BEFORE THE
COMMISSIONER, FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

In the Matter of

POLYCHLORINATED BIPHENYLS
Proposal to Amend 21 C.F.R.
Parts 3, 121, 122, 128

COMMENTS OF AMERICAN PAPER INSTITUTE, INC.
ON FDA'S FINAL ENVIRONMENTAL
IMPACT STATEMENT

FDA's Final Environmental Impact Statement (FEIS), released December 21, 1972 (37 Fed. Reg. 28201), was intended to evaluate the environmental impact of its forthcoming order on polychlorinated biphenyls (PCBs). This order will (1) prohibit the use of PCB-containing materials in food packaging plants "to preclude direct accidental PCB contamination of animal feed, food, and food-packaging materials"; (2) exclude from food-packaging materials the use of pulp from reclaimed fibers containing PCBs "which may migrate to food"; and (3) set temporary tolerances for unavoidable PCB residues in food-packaging materials and in certain foods.

The temporary tolerance to be imposed on paper

food packaging materials is 10 p.p.m.,[1] with an exemption for those "separated from the packaged food by a functional barrier impermeable to PCB migration" (FEIS 5).

The FEIS is, in the American Paper Institute's view, so grossly deficient that FDA has wholly failed in its statutory duty to prepare the detailed evaluation of the environmental impact of and alternatives to its proposed PCB order required by Section 102(2)(C) of the National Environmental Policy Act of 1969 ("NEPA").[2] Until FDA has complied with NEPA's procedural requirements by filing an adequate statement, it cannot validly promulgate a final PCB order.

The Legal Standard Governing Environmental Impact Statements. Section 102(2)(C) of NEPA requires impact statements to discuss:

1/ The March 18, 1972 proposal would have imposed a tolerance on all food packaging materials, including plastics, textiles and other non-paper materials. In contrast, the newly proposed tolerance would be confined to paper food packaging materials. The FEIS does not in any way explore the impact of this change.

2/ 42 U.S.C. 4332(2)(C).

> (i) the environmental impact of the proposed action,
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
> (iii) alternatives to the proposed action,
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.3/

The statement should reflect "... a rather finely tuned and 'systematic' balancing analysis in each instance."4/ Such an analysis will insure

> "... that each agency decision maker has before him and takes into proper account all possible approaches to a particular project (including total abandonment of the project) which would alter the environmental impact and the cost-benefit balance."5/

3/ 42 U.S.C. 4332(2)(C).

4/ Calvert Cliffs' Coord. Com. v. AEC, 449 F.2d 1109, 1113 (D.C. Cir. 1971).

5/ Id. at 1114. See also the Council on Environmental Quality Guidelines which provide:

> "A rigorous exploration and objective evaluation of alternative actions that might avoid some or all of the adverse environmental effects is essential. Sufficient analysis of such alternatives and their costs and impact on the environment should accompany the proposed action through the agency review process in order not to foreclose prematurely options which might have less detrimental effects." 36 Fed. Reg. 7724, 7725 (April 23, 1971).

The function of an FEIS then is not to dictate the choice of any particular course of action but merely to insure that the environmental impact of all alternatives is carefully weighed before that choice is made.

FDA's duty to prepare a thorough impact statement is strictest where its proposal will have a major economic impact on the paper recycling industry,[6] an industry which Congress has expressly required FDA -- along with all other federal agencies -- actively to protect and promote in order to further important national goals. NEPA makes "environmental protection a part of the mandate of every federal agency ..."[7] and that mandate includes the goal of "maximum attainable recycling of depletable resources."[8]

6/ The combination paperboard sector of the paper industry will be hardest hit by the regulation. The principal source of PCBs in paper food packaging material is a grade of waste furnish containing carbonless copy paper which cannot, except by the use of much higher cost grades, be entirely eliminated from the manufacture of combination paperboard food packaging material. The use of PCBs in carbonless copy paper has been discontinued with a corresponding reduction in the levels of PCBs in food packaging material.

7/ Calvert Cliffs' Coord. Com. v. AEC, 449 F.2d at 1112.

8/ 42 U.S.C. 4331(b)(6).

In light of this national goal, the direct effect of the PCB regulation on the recycling portion of the paper industry is not mere private economic injury. It produces consequences directly counter to a public policy determination of Congress: lost recycling capacity or utilization, increased solid waste disposal problems, more rapid use of timber resources, and a shift from recyclable products to non-recyclable substitutes.

In these circumstances NEPA requires FDA at a minimum to conduct a searching exploration of the environmental impact of its proposal and alternative proposals. But the FEIS does not do so.

1. There is virtually no evaluation of the environmental effect of adopting a 10 p.p.m. tolerance on paper food packaging material, and in particular of the impact on recycling mills, solid waste disposal systems, or timber resources.

2. Numerous reasonable alternatives to the proposed regulation are not mentioned, much less discussed, and accordingly their environmental impact is never weighed.

3. The environmental impact of the regulatory alternatives which are discussed is either ignored or

superficially treated.[9/]

I. The FEIS Fails to Evaluate the Impact of the Proposed Tolerance on Paper Food Packaging Materials, the Exemption for Non-paper Materials, and the Proposed Food Additive Amendment.

A. The most glaring defect in the FEIS is its failure to explore the environmental impact of the proposed 10 p.p.m. tolerance on paper food packaging materials. While acknowledging that "[c]ompliance with the rule making will not be without potential adverse effects on the quality of the human environment" (FEIS 19), the Commissioner does not attempt to describe them, quantify them or indeed to discuss them at all. He only notes that, whatever these are, they are avoidable:

> "... a clear understanding of the purpose and intent of the rule making, combined with an exercise of caution and judgment, will avoid these potential adverse effects." (Id.)

This generalized approach is not the focused balancing of environmental benefits and costs NEPA requires.

The Commissioner merely concludes with no examination of the facts, that "... the tolerance [on paper FPM] would not be detrimental to the recycling waste program"(FEIS 20).

9/ The FEIS merely lists industry comments spelling out the reasons why the tolerance would be detrimental to the paper recycling industry and to solid waste disposal systems (FEIS 4-5). But it never responds in kind to these comments.

He assumes without analysis that a 10 p.p.m. tolerance will not have adverse effects if coupled with the exemption of paper food packaging material separated from the packaged food "by a functional barrier impermeable to PCB migration" (FEIS 21).[10/] But the extent to which the "impermeable barrier" exemption reduces the adverse effect of the tolerance on recycling is not described or evaluated. If the exemption is confined to cans and bottles -- as the term "impermeable" suggests -- it would not ameliorate the regulation's impact on recycling mills. The corrugated containers in which cans and bottles are packed are overwhelmingly made from virgin stock.

The FEIS makes one and only one nonconclusory factual assertion in assessing the environmental impact of the 10 p.p.m. tolerance on recycling mills producing paper food packaging material:

> "Any paper food-packaging material not in compliance with the tolerance of 10 p.p.m. PCB's will be usable for all other forms of packaging ..." (Id.)

But this is plainly erroneous. Over-tolerance paper food packaging material can rarely be sold for alternate purposes,

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10/ It does not appear that the term "functional barrier" or "impermeable" will be defined.

as API has indicated earlier.[11] By the time its PCB content has been determined, the packaging will have been made to precise specifications suitable for a single buyer and product alone. FDA continues to misunderstand this consequence of over-tolerance material and its likely economic impact: mill closings with consequent loss of recycling capacity and employment.

Moreover, nowhere does the FEIS appraise the extent to which added costs entailed in a tolerance may shift consumer or processor demand to non-recycled substitutes. Yet a price increase for recycled products, with a potential for mill shutdowns, would be inevitable in these circumstances.

The Department of Commerce's criticism of the draft statement applies with equal force to the FEIS -- it fails to "address recycling in depth to protect against any economic and hence function dislocation of this important conservation effort."[12]

B. The FEIS totally ignores the environmental impact of its proposal to exempt non-paper food packaging materials

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11/ See Comments of American Paper Institute, Inc. at 47-49, In the Matter of Polychlorinated Biphenyls (July 17, 1972) (hereafter API Comments).

12/ Letter from Sidney R. Galler, Deputy Assistant Secretary for Environmental Affairs, Department of Commerce, to FDA Hearing Clerk, p. 3, Sept. 15, 1972 (emphasis added) (hereafter Galler letter).

from the 10 p.p.m. tolerance. It is not clear whether the effect of this exemption is complete deregulation, i.e., establishment of an infinite tolerance, or imposition of a zero tolerance. If FDA has effectively exempted PCB-containing substitutes for paper food packaging material from any regulation, it has thereby expressed a clear and thus far unjustified preference for those substitutes.[13/] Though that preference must necessarily result in declining use of recycled products, this decline is not appraised. Similarly, if a zero tolerance is established for food packaging materials such as plastics and textile, the FEIS does not weigh the impact of that tolerance on the affected industries and the environment.

C. The FEIS is also defective because it discusses in only a cursory manner the effect of the proposed food additive regulation amendment. 21 C.F.R. §121.2546. This section

> "... will prohibit the inclusion in the recycling process of pulp that contains any poisonous or deleterious substance which may migrate to food from use in food-packaging ... . The effect of this amendment will be the exclusion of PCB-containing carbonless copy papers from reclaimed and salvaged fibers." (FEIS 20-21).

13/ The underlying data in FDA's own Survey of Polychlorinated Biphenyls in Foods Packaged in Paper Products (1972) shows that food packaging materials other than paper contained significant PCB amounts.

According to FDA, there will be no effect on recycling programs because "the paper industry is currently following [the] practice" of excluding carbonless copy paper (FEIS 21). But again, as the Department of Commerce observed in commenting on the draft statement, the extent of the practice of removing "carbonless" copy paper throughout the recycling industry "is not stated, nor is the effectiveness of that practice in reaching the temporary tolerance limit stated."14/

Although the industry has made a major effort to limit and prevent PCB-bearing material from entering the recycled paper-making process, the fact is that the previous widespread distribution of carbonless copy paper containing PCBs, including that in government agencies, makes complete exclusion of such material from waste furnishes currently used in recycling mills virtually impossible for the near future. In the words of the Department of Commerce:

> "Because such a very small quantity of carbonless carbon paper per ton of waste paper when recycled exceeds the proposed tolerances, it is unlikely that the tolerance limit can be met without significant additional costs to the recycling industry thus reducing its competitiveness in the market and its chances of survival. When carbonless carbon paper is combined with unknown materials containing PCB's the problem is further compounded, making the tolerance limits even more difficult to achieve."15/

14/ Galler letter, p. 3.

15/ Id.

To insure exclusion of such materials from the production process would require using higher cost waste materials. This in turn raises the price of the finished products substantially.

If the entire combination paperboard industry is required to exclude all PCB-bearing carbonless copy paper from its waste-fiber furnish, it must shift from a white ledger grade furnish fortop-liner to a significantly higher priced substitute. As the previously submitted A.D. Little Study, "Costs of PCB Compliance", establishes,

> "This [substitute] costs about $25 more per ton than the white ledger grade. Since the top liner constitutes about 15% by weight of the total combination board, a $25 per ton increase in its fiber furnish corresponds to an increase of about $3.75/ton in the resultant board.
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> "Tab card stock at a $25/ton price differential may not be available to all mills that produce foodboard grades. Other suitable grades may have a $50-60/ton price differential. In such instances the increased price of the top liner fiber furnish would add $7.50 to $9.00 per ton of finish board."16/

16/ Arthur D. Little, Inc., The Potential Economic Impact on the Combination Paperboard Industry of Compliance with the Proposed PCB Tolerance at 23 (July 1972).

FDA makes no attempt to quantify these costs either in terms of money, loss of recycling capacity, shift to non-recyclable materials, effect on timber resources, or other factors. The environmental impact of the food additive amendment is simply ignored.

II. The Impact Statement Fails to List or Discuss Several Reasonable Alternatives to FDA's Proposal.

An impact statement must include a discussion of "alternatives to the proposed action"[17] as well as the environmental effects of these alternatives.[18]

A. The Alternative of not Regulating The PCB Content of Food and Food Packaging Material.

One alternative the Calvert Cliffs' decision requires FDA to consider is "total abandonment of the project."[19] Here "total abandonment" would mean imposing no tolerances on food or food packaging material. Yet this option is a realistic one in view of FDA's acknowledgment that the dietary intake of PCBs is of an extremely low order:

17/ 42 U.S.C. 4332(2)(C)(iii).

18/ National Resources Defense Council v. Morton, 458 F.2d 827, 834 (D.C. Cir. 1972).

19/ Calvert Cliffs' Coord. Com. v. AEC, 449 F.2d 1109, 1114 (D.C. Cir. 1971).

> "The dietary intake of PCBs, as shown in the FDA's total diet studies for the past two and one half years, is of a low order (less than 0.0001 milligram per kilogram of body weight per day in a high consumption diet)." (FEIS 11-12).

For a 70 kilogram person, the average dietary intake would be 0.007 milligram per day. Yet, according to FDA,

> "Toxicological information available indicates that the acceptable daily intake of PCBs, applying appropriate safety factors, ranges from 0.175 to 1.4 milligram/day for an adult." (FEIS 12). 20/

The lower safety figure is some 25 times greater than the average dietary ingestion of PCBs. At the higher safe level which FDA adopts, the average daily intake of PCBs would have to increase over 200 times before posing any possible threat to the consumer. In short, since present average dietary intake of PCBs is far below what FDA considers to be safe, the alternative of no tolerances on food and food packaging materials should have been explored.

20/ The "appropriate safety factor" referred to is the 100/1 factor applied to the "no effect" level in animals. (See 21 C.F.R. 121.5). Thus the current average dietary intake of PCBs is 1/2500th (1/(25 x 100)) of the "no effect" level in animals.

B. The Alternative of Exempting Aroclor 1242 from the Regulation.

Another alternative which FDA does not weigh is an exemption of Aroclor 1242, the PCB predominantly found in paper and paperboard and the least chlorinated form of PCB found in the environment. Since Aroclor 1242 has been the PCB produced in greatest volume domestically, it would be expected to be the PCB most widespread in the environment. The available evidence indicates, however, that the more highly chlorinated the PCBs are, the more persistent they are in the environment. In contrast, the lower chlorinated Aroclor 1242 is metabolized or otherwise decomposed,[21/] and thus has not been shown to accumulate in human tissue. In these circumstances, the alternative of exempting Aroclor 1242 from the tolerance ought to have been explored by FDA and its environmental impact evaluated.

C. The Alternative of a Higher Tolerance on Food Packaging Materials.

FDA never considers the alternative of a tolerance higher than 10 p.p.m., either in terms of the public health or its impact on recycling. In view of the diminishing occurrence of PCBs in recycled paper products and the low order of dietary intake, this was a reasonable alternative which required FEIS evaluation.

21/ See Comments of American Paper Institute, Inc. at 22-25 (July 17, 1972).

III. The Environmental Impact of The Regulatory Alternatives Which Are Mentioned Is Inadequately Discussed.

A. The Alternative of Institution of Nationwide Controls over PCB Materials and Disposal.

FDA identifies nationwide controls by other governmental agencies as a reasonable alternative to its proposal:

> "... FDA asserts that, in order to reduce and eliminate the causes of unavoidable and indirect environmental contamination of food, nationwide controls and preventive measures concerning uses, handling, disposal of PCBs and PCB-containing materials, other than regulatory actions by the Administration, must be instituted by parties other than the FDA ... . If nationwide controls are instituted and implemented, this will result in a lower concentration of PCBs in the ecological system and will reflect a diminishing exposure of humans, wildlife, and fish and other marine life to all sources of PCBs." (FEIS 18-19).

But it neglects to discuss the environmental impact of this measure, or examine whether implementation of those controls would have more, less, or the same environmental impact, particularly on recycling, as a 10 p.p.m. tolerance on paper food packaging material.

FDA's view that it need discuss only those regulatory alternatives which it can "adopt and put into

effect", and not those within the jurisdiction of other agencies as well, was expressly rejected in National Resources Defense Council, Inc. v. Morton, 458 F.2d 827, 834 (D.C. Cir. 1972).[22] Its duty to examine options beyond the ambit of its own regulatory authority is particularly great, said the court, "[w]hen the proposed action is an integral part of a coordinated plan to deal with a broad problem ..."[23]:

> "The Executive's proposed solution to a national problem, or a set of inter-related problems, may call for each of several departments or agencies to take a specific action; this cannot mean that the only discussion of alternatives required in the ensuing environmental impact statements would be the discussion by each department of the particular actions it could take as an alternative to the proposal underlying its impact statement." 458 F.2d at 835.

That the PCB problem is a national one of the type described by the court is clear from the convening of an interdepartmental task force. By narrowly focusing on its own resources, and blinding itself to those of other regulatory agencies, FDA has erred.

22/ FDA's view was also criticized by the Department of Commerce. Galler letter, p. 2.

23/ 458 F.2d at 835.

B. The Alternative of Eliminating PCB-bearing Carbonless Copy Paper from Existing Inventories.

FDA disregarded another specific alternative to the 10 p.p.m. tolerance: removal of carbonless copy paper containing PCBs from currently available supplies (e.g., a national program for eliminating use of such PCB-bearing carbonless copy papers as W-2 forms). Mentioned by the Environmental Protection Agency in its comments on FDA's draft environmental impact statement, [24/] this measure would assure that a primary source of PCBs found in food packaging material would be eliminated.

The only reason assigned for not appraising this alternative is that FDA "lacks jurisdiction to require removal from existing inventories of carbonless copy paper containing PCBS" (FEIS 6).

But, as indicated above, the effectiveness of viable alternatives cannot be disregarded simply because their implementation is entrusted to another agency.

C. Impact of Alternative to Food Packaging Materials Tolerance.

FDA's one-page discussion of the alternatives to the tolerance on food packaging material considers only

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24/ See letter from Sheldon Myers, Director, Office of Federal Activities, Environmental Protection Agency, to FDA Hearing Clerk, September 14, 1972.

one possibility: "The establishment of PCB tolerances for the packaged food" (FEIS 26). Its impact is not examined.

The reason FDA assigns for rejecting this option is that

> "Toxicological information on the chronic effects of PCB's is not sufficient to serve as the basis for setting tolerances for all packaged foods" (FEIS 26).

But, as the Department of Commerce observed in its Comments on the Draft Environmental Impact Statement, a packaged food tolerance

> "... is highly desirable, because it would provide the necessary incentives to the food packaging and processing industry to research and develop alternative solutions to the control of PCB's in food from any source."25/

Despite its desirability Commerce believed, presumably based on FDA's assertion, that this option was not feasible:

> "The rational[sic] for not establishing the PCB tolerance of the food itself ... is only valid because present information about the chronic toxicological effects of PCB's is not sufficient."26/

25/ Galler letter, p. 4.

26/ Galler letter, p. 4.

The alleged insufficiency of toxicological data to set tolerances for all foods, then, is the lynchpin of FDA's rejection of that alternative. But FDA never explains why it can set tolerances for some foods but not others. If FDA can set tolerances for some foods, it must have toxicological information sufficient to do so for all foods, since PCBs, if they are harmful to ingest, obviously do not become less harmful if ingested as part of a food for which no tolerance has been adopted.

FDA never explains this anomaly. In short, the reasons it assigns for dismissing the alternative of food tolerances alone are self-contradictory and inadequate.

D. Impact of Alternatives to Food Tolerances Ignored.

In examining the alternatives to temporary tolerances for PCBs in food, the FEIS mentions two possibilities. FDA can refrain from promulgating any tolerance for food or declare any food containing PCBs illegal (FEIS 27). Again there is no discussion of the impact of either of these courses but merely a bare recital that "[t]hese alternatives would serve no useful purposes" (FEIS 28).

CONCLUSION

Lacking both depth and scope, the FEIS fails properly to appraise the environmental consequences of its proposed PCB order.

API's discussion of the statement's deficiencies is not intended to suggest that any single alternative must ultimately be adopted. It is intended to underscore NEPA's requirement that a thorough evaluation of all alternatives and their environmental impact must precede the regulatory choice which is made, particularly in light of the potential adverse effect on recycling. Until that is done, and opportunity for comment afforded, FDA cannot issue a valid order.

Respectfully submitted,

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