normally be consumed after heating or adding hot fluid.

T = Trace.

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Table 2

COMPARATIVE PCB FINDINGS IN RECYCLED PAPERBOARD PACKAGING

Food Category	FY 1972 # of Samples	FY 1972 % Positive	FY 1972 Average PPM	Food Category	FY 1974 # of Samples	FY 1974 % Positive	FY 1974 Average PPM	Standard Deviation
Crackers, Bread Crumbs, etc.	55	89.0	16.8	Corn Flakes/Bread Crumbs	7	57.0	5.13	10.25
Prepared Mixes, Dry	37	94.0	8.2	Corn Starch	2	50.0	1.03	1.45
Rice, Oatmeal, Farina, etc.	29	93.0	16.0	Biscuit Mix/Corn Meal	5	100.0	.70	.44
Infant Cereals	14	99.8	5.2	Pancake/Waffle Mix	7	86.0	2.78	2.82
Breakfast Cereals, Ready-to-eat	31	87.0	9.9	Mashed Potatoes (Instant)	3	33.0	.33	.58
Macaroni & Noodle Products	34	97.0	29.1	Rice	26	69.0	1.08	1.67
				Grits	2	50.0	T	-
				Cereal (other)	31	81.0	1.03	.96
				Infant Cereals	7	29.0	1.68	3.28
				Cereal (Ready-to-eat)	2	50.0	.70	.98
				Macaroni (Plain)	15	93.0	1.39	1.16
				Macaroni (Part of Packaged Dinner)	7	57.0	1.50	1.51
				Salt	1	100.0	T	-
Grand Total	200	92.0 (weighted avg.)	15.3		115	72.0 (weighted avg.)	1.49	2.97

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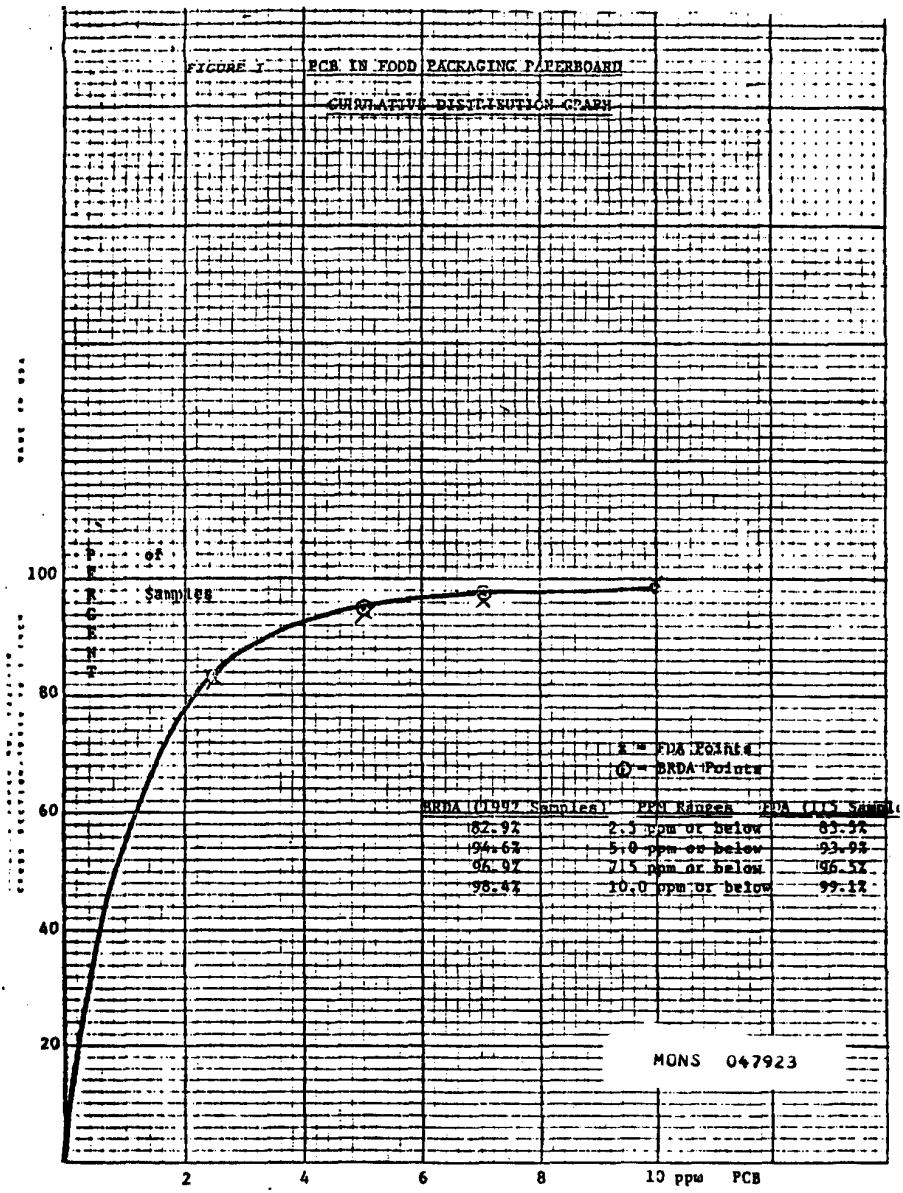
FIGURE 1 PCB IN FOOD PACKAGING PAPERBOARD

CUMULATIVE DISTRIBUTION GRAPH



BRDA (1997 Samples)	PPM Ranges	FDA (115 Samples)
82.9%	2.5 ppm or below	83.5%
94.6%	5.0 ppm or below	93.9%
96.9%	7.5 ppm or below	96.5%
98.4%	10.0 ppm or below	99.1%

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