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August 4, 1980

Route to:
John Caldwell
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To: SPI-Food, Drug and Cosmetic Packaging Materials Committee

Re: Polychlorinated Biphenyls; Current Good Manufacturing Practice Relating to Poisonous and Deleterious Substances in Food, Feed and Food-Packaging Materials Plants; Docket No. 80N-0128; SPI Comments

Ladies and Gentlemen:

In accordance with the instructions we received during the meeting of the Committee on June 11-12, 1980, we have prepared "draft" Comments setting forth SPI's objections to the subject Food and Drug Administration (FDA) proposed rule making. We have not addressed any Comments to the United States Department of Agriculture (USDA) and Environmental Protection Agency (EPA) proposals since these deal only with meat, poultry, or egg-producing plants (USDA), or pesticide plants (EPA). We are enclosing a copy for your review and suggested changes.

You will note that the objections to the regulation are based on the fact that they are:

(a) unnecessary since no food contamination problems have ever resulted nor are they likely to result as a consequence of contamination of plastics packaging materials by polychlorinated biphenyls (PCBs);

(b) the economic impact of implementing the regulation will be extreme although it is not feasible for SPI to estimate such a cost;

(c) the regulation is anti-competitive; and

(d) the regulation is unnecessary because current Food and Drug Administration (FDA) and Environmental Protection Agency (EPA) regulations are already in place to control any possible PCB problems that might affect plastics food-packaging materials.

After you have had an opportunity to review these Comments, we would welcome your suggestions and recommendations so that we can prepare a final version for presentation to the Agency in a timely fashion. We also suggest that, if your companies have not already done so, you file your own Comments with FDA and provide more specific estimates of your costs of complying with this regulation.

We would appreciate hearing from you about our draft before mid-September so we will have time for revising and circulating a final version. In the meantime, if any of you have any questions about any aspect of this matter, please do not hesitate to contact us.

Cordially yours,

Jerome H. Heckman

Enclosure

DRAFT

August 4, 1980

Before The
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Washington, D.C.

Current Good Manufacturing Practice Relating to Poisonous and Deleterious Substances in Food, Feed and Food-Packaging Materials Plants	Docket No. 80N-0128

COMMENTS OF
THE SOCIETY OF THE PLASTICS
INDUSTRY, INC.

Responsive to the Food and Drug Administration's (FDA) request for Comments on its proposed amendments to several of its regulations relating to the use of polychlorinated biphenyls (PCBs) in sealed electric transformers and capacitors used in or around food, feed, and food- and feed-packaging materials plants or storage facilities published on May 9, 1980, the following statement is submitted on behalf of the Food, Drug and Cosmetic Packaging Materials Committee of The Society of the Plastics Industry, Inc. (hereinafter called "SPI" or "The Society").*/

*/ The Society of the Plastics Industry, Inc. (SPI) is a Corporation organized under the Not-for-Profit Corporation Law of the State of New York. Its 1400 member companies and individuals and 49 operating units include those who supply raw materials, process or manufacture plastics or plastics products; engineer or construct molds or similar accessory equipment for the plastics industry; and engage in the manufacture of machinery used to make plastics products or materials of all types. SPI is the major national trade association of the plastics industry. The majority of its members are the processors and converters of plastic resins into end products which represent 75% of the dollar volume sales of plastics in this country.

I.

INTRODUCTORY STATEMENT

The roster of the Food, Drug and Cosmetic Packaging Materials Committee of SPI includes approximately 150 member companies, many of whom manufacture food- and feed-packaging materials made of plastics, and substances used in the manufacture of such packaging materials. To the extent that the proposed rules will be applicable to plants manufacturing food- and feed-packaging materials made from plastics, SPI and the Committee has a clear and direct interest in these proceedings. As will be set forth in more detail below, it is the Committee's and the Society's position that the subject proposal, insofar as it is applicable to food- and feed-packaging materials plants is so unreasonable and unnecessary, as to amount to an abuse of regulatory discretion.*/

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*/ Indus. Union Dep't v. Am. Petroleum Inst., Nos. 78-911 and 78-1036 (July 2, 1980), Mr. Chief Justice Burger, in his concurring opinion stated:

> Nevertheless, when discharging his duties under the statute, the Secretary is well admonished to remember that a heavy responsibility burdens his authority. Inherent in this statutory scheme is authority ro refrain from regulation of insignficant or de minimis risks. . . . When the administrative record reveals only scant or minimal risk of material health impairment, responsible administration calls for avoidance of extravagant, comprehensive regulation. Perfect safety is a chimera; regulation must not strangle human activity in the search for the impossible.

Slip. Op. at 2-3.

II.

PLASTICS PACKAGING MATERIALS DO NOT NOW AND NEVER HAVE BEEN IMPLICATED IN PCB CONTAMINATION OF FOOD SUPPLIES

Because of a justifiable concern about possible contamination of food and feed by PCBs, FDA has proposed that all PCB-containing electrical transformers and capacitors (containing more than three pounds of fluid dielectric) be removed from, in, and even about plants manufacturing packaging materials for food and feed.

It is well-known that certain types of paper food-packaging materials made from recycled stock were widely believed to present a PCB problem, one which was addressed in a rule making proceeding begun on March 18, 1972 (37 Fed. Reg. 5705) and essentially completed on July 6, 1973 (38 Fed. Reg. 18096). As we understand the matter, the situation which gave rise to the 1972-73 proceedings is now under control and no new problems of paper contamination by PCBs or any other source have arisen. In that same proceeding, FDA originally proposed to include a PCB residue tolerance on all packaging materials; however, in response to SPI's Comments, the Agency agreed that there was no evidence to indicate that PCBs occur in plastics or other non-paper food-packaging materials as a result of unavoidable contamination. Consequently, we are at a loss to understand why FDA, in the present proposed regulation, has decided to include plants manufacturing food- and feed-packaging materials from plastics, there being no indication that contamination of

plastics packaging materials with PCBs leading to food contamination has occurred in the seven years since the final regulation was promulgated.

If the proposed rule placed a relatively minor burden on the plastics packaging manufacturing industry, there might be less reason to submit these Comments. Since the proposal has not been, nor can it be, justified on the basis of any actual or even hypothetical*/ public health need, the enormous cost of compliance becomes a major concern to the industry. A consideration of the structure of the plastics food-packaging materials industry and the economic consequences of the proposed regulation is set forth immediately below.

III.

THE PLASTICS FOOD PACKAGING MATERIALS INDUSTRY INVOLVES A CHAIN OF MANUFACTURING OPERATIONS ALL OF WHICH WOULD BE SUBJECT TO THE PROPOSED REGULATION

Basic chemicals are reacted to form polymeric materials. These polymers are generally manufactured on a large-scale at a relatively few locations and are intended for a wide variety of end-use applications including--but by no means limited to--food- and feed-packaging materials. The

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*/ Significant contamination of plastics packaging materials to the extent that migration of PCBs to food or feed packaged in such material would be a public health problem is highly unlikely. The presence of even small quantities of a foreign substance such as PCB in plastics packaging materials would almost inevitably be apparent during the ordinary quality control procedures employed in the manufacture of such materials. The presence of PCBs at a significant concentration would affect the color, clarity, mechanical properties and other characteristics of the finished polymer.

basic polymers are then mixed, i.e., compounded, with a variety of substances used to modify the characteristics of the polymer and provide desired characteristics to the end-products. These operations are more widely dispersed than the manufacture of the basic polymer, although some basic polymer manufacturers do, in fact, compound their products. Some polymers are formulated with the intention that they be used for food- and feed-packaging, whereas others are compounded for general purposes that may include food- and feed packaging. Still other products are formulated in the same facilities for end-uses that do not include food- and feed-packaging materials. At the next step in the sequence, the formulated polymeric materials are shaped into end-products including containers, sheet and film. These may be used as formed or may be subsequently reshaped to form the products used in the packaging industry. Here again, many of the products are designed for general purpose applications, some of which may include but are not limited to food- and feed-packaging. The number of such plants that manufacture plastics end-products that may be used for food and feed manufacturing is quite large. Finally, only some of these finished products are sold to actual food and feed manufacturers who use them for packaging their products.*/

The number of processors that manufacture packaging materials is quite large and is not accurately known. It is estimated that there may be as many as 50,000 such firms. Inasmuch as many of them are not members of

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*/ To further complicate the picture, some food or feed manufacturers purchase compounds and manufacture, in-house, their own packaging materials.

SPI, it is impossible for The Society to accurately survey the industry and attempt to develop an estimate of the overall costs of removing and replacing or refilling electrical transformers and capacitors in or about their premises. Although SPI cannot make an estimate of the overall cost of compliance with the completely unnecessary proposed requirement, we expect that individual manufacturers of food- or feed-packaging materials may supply estimates of their own costs which will provide a basis for the Agency to calculate or at least estimate the overall cost.

It is clear, however, that these numerous small businesses will be severely affected if the proposed regulations are promulgated. All use electrically powered equipment so several transformers or capacitors must be present in every such plant. In many cases, the owners of these small enterprises do not know whether their transformers or capacitors contain PCB fluids, nor can they readily (and safely!) make this determination on their own. In any case, the cost of compliance would be a major burden for many of these small concerns. To the extent that the extra costs will force some to withdraw from the processing of plastics into food- and feed-packaging materials, the proposed regulation will be anti-competitive and could foster a trend toward increasing concentration of the industry into fewer of the larger companies.

In light of the lack of a clear definition of a food- or feed-packaging materials plant in the proposed new regulations, the cost of compliance will be still further magnified. Since the manufacturers of monomers and polymer additives are making materials which may ultimately be included in food-pack-

aging materials, are their plants subject to the regulation? As to compounders who provide formulated plastics for a variety of products--only some of which may include food-packaging materials--are their plants covered by the proposed regulation? Are the processors who make general purpose packaging materials--some of which may be used for food-packaging purposes--covered by the proposal, even though most of their products are not used for food-packaging? In short, does not this loosely written and completely unnecessary regulation assert FDA jurisdiction over so broad a universe as to make it patently irrational?

IV.

CURRENT EPA REGULATIONS NOW CONTROL THE PCB PROBLEM AS IT RELATES TO PACKAGING MATERIALS

Not only has FDA failed to document the need for the proposed regulation, another federal agency has--in fact--regulations in place to deal with the overall problem of environmental contamination by PCBs, the only potential problem associated with the use of PCB in electrical equipment in plastics plants. The present regulations of the Environmental Protection Agency would appear to be adequate for the purpose. They also provide for a reasonable phase-out of electrical equipment containing PCBs in an orderly fashion, instead of the dangerous and completely unnecessary FDA proposal that all PCB-containing transformers and capacitors (except capacitors containing less than three pounds of fluid) used or stored in or around such establishments be

preciptously replaced or removed, or that the PCB fluid in the transformers be replaced forthwith.

V.

CONCLUSION

Section 109.15 of FDA's regulations already provides for the removal from establishments manufacturing food-packaging materials of PCB heat exchange fluid, or any other PCB-containing equipment, machinery and materials where there is a reasonable expectation that PCB contamination of food-packaging materials could result. Inasmuch as no evidence has been provided to justify further controls, SPI urges that the proposed § 109.15 amendments be withdrawn in their entirety allowing the presently effective regulation to remain unchanged.

Respectfully submitted,

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

DRAFT

By _____

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