SUMMARY OF COMMENTS
FDA PROPOSED RULE MAKING - PCB's

COMMENT BY	AREAS OF CONCERN	COMMENT
Einar T. Wulfsberg	FDA authority tolerance levels.	Questions FDA authority to issue regulations on PCB's. Questions setting of tolerances based on attainability rather than toxicology.
American Paper Institute	Extension of comment period. Copies of supportive information.	Requested: Copies of all information supporting statements in rule making. Copy of Interdepartmental PCB Task Force Report. Copy of environmental impact statement. Extension of comment period to forty-five days after receipt of above.
Packaging Corporation of America	Analytical methodology migration of PCB.	Proposed improved and faster analytical procedure and the establishment of the transfer rates of PCB's to food before regulations are imposed.
TXI Paper Products	Limitations in food packaging.	Limits set are unrealistic and impractical because of inadequate testing and lack of sufficient supporting data for the proposed 5 ppm limit.
Menasha Corporation	Limitations on food packaging.	Proposal is unrealistic because of complex analytic procedures, lack of imminent health problem, minimum migration to food. Requests corrugated outer containers be excluded.
Interstate Folding Box Company	Limitations on food packaging.	Proposal is premature, impractical, overly strict, and may cause harm to recycle programs. Amount in package should not be the same as amount in food. Must consider migration and presence of liners.

MONS 043404

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Federal Paper Board Company	Limitations on food packaging.	Requested postponement until better analytical methods are developed, there is more evidence to support toxicological data and transfer rates are established.
The Boxboard Research and Development Association	PCB levels in boxboard.	Sought an extension of 30 days to complete studies on the current levels of PCB in paperboard and the reliability of the present testing method.
Mead Paperboard Products	Limitations on paperboard.	Proposal will have damaging affect on recycling effort.
Michigan Carton Company	Limitations on paperboard.	Proposal will have damaging effect on recycling effort.
Consolidated Packaging Corporation	Limitations on food packaging.	Proposal is premature, presumptive of many factors yet to be proved and involves considerable extrapolation. Will affect recycle program.
Inmont Company	Limitations on food packaging	Standards should allow some deviation and an additional 60 days should be given for compliance over and above the proposed 30-day compliance period. Mentioned problems in heat transfer conversion requiring time for flushing and final fill.
The Packaging Institute	Analytical methodology and barriers in packaging materials.	Need improved analytical procedure for non-paper materials and evaluation of a wide range of materials as PCB barriers. Requested 4 months extension.

MDNS 043405

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Society of Plastics Industry	Limitations on plastic packaging materials.	Plastics packaging industry will be in dilemma of proving compliance with no scientific means of doing so. No reason to believe PCB in food from plastics packaging material. Request plastics be excluded from coverage or at least delay for 180 days until studies are completed.
Environmental Defense Fund	Food tolerances.	Tolerances are inadequate to protect human health and welfare. Strongly urged FDA to revise tolerances downward by a factor 5-10.
Virginia Institute of Marine Sciences	Shellfish tolerances.	Zero tolerance for shellfish would be harmful to industry, unreasonable, unfounded. Should include shellfish with fish at 5 ppm or shellfish be specifically excluded from the proposal.
Container Corporation of America	Sampling, analysis and compliance	Requested extended period until appropriate sampling, testing procedure and compliance standards were proposed by FDA and were given reasonable opportunity to consider and comment. Regulation should be based on food content rather than package.
Clevepak Corporation	Non-paper packaging materials.	Requested extension of comment time to 4 months.
Reynolds Aluminum	Non-paper packaging materials.	Noted lack of testing procedures for non-paper materials, effectiveness of barrier materials and insufficient data on presence of PCB in materials other than paper. Requested 120 days extension of comment period.

MONS 043406

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Diamond National Corporation	Food packaging materials.	Request section of packaging materials be withheld until studies on migration are completed.
John Strange Paperboard Division Menasha Corp.	Analytical procedures.	Analysis is complex and lengthy and results are erratic. Requests section on food packaging materials be withheld.
Can Manufacturers' Institute	Non-paper food packaging materials.	Requests change to refer specifically to paper food packaging materials where it is reasonable to expect the contained PCB to become a component of the packaged food.
Dow Chemical Company	Food packaging materials.	Sought clarification of types of materials covered and whether all materials were to be governed by the same limits. Asked that an accurate and commonly accepted methodology be provided for PCB determination. Offered method for plastics. Requested clarification of what is meant by "PCB". Questioned whether use of the classification "temporary" is realistic.
Mead Corporation	Limitations on food packaging materials.	Calls present proposal unworkable. Suggested set guidelines for all foods in FDA market basket survey and use these guidelines to establish levels in packaging materials depended on weigh ratios, barriers and expected migration.

MONS 043407

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
Ralston Purina Company	PCB concentrations in food and animal feed.	Objected to use of concentration in fat content of food. Suggested tolerances be on "as is" basis. Suggested 0.6 ppm as an "as is" tolerance. Asked for mention of difference between "complete" animal feeds and "concentrates". Recommended 5 ppm PCB in pet foods.
American Feed Manufacturers Association	Animal feed.	Proposes reference to "finished" feed be changed to "complete" animal feed. Supplements and concentrates be allowed 0.5 ppm on a complete feed basis. Recommended 1 ppm for ingredients not of animal or marine origin. Noted use of the phrase "harmful or deleterious" and claimed it a practical impossibility to eliminate all substances that could conceivably be harmful. Notes important use of PCB transformers in plants.
Acco Feeds	Animal feed.	Endorsed American Feed Manufacturers Assoc. comments.
Certified Ballast Manufacturers Association	Lamp ballasts	Sought confirmation that proposal does not apply to fluorescent lamp ballasts.
General Electric Company	Capacitors and transformers	Called for distinction in equipment in physical contact with food, feed or packaging material and the equipment relating to power supply.
Aerovox Corporation	Capacitors	Emphasized that capacitor failure is obvious and corrective actions can be quickly implemented.

MONS 043408

SUMMARY OF COMMENTS

COMMENT BY	AREAS OF CONCERN	COMMENT
The Boxboard Research and Development Association	Paper packaging material.	Cited that lower chlorinated PCB's degrade and have no harmful effects on warm blooded animals even at extreme feed levels.
Fibreboard Corporation	Paper packaging material.	Suggested that 15 ppm be set for maximum PCB in food packaging.
Anaconda Aluminum Company	Non-paper packaging material.	Requested an additional 90 days of comment.
Brown Company	Paper packaging materials.	Calls the proposal an unenforceable law, therefore, an embarrassment to the Government and can harm the recycling industry.
Stone Container Corporation	No details available	
Lowe Paper Company	No details available	
Milprint	No details available	

MONS 043409