DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION

In the Matter of	)	
	)	
POLYCHLORINATED BIPHENYLS (PCB's)	)	New Docket No. 75-N-001
In Paper Food-Packaging Materials	)	
	)	
	)	

WITNESS LIST OF AMERICAN PAPER INSTITUTE

The American Paper Institute intends to introduce the testimony of the following persons into the record of this proceeding:

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October 2, 1975

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION

In the Matter of	)	
	)	Docket No. 75N-0013
Polychlorinated Biphenyls (PCB's)	)	(Former Dkt. No. FDC-82)
in Paper Food-Packaging Materials	)	
	)	

NARRATIVE STATEMENT

Pursuant to proposed 21 CFR §2.153(a)(4) and the Order of the Administrative Law Judge entered herein, the following constitutes the narrative statement of the American Paper Institute (API) on the issues designated for hearing in the March 12, 1975, Order in this proceeding (40 Fed. Reg. 11563).

1. WHAT THE BUREAU OF FOODS MUST SHOW.

This is a proceeding under Section 406 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §346, in which the Bureau of Foods seeks to establish a "tolerance" for PCB's in paper food packaging material. The principal effect of the promulgation of a tolerance by the Commissioner of Food and Drugs would be to relieve FDA of the necessity of proving in a court seizure action that seized paper food packaging material exceeding the tolerance posed an actual threat to public health.

In order to obtain the conclusive presumption of injury to public health which becomes available once a tolerance is validly promulgated, the Bureau of Foods, as the proponent of the tolerance, bears the burden of proof. Unless its Narrative Statement inaccurately or incompletely reflects its intended evidentiary case, however, the Bureau of Foods has already indicated, particularly with regard to Issue A, that it will not even attempt to meet its burden to satisfy the statutory requirements governing the issuance of tolerance. The mere incantation of the phrase "protection of the public health" is not an adequate substitute for scientific proof, and certainly not a response to the evidence, much of it from FDA, showing no conceivable danger to human health related to PCB's in paper food packaging material. By the following outline of position API does not intend to assume the Bureau of Food's burden nor to relieve the Bureau from strict proof of all elements essential to support the issuance of the tolerance it has proposed.

2. ISSUE A Do PCB's at current levels of dietary intake pose a threat of potential chronic toxicity so as to require the issuance of a 10 p.p.m. tolerance on food packaging?

A. Three distinct elements must be shown by the Bureau

of Foods to justify the establishment of a tolerance in PCB's in a food (or in paper, assuming it is a food) under Section 406. First, it must be shown what the dietary intake of PCB's actually is. Then the Bureau must establish that this level of intake is higher than the safe dietary level determined in accordance with prudent toxicological practice. Absent this latter showing it cannot be held that a tolerance is "necessary for the protection of the public health" under section 406 of the Act. Assuming that this could be demonstrated, then the Bureau is required to prove that paper packaging materials make a significant contribution to the total dietary intake of PCB's. Only then could tolerances rationally be set and the total "pie" (overall dietary intake) be divided up between food categories by setting tolerances for each so as to reduce dietary intake below the safe level. The statute is clear that, absent any of these showings, the Bureau will have failed to meet its burden of establishing a basis for the particular tolerance of 10 p.p.m. it has proposed.

Yet, in its Narrative Statement, the Bureau does not indicate even a rudimentary appreciation of the nature of the proof it must put forth or slightest intent to bear its burden. Rather the Bureau invokes only its own general ipse dixit:

> Based on data concerning the dietary intake of PCB's from various sources the Bureau of Foods has concluded that PCB's present a sufficient potential long-term human toxicity hazard to require the promulgation of a tolerance of 10 parts per million for these substances in paper food packaging material . . ." (Narrative Statement, 2)

In a proceeding before the delegate of the Commissioner of Food and Drugs, the Bureau may not take refuge in the invocation of its own expertise. However, that is the sum total of the Bureau's analysis of Issue A. In API's view it gives absolutely no notice of the Bureau's contentions, if any, on the critical issues of dietary intake of PCB's, the safe level of such intake, and the relative contribution of PCB's by different foods to dietary intake. If its Narrative Statement is a fair summary of the Bureau's case, that presentation will wholly fail to establish the need for a tolerance and will not support a departure from the conventional regulatory approach of proving injury to the public health in seizure actions.

B. However, in addressing the issue of public health raised in this case, API does not rest its position simply on the inadequacies of the Bureau's presentation. Rather, it will go on to show, principally from FDA's own studies, that there is no potential long-term human toxicity hazard from dietary intake of PCB's at the levels that are currently being ingested.

To begin with, dietary intake is of an extraordinary low order. For the period from October 1972 through January 1975 the dietary intake was on the average approximately 118 parts per trillion in the total diet according to FDA's total diet studies. Looking at the more recent periods of 1974 and 1975, the overall dietary intake is not even quantifiable by the method used by FDA in reaching its 1973 estimate of dietary PCB intake of 4.2 micrograms per adult per day (equivalent to 2.8 parts per billion in the total diet) (38 Fed. Reg. 18097, July 6, 1973) Quantifiable PCB's, according to FDA's total diet studies have literally vanished.

Moreover, those current readings made by FDA indicating PCB's may be in the diet are at "trace" levels far below the analytic reliability of the testing method employed. Given the extreme difficulty of identifying PCB's at low levels, these trace readings require specific chemical confirmation to determine the actual compound present. Typically, however, FDA does not perform this needed confirmatory analysis. Thus the significance of "trace" of PCB's as shown by the total diet studies is far from clear.

The chronic toxicity of PCB's may be evaluated from two standpoints. One is on the basis of the application of the standard 1/100 safety factor to the no-effect level shown in long term rat and dog studies. The no-effect level is the long term dietary level at which thorough investigation

of test animals reveals normal tissues, blood, body weight, etc. The use of the hundred-fold reduction safeguards against variations between human and animal metabolism characteristics and toxicological sensitivity and allows for extreme individual variations of human dietary intake. This method is typically used by FDA in assessing chronic toxicity of a chemical in approving food additive petitions made under Section 409 of the Food, Drug and Cosmetic Act and for many other purposes.

The no-effect level in those species for PCB's is 10 p.p.m. in the total diet. One one hundredth of this level is 0.1 p.p.m. or 100 parts per billion (100,000 parts per trillion) Current dietary intake (118 p.p.t. or less) is vastly below 100,000 p.p.t. the safe level as calculated by this method.

Alternately, on the hypothesis that at least one PCB, Aroclor 1260, (which is not the PCB present in paper-food packaging material)[1/] has been identified by a recent study as a potential carcinogen, a different even more conservative safety factor might be used. This safety factor would be based on the statistical model derived by Nathan Mantel and William Bryan, two eminent statisticians formerly associated with the National

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1/ PCB's are a mixture of different but related chlorinated biphenyls. Aroclor 1260 is 60% chlorine by weight and is the most highly chlorinated PCB manufactured in this country.

Cancer Institute. This method is an extraordinarily conservative approach for estimating a safe dose of a carcinogenic compound. Indeed, in dealing with substances which have been authoritatively identified as potent carcinogens FDA has "watered down" the Mantel-Bryan method to make it less conservative. API will show that under the Mantel-Bryan procedure, in its most rigorous form as well as in the diluted FDA modification, dietary intake of PCB's is still far less than the safe dose.

2. ISSUE B In proposing the tolerance has the Commissioner taken proper account of the extent to which PCB's cannot be avoided in the production of paper food packaging material?

API agrees with the Bureau of Foods that some PCB's are unavoidably included in paper food packaging material even under the most careful manufacturing and testing conditions. This factor has not been taken adequate account of in the proposed tolerance. Because PCB's are unavoidably included in paper packaging, the inevitable effect of the tolerance will be to impose new costs on the recycling segment of paper industry, the economically weakest part of that industry. To a certain extent, these costs have already been incurred as a result of the proposal of the tolerance even though it has not yet been found lawful after hearing. Direct increased costs have resulted primarily from expanded

testing requirements, higher furnish (raw material) costs, and, decreasingly, from the disposition of over-tolerance production. In addition, a tolerance on PCB's in recycled paper board will arbitrarily stigmatize it and cause substantial shifts of customers to virgin board. Finally, the proposed order will expose foodboard manufacturers to excessive financial liability for seizure-related customer losses resulting from inadvertent production of over-tolerance material which cannot be detected even with model testing procedures.

API will show that the impact of these increased costs will continue to diminish new investment in the recycling sector of the paper industry, retard the rate of recycling growth, and put increased pressure upon food processors to shift from the use of recycled paper packaging to non-recycled alternatives. The necessary effect of these pressures is a loss of recycling capacity. In turn, paper once recycled will become a part of the waste stream thus burdening still further overburdened municipal waste systems. These results are inevitable given that PCB's are unavoidably included in the process of making recycled paperboard.

Had the Commissioner properly taken full account of the unavoidability of PCB's in paper food-packaging, particularly in light of the insignificant contribution PCB's in paper packaging makes to total dietary intake of PCB's, he would have se-

lected a regulatory approach not imposing such costs and yet protecting the public, if that is necessary. In short, the Commissioner would have regulated PCB's through conventional food tolerances which obviously deal with the root of legitimate concern. Food tolerances, if properly set, would adequately protect the public from any threat of chronic toxicity while the current unprecedented effort to extend regulatory controls of PCB's to packaging brings with it major adverse consequences to the national recycling effort.

3. ISSUE C Does the proposed tolerance properly recognize the existence of barrier materials preventing or retarding PCB migration from packaging to food?

The proposed regulation states it would exempt packaging from the 10 p.p.m. tolerance when PCB's are separated from food by an "impermeable" barrier, asserted by FDA to be only metal cans, bottles and polyvinilidene chloride (PVDC) plastic films. Two sets of circumstances require recognition of barriers which, though not totally impermeable to PCB migration, are nevertheless effective in preventing all but trivial PCB migration.

A. API agrees with FDA that the source of PCB's in paper food packaging material is, and has been, the unavoidable inclusion in the paper recycling process of carbonless copy paper which is still entering the waste stream in diminishing quantities though its manufacture has long been

discontinued. This carbonless copy paper employed microcapsules enclosing ink containing PCB's. A substantial proportion of these capsules survive the manufacturing process and are present in packaging unruptured. If intact in foodboard, these microcapsules are, however, impermeable to migration of PCB. Thus the PCB within the microcapsule is incapable of migrating from the packaging to the food. FDA has not recognized the effectiveness of the microcapsule barrier to PCB migration in any manner whatsoever. In fact, the method proposed by FDA to determine the PCB content of food board (and thus compliance with the tolerance) prescribes that these effective barriers be dissolved in the chemical extraction process of preparing a sample of packaging for testing for PCB content. Thus all the PCB's contained therein are measured, when in fact all PCB's in packaging are not available to migrate to food because they are separated from the board by the impermeable capsule wall. In this way, the indicated level of PCB's available for migration to food is grossly distorted by FDA's testing procedure.

The use of a different chemical extraction technique (hexane extraction) would not destroy the effective barrier constituted by the microcapsule or measure other PCB's which cannot migrate. API will show that FDA should use this different analytic procedure in determining compliance with any proposed tolerance for PCB's in packaging, because

it would not measure the PCB in food board which is unavailable for migration, but only the available PCB.

B. Given the very low level of PCB's now present in food board, API will show that a number of packaging barriers in common use adequately protect food against migration of PCB's from paper board. Numerous tests have been conducted on a number of barriers presently in use and these tests establish beyond doubt that virtually every barrier now in commercial use is functional in preventing or greatly retarding PCB migration. FDA's rigid instance upon absolute impermeability in a barrier is totally inconsistent with the stated goal of reducing average dietary intake of PCB's and needlessly inflicts added costs on the recycling sector of the paper industry and ultimately on the waste management system and the consumer without compensating benefit. Accordingly, API will show that even were the Bureau's overall attempt to regulate paper food packaging material for PCB's valid, its effort to extend its regulation to board separated from food by barrier is arbitrary and unsustainable.

4. ISSUE D Whether paper food packaging material is a demonstrated source of PCB's contained in the packaged food.

Assuming arguendo that PCB's are present in the total diet at a potentially harmful level, and thus that

food tolerances for them are proper, nevertheless the amount of PCB's entering the human diet from paper food-packaging material is negligible, indeed unquantifiable, and toxicologically an insignificant contribution to the total dietary intake. Accordingly no tolerance is justifiable under the statute or under consistent FDA practices. In remarkably similar tolerance-setting contexts relating to lead, mercury and aflatoxin (one of the most potent carcinogens known), FDA has clearly (and necessarily) distinguished between significant and insignificant sources of poisonous substances in terms of total dietary intake. Specifically, FDA has proposed tolerances only for significant dietary sources of a poison, or alternately has refused to lower a tolerance on a significant source to take account of a minor contribution to the total ingested from a secondary, insignificant source. API will show that FDA's total diet studies establish that paper packaging is not a source of detectable PCB's in food even in trace amounts and therefore is insignificant from a regulatory standpoint. Again, the Bureau of Foods has not even alleged to date that paper food-packaging is a substantial source of PCBs.

Specifically, API will show that the total diet studies indicate that, in the food category of grains and cereal, the only one where foods are predominantly packaged

in recycled paper board, there has been a total elimination of dietary PCB intake. In this food category, not even trace readings of PCB's are detected according to the most recent information furnished to API by the Bureau of Foods. However, if PCB's do migrate from packaging to food, a quantifiable residue of PCB's would have to be found in this food category. Their absence in this food class establishes that at current levels of PCB's in the food board there is no migration, and the packaging is not a demonstrated source of PCB's in the food since there is no PCB in the relevant food category.

The explanation for this phenomenon, in API's view, begins with the fact that PCB levels in food board has declined virtually to the vanishing point. API will show that in 1975, for example, over 80 percent of food board production tested under the joint FDA-Boxboard Research & Development Association Cooperative Quality Assurance Program was below 2.5 parts per million and that over 99 percent was below 10 parts per million. FDA's own compliance program evaluation in its second packaged-food survey confirms the radical decline of PCB's in foodboard. Moreover, these results must be considered in conjunction with the data suggesting that much of the PCB's measured by the method currently mandated by FDA is not available for migration and further that much available PCB does not migrate.

In sum paper food packaging is not a demonstrated source of dietary intake of PCB's.

Respectfully submitted,

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October 2, 1975

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION

In the Matter of:	)	
	)	
POLYCHLORINATED BIPHENYLS (PCB's)	)	Docket No. 75 N-0013
	)	
In Paper Food-Packaging Materials	)	
	)	

SUPPLEMENTAL DESIGNATION OF RELEVANT PORTIONS OF ADMINISTRATIVE RECORD

Pursuant to proposed 21 CFR 2.153 and the order of the Administrative Law Judge entered herein, the American Paper Institute designates the following as relevant portions of the administrative record in this proceeding. These designations supplement those of the Bureau of Foods.

1. Notice of Proposed Rule Making for Polychlorinated Biphenyls -- 37 Fed. Reg. 5707 (March 18, 1972).
2. Draft Environmental Impact Statement, Notice of Proposed Rule Making, Polychlorinated Biphenyls, May 8, 1972.
3. Letter from Hudson B. Drake, Department of Commerce, to Sam D. Fine, Associate Commissioner for Compliance, May 9, 1972.
4. Letter from Sam D. Fine, Associate Commissioner for Compliance, to Hudson B. Drake, Department of Commerce, May 22, 1972.

5. Comments of the National Association of Secondary Materials Industries, Inc. (NASMI) to the March 20, 1972, Food and Drug Administration's Proposed Regulations on Polychlorinated Biphenyls (PCB's), July 14, 1972.
6. Letter from Sheldon Meyers, Director, Office of Federal Activities, Environmental Protection Agency, to the Hearing Clerk, commenting on the proposed rule making, September 14, 1972.
7. Letter from Sidney R. Galler, Deputy Assistant Secretary for Environmental Affairs, Department of Commerce, to Robert C. Brandenburg, Acting Deputy Associate Commissioner for Compliance, commenting on the proposed rule making, September 15, 1972.
8. Letter from Gerald F. Combs, Nutrition and Food Safety Coordinator, Department of Agriculture, to Dr. L. L. Ramsey, Associate Director, Regulatory Programs, commenting on the Draft Environmental Impact Statement, October 18, 1972.

9. Comments of American Paper Institute, Inc. on FDA's Final Environmental Impact Statement, January 22, 1973.

10. Letter from Selma M. Levine to the Hearing Clerk re the need for a thirty day period for comments on the Final Environmental Impact Statement before the issuance of the final order, March 15, 1973.

11. Letter from Selma M. Levine and Stephen M. Truitt to Sherwin Gardiner, Acting Commissioner of Food and Drugs, requesting updating by FDA of its 1971 Packaged Food Survey, March 20, 1973.

12. Letter from Newark Boxboard Co. by its attorney Endicott Peabody to Sherwin Gardiner, Acting Commissioner, requesting that regulation of PCB content in paperboard packaging be withheld from the regulation pending the obtaining of further information, May 9, 1973.

13. Letter from Sam D. Fine, Associate Commissioner for Compliance, to Endicott Peabody, counsel for Newark Boxboard Co.,

replying to Newark's request for the indefinite deferral of a PCB tolerance in paper food-packaging material, May 7, 1973.

14. Letter from Sherwin Gardiner, Acting Commissioner, to Edwin A. Locke of API re compliance procedures, quality control and the use of barriers, May 18, 1973.

15. Letter from Sam D. Fine, Associate Commissioner for Compliance, to Selma M. Levine, enclosing a copy of FDA's Compliance Procedures for Polychlorinated Biphenyls Regulations for Paper Packaged Foods, June 29, 1973.

16. Letter from Selma M. Levine to Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, requesting dismissal of the PCB proceeding, January 17, 1975.

17. Letter from Dr. Alexander M. Schmidt, Commissioner of Food and Drugs, to Selma M. Levine, denying the request for dismissal, February 11, 1975.

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DEPARTMENT OF HEALTH, EDUCATION AND WELFARE
FOOD AND DRUG ADMINISTRATION

In the Matter of		
POLYCHLORINATED BIPHENYLS (PCB's) In Paper Food-Packaging Materials	)	New Docket No. 75-N-0013

STATEMENT OF AMERICAN PAPER INSTITUTE

On behalf of the American Paper Institute (API), the undersigned certify that to the best of their knowledge and belief, API's submission to the Hearing Clerk of documentary evidence in its files, evidence on which it relies, and its narrative statement complies with the requirements of proposed 21 CFR 2.153.

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