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October 10, 1972

Hearing Clerk
Department of Health, Education
and Welfare
Room 6-88
5600 Fishers Lane
Rockville, Maryland 20852

Re: Food and Drug Administration
"Proposal Regarding Regulation
of Prior Sanctioned Food In-
gredients"; 37 Fed. Reg. 16407

Dear Sir:

Pursuant to Section 4 of the Administrative Procedure Act, as amended, 5 U.S.C. §553(c), and the referenced Food and Drug Administration Notice of Proposed Rulemaking published on August 12, 1972, The Society of the Plastics Industry, Inc. (SPI), by its attorneys, and acting through its Food, Drug and Cosmetic Packaging Materials Committee, 1/ hereby

1/ The Society of the Plastics Industry, Inc. (SPI) is a Corporation organized under the Membership Corporation Law of the State of New York. It is composed of approximately 1200 member companies and individuals 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, its membership being responsible for an estimated 75% of the total dollar volume of sales of plastics in this country. The Food and Drug Administration is quite familiar with the constitution and activities of the Society as a result of our many filings and participation in other proceedings of direct consequence to plastics producers. Copies of SPI membership directories, organization charts, (con't.)

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respectfully submits its views with regard to the above-designated proposed amendment to Part 121 of the Food and Drug Administration's Regulations.

I
INTRODUCTION AND PRELIMINARY
STATEMENT OF POSITION

The Society is in general agreement with the intent of the subject proposal. We believe it is both helpful and appropriate to publicly list those materials for which prior sanctions have been issued subject to the expressed understanding that the absence of a material from listing under Subpart E of Part 121 does not affect the prior sanctioned status of such a material. Furthermore, the Society is proposing that Subpart E of Part 121 be further amended to include those resins which have been listed as prior sanctioned on pages 2 and 3 of the SPI Bulletin "Good Manufacturing Practices" Criteria for Plastic Resins "Prior Sanctioned" Under the Food Additives Amendment of 1958, March 1963, a copy of which is attached.

Furthermore, we respectfully submit that this is an appropriate time to amend the nomenclature of one resin and one plasticizer which appeared first in the referenced Lehman list and were then carried over to the list of resins in the attached SPI Bulletin, or in the present Regulation 121.2001(E). We are not proposing here that new substances be added to the prior sanction list; but rather that the published names of two listed substances be changed to conform to present standards of scientific nomenclature.

Finally, we believe it would further the purposes intended by the subject proposed rulemaking if the Food and Drug Administration were to add to the proposed publicly affirmed prior sanction list the widely used basic resin styrene-acrylonitrile copolymer (SAN).

^{1/}(con't) and the like have been supplied to FDA in connection with some of these filings. Any further background information desired can be supplied immediately upon request by the Food and Drug Administration.

II
ABSENCE FROM LISTING MUST NOT
AFFECT PRIOR SANCTION STATUS

Section 201(s) of the Federal Food, Drug and Cosmetic Act excludes from the definition of "food additive," and therefore excludes from the requirement that food additives be regulated, "[a]ny substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph..." Inasmuch as the Act does not require that this prior sanction or approval be confirmed or published by the Food and Drug Administration, we believe that the exempt status under Section 201(s) cannot properly be affected by publication as set forth in the proposed rulemaking. Accordingly, in the interest of clarifying the status of all such materials, we propose that §121.2000 General be amended to include a new subparagraph to be lettered (b) and relettering the present (b) as (c) as follows:

§121.2000 General

* * *

(b) The prior sanction status of Food ingredients will not be affected under Section 201(s) of the Act merely by virtue of such ingredient not being listed in Subpart E of Part 121.

* * *

III
INCLUSION OF RESINS LISTED
AS PRIOR SANCTIONED BY SPI

Shortly after the enactment of the Food Additives Amendment of 1958, and in response to a widely felt need in the plastics industry, SPI published a Bulletin defining "good manufacturing practices" for polymers. These criteria were compiled for those resins which were published in the

widely disseminated Lehman list.^{2/} These resins, with the exception of polyethylene, were reaffirmed as "prior sanctioned" by the Food and Drug Administration in a letter dated July 22, 1960. A copy of this letter is included in the Bulletin which is attached to these Comments. Since the list on pages 2 and 3 of the Bulletin has not only been affirmed but has also been widely referenced by the Food and Drug Administration in the years subsequent to 1958 as a listing of prior sanctioned resins, we believe it is prudent at this time to propose formally that all the resins listed in the Bulletin on pages 2 and 3, and conforming to the end characteristics set forth in the Bulletin, be listed in the proposed Subpart E; §121.2xxx.

At the time Dr. Lehman published his article, the resin known commercially as Saran was popularly, but somewhat inaccurately, considered to be polyvinylidene chloride. When the SPI Bulletin was prepared, his terminology was maintained, and "Polyvinylidene Chloride" is listed as item 5 in the SPI Bulletin. However, the resin then and now was and is a vinylidene chloride-vinyl chloride copolymer and is more properly designated as poly(vinylidene chloride-co-vinyl chloride). Accordingly, The Society of the Plastics Industry respectfully submits that item 5 in the list of resins which is now being proposed for inclusion in the proposed Subpart E, be amended to correct the nomenclature without any change in the listed end characteristics, as follows:

5. Poly (vinylidene chloride-co-vinyl chloride) 7

IV
PROPOSAL TO LIST
POLY(STYRENE-CO-ACRYLONITRILE)

Subsequent to the publication of the Lehman list, but prior to the enactment of the Food Additives Amendment of 1958, several chemical companies

^{2/} Lehman, A.J., Quart. Bull. Assn. Food and Drug Officials of the United States, XX, No. 4, p. 159-168, October, 1956.

submitted data regarding Poly (styrene-co-acrylonitrile) (SAN) to the Food and Drug Administration and requested its opinion regarding the safe use of this resin. The FDA agreed that the use of SAN as a food wrap was safe, and a sample of its letters which constitutes a prior sanction is attached.

Accordingly, The Society of the Plastics Industry respectfully submits that the proposed Subpart E, §121.2xxx be further amended to include:

* * *

§121.2xxx Poly(styrene-co-acrylonitrile)
Total residual monomer is primarily styrene and is less than 0.6% as determined by a method for residual styrene monomer as given in §121.2510(d).

V

CHANGE OF PLASTICIZER NOMENCLATURE

As evidenced by the exchange of correspondence between the Food and Drug Administration and The Dow Chemical Company, copies of which are attached for ease in reference, it appears that the name of the plasticizer which is presently listed in Regulation §121.2001(E) as 3-(2-Xenoyl)-1,2-epoxy propane should be amended to more accurately conform to the usage prescribed by Chemical Abstracts. Accordingly, The Society of the Plastics Industry, Inc. respectfully submits that the name of the plasticizer be changed from that quoted above to: 3(2-xenoxy)-1,2 epoxy propane.

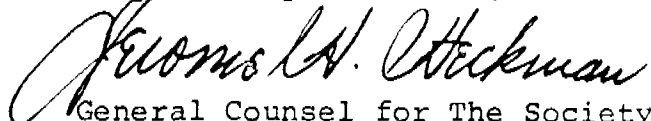
VI

SUMMARY

The Society of the Plastics Industry, Inc. urges the adoption of the subject proposal in substantially the form set forth but respectfully submits that it would more readily achieve its intended

purpose by including the amendments explicitly proposed in Sections II, III, IV and V above.

Respectfully submitted,


General Counsel for The Society
of the Plastics Industry, Inc.

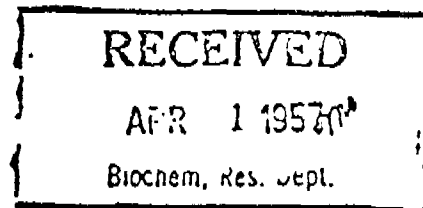
Of Counsel:

Keller and Heckman
1150 17th Street, N.W.
Washington, D. C. 20036

DEPARTMENT OF
HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON 25, D. C.

March 27, 1957

The Dow Chemical Company
Attention: Mr. D. D. McCollister
Biochemical Research Department
12-634 Building
Midland, Michigan



Gentlemen:

Your letter of March 15, 1957, addressed to Mr. L. L. Ramsey, has been referred to us for reply.

Relying on the data and information you have submitted, we agree that Styrex 767 (a copolymer of styrene and acrylonitrile) is acceptable as a packaging material involving direct contact with foods.

Sincerely yours,

Chester T. Hubble
Assistant to the Director
Bureau of Enforcement

ASI-PR 0001260