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Dr. Karl A. Hochschwender
American Hoechst Corporation
Route 202-206 North Bridgewater
Post Office Box 2500
Somerville, New Jersey 08876

Re: Polychlorinated
Biphenyls (PCB's)

Dear Karl:

You will recall that on March 18, 1972, there appeared in the Federal Register a Notice of Proposed Rulemaking which concerned itself with means for limiting the contamination of animal food, food, and food-packaging materials by polychlorinated biphenyls (PCB's), recognizing that some contamination was unavoidable because PCB's are so widespread throughout the environment. As you also know, the Society of the Plastics Industry filed Comments regarding the proposals through the Food, Drug and Cosmetic Packaging Materials Committee. Now, on Friday, July 6, 1973, the Food and Drug Administration has published a series of final orders on this matter. We are enclosing a copy of the new regulations which appear at 38 Fed. Reg. 18096-18103. We are also including the notice published at 38 Fed. Reg. 18104 regarding the availability of a supplement to the Final Environmental Impact Statement on this subject.

Of most direct interest is the new Part 122 which has been added to the Food and Drug Regulations entitled "UNAVOIDABLE CONTAMINANTS IN FOOD AND FOOD PACKAGING MATERIALS. Subpart B - Industrial Contaminants in Food and Food Packaging Material," and especially §122.10 which sets forth the temporary tolerances for polychlorinated biphenyls (PCB's).

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You will note that subparagraph (a)(1) through (a)(10) present the temporary tolerances for residue of PCB in various foods, animal feed components, and in paper food-packaging materials. The tolerance for the paper food-packaging material is set at 10 parts per million except that the tolerance will not apply to paper food-packaging material separated from the food by a functional barrier impermeable to migration of PCB's.

This final Regulation reflects the Comments that we filed urging that plastic food-packaging material be removed from the list of materials requiring the setting of a tolerance. However, we are fearful that some may misunderstand the significance of the preamble to the regulation which states in item 9(a):

> "The Commissioner agrees with this recommendation because there is no evidence to indicate that PCB's occur in plastic or other non-paper food-packaging materials as a result of unavoidable contamination. For this reason, no basis exists for establishing a tolerance under Section 406 of the Federal Food, Drug and Cosmetic Act for these articles. Therefore, the wording of §122.10(a)(9) is revised to apply only to paper food-packaging materials. This exemption means that no PCB's whatever may be present, either as a result of purposeful addition or industrial accidents, in plastic and other non-paper food-packaging materials. The provisions in the Statement of General Policy or Interpretation under Part 3, which prohibits the use of PCB-containing equipment and materials, are applicable to those establishments engaged in the plastic and other non-paper food-packaging materials." (Emphasis supplied.)

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First, it must be recognized that, while we do consider the somewhat strangely worded allusion to plastics and other materials in the nature of an unfortunate "FDA curve-ball," a preamble is not part of the Food Additive Regulations and will not appear in CFR or the other permanent regulatory codes which are published. Furthermore, it is our opinion that this statement must be taken in the context that although PCB's are unavoidable environmental contaminants, it is avoidable contamination that must be controlled. This means that the procedures set forth under Part 3, specifically §3.93, must be followed and every effort made to eliminate all use of PCB's in plants manufacturing plastic food-packaging materials except for the use of PCB's in electrical condensers and transformers containing PCB in sealed containers. With proper precautions to eliminate the possibility of contamination of plastic food-packaging materials as a result of industrial accidents, and, of course, the avoidance of the use of PCB's deliberately added to such materials, compliance with the Regulations will have been effected.

We realize that many of you could perhaps be faced with the problem of a customer who does read the preamble and then asks you for some type of assurance that no PCB's are present in any plastic food-packaging material that you supply. Should such an inquiry be received, our recommendation would be that you advise the customer about the fact that the Food and Drug Administration did not impose a tolerance on plastic packaging materials because it is not anticipated that PCB's will be found therein, and that you are complying with all good manufacturing practices requirements so that there is no reason to anticipate the presence of PCB's inasmuch as all potential sources for PCB contamination have been eliminated from your plant, and you do not employ potentially contaminated reprocessed materials (as is common in the paper industry). Thus, you can assume that there is no contamination from "purposeful additions or industrial accidents," which is all Section 9 requires.

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It should be noted that although these new Regulations provide a reasonable framework within which the plastics packaging industry may function, they do require that manufacturers and processors pay strict attention to good manufacturing practices so that avoidable contamination does not occur. Moreover, as has clearly been stated in the past, if problems are found to arise indicating that a tolerance for PCB in other food-packaging materials should be set, the Food and Drug Administration intends to do so.

The preamble discussed Comments that concern the use of a barrier between paper packaging material that contained PCB and the food that was packaged. This discussion appears in Section 9.d.(2), column 1, page 18100. The Food and Drug Administration has not endorsed any particular barrier material other than metal cans and glass bottles as "obvious examples." It has stated that it "would not object to the use of flexible materials...as barriers provided there is no evidence of migration of PCB's to the foods."

It is our opinion that it is the food packager who has the primary responsibility for complying with this requirement, but experience has taught us that the basic technical work will probably have to be done by the material suppliers. It is our further opinion that when tests have been conducted that demonstrate there is no reasonable expectation of migration of PCB from paper containing more than 10 parts per million of PCB into food through the barrier, such a barrier material would permit the use of paper packaging products under the exemption set forth in §122.10(a)(9).

If you have any questions about any aspect of this matter we hope you will not hesitate to contact us. In the meantime we believe the matter has been as satisfactorily resolved as possible and will remain so provided all parties exercise proper diligence.

Cordially yours,

cc: All Members of the SPI, Food, Drug and Cosmetic Packaging Materials Committee

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