September 15, 1972

Mr. Robert C. Brandenburg
Acting Deputy Associate Commissioner
for Compliance
Department of Health, Education and Welfare
Public Health Service
Food and Drug Administration
Rockville, Maryland 20852

Dear Mr. Brandenburg:

The draft environmental impact statement, Notice of Proposed Rule Making, Polychlorinated Biphenyls which accompanied your letter of August 21, 1972 has been received by the Department of Commerce for review and comment.

The Department of Commerce has reviewed the draft environmental statement and has the following comments to offer for your consideration. We believe this statement should be redrafted and recirculated.

General Comments

1. Little or no discussion of the toxicological effects of PCB's on human health or the effects of PCB's on biota is included in the statement, making it very difficult to appraise the relevance of and basis for the PCB levels proposed. Information on these subjects should be added to the statement.

2. The rules as stated in the statement are incomplete. The time required for compliance, the testing to determine the presence of PCB's and the verification of the absence of PCB's has been omitted and should be included for comment. The 30 day period for compliance as stated in the Federal Register, Volume 37, No. 54 of March 18, 1972, will pose

MONS 093226

hardships to industry, especially if new equipment is required within this period. Further, it is unlikely that testing facilities and instrumentation are adequate to perform the work required by the rules in the necessary 30 day period.

3. While the general intent of the rules is clear, the omission of coatings and paints from food-packaging material establishments and food establishments may make the interpretation and enforcement of "the elimination of any other PCB-containing materials wherever there is a reasonable expectation that such materials could cause food to become contaminated with PCB's" difficult. The same circumstances may also occur because the rules do not clearly cover machinery for manufacturing, processing, storing and handling consistently for all three categories of establishments. Similarly, the statement does not address handling and storage for transportation and in-transit storage facilities or equipment.

4. While the environmental impact of the removal and disposal of PCB-containing materials is discussed, no indication of the need for or existence of rules controling removal and disposal is made in the statement. This issue should be addressed irrespective of FDA's jurisdiction of it.

5. The statement indicates that some materials which would replace PCB-containing materials would have similar characteristics to those of PCB's because of the use conditions. If it is implied that those replacement materials be subject to the Environmental Impact Statement review process this statement should clearly affirm or deny that implication.

6. In our judgment, this impact statement does not meet the NEPA requirement for "a detailed statement by the responsible official"; nor does it follow the format provided by NEPA. In particular, a cost/benefit analysis has been omitted. Not only is one required, but in this case, it is of

special importance because the impact statement contains no other economic or social information and the control of PCB's has potentially a considerable economic impact. Also, the health benefits have not yet been clearly established. A thorough and comprehensive cost/benefit rational and analysis should be included in the statement.

7. While the actions necessary to remove PCB's from equipment according to the proposed rules are reasonably clear, the discussion of the removal of PCB-containing materials from the waste recycling program is not clear or complete enough to appraise the effects of the proposed rules on industry. Some "carbonless" carbon paper may be being removed from the recycling process now, but the extent of that practice throughout that industry is not stated, nor is the effectiveness of that practice in reaching the temporary tolerance limit stated. 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. The actions by the recycling industry necessary to meet the proposed rules are in the main different from and more difficult than those the virgin paper industry must take. While the intent of FDA is not to propose rules detrimental to the waste recycling program, that in fact may very well be the effect. The impact statement should address recycling in depth to protect against any economic and hence function dislocation of this important conservation effort.

8. The statement does not discuss the temporal aspects of the temporary tolerances, nor the ways by which a "sufficient period of time to permit elimination of such (PCB) residues at the earliest practical time" is to be determined. These issues are components of the economic impact of the rules and information about the expected duration of the temporary tolerances and some definition of "sufficient" and "earliest practical time" should be included in the statement.

9. The rational for not establishing the PCB tolerance of the food itself described under Alternatives on page 16 is only valid because present information about the chronic toxicological effects of PCB's is not sufficient.

This alternative 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. It would further the development of not only new products but the development of new and improved tests and instrumentation as well as produce a better understanding of the chemical and physical composition and behavior of PCB's. Conversely, prescriptive restrictions on products ancillary to the real purpose of the proposed rules serve only to discourage the type of technological invention that a rule on the PCB tolerance of food would foster. A part of the rational for not setting food tolerances should be amended in the statement so that once toxicological effects are adequately determined, limits could be adjusted accordingly.

In summary, we believe the impact statement is not adequate for the type of balanced factual consideration expedited under NEPA and suggest that it be rewritten with more information and redistributed for comment.

Sincerely,

Sidney R. Galler
Deputy Assistant Secretary
for Environmental Affairs

MONS 093229