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October 26, 1972

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

Re: Proposal for Use of Colorants
for Plastics (37 Fed. Reg. 11255)

Gentlemen:

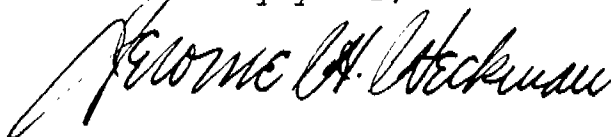
As you know, the Society of the Plastics Industry, Inc. filed Comments on August 4, 1972 with the Hearing Clerk in connection with the subject proposed rulemaking. One of our members has since called to our attention that the Comments may be somewhat ambiguous and has requested that we supplement those Comments with a clarifying statement.

The enclosure represents a draft of the supplementary statement which we have prepared and which, we hope, is self-explanatory. After you have had a chance to consider it, we would appreciate your comments and recommendations as to whether to file it; and/or if any changes are required.

As you know, the time for Comments on the proposed Regulation has been extended to November 13, 1972. Accordingly, I would appreciate receiving your recommendations no later than November 9 so that we can prepare a final version of the supplementary statement for timely submission to the Hearing Clerk.

If there are any questions about the need for, the substance of, or any other aspect of this draft, we hope you will feel free to contact us.

Cordially yours,



Enclosure

ASI-PR 0001240

DRAFT

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

Re: Proposal for Use of Colorants
for Plastics (37 Fed. Reg. 11255)

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 June 6, 1972, The Society of the Plastics Industry, Inc. (SPI), by its attorneys, and acting through its Food, Drug and Cosmetic Packaging Materials Committee, submitted its views with regard to the above-designated proposal in a set of Comments dated August 4, 1972. In a subsequent notice (37 Fed. Reg. 18562) the time for filing Comments was extended to November 13, 1972.

In general, the Society remains committed to all of the views we expressed on August 4 and once again urges that they be given favorable consideration. It has, however, been indicated to us that one aspect of our said Comments may not have been altogether clear and explicit; thus, we are hereby supplementing the previous statement as follows.

On August 4, we recommended, inter alia, that if the Food and Drug Administration deems it essential to set forth

the names of specific colorants as proposed, such listings should be amended to delete the limitations for use with specific polymers, and the regulations should provide for the publication of suitable analytical methods. It was intended that the portion of these comments that concerned limitations as to the polymers with which the colorants could be used should apply to all those colorants that carried such a limitation. Likewise, the portion of the comments that concerned analytical methods should apply only to chromium oxide green, phthalocyanine green, and quinacridone red since only these colorants carried migration limits.

These latter three colorants are widely used with many plastics and the safety of such use is assured by the extremely limited solubility of the colorants in foods, by the very limited contact between the colorant in the plastic and the food contained in the package, and by the chemical inertness of the colorants.

If, however, FDA persists in the view that limitations on the quantity of the colorants that might enter the diet are required, SPI suggests that proper limitations should be related to what might theoretically become a component of foods. Thus, there is no logical reason whatsoever to restrict the use of these valuable and technologically necessary colorants to use with specifically enumerated plastics providing the quantity extracted by suitable tests is sufficiently

low to protect the public health and safety. To do otherwise would probably lead to the filing of many food additive petitions to extend the range of polymers with which these colorants could be used. This would place an additional and unnecessary burden upon both the industry and the Food and Drug Administration with no benefit to the public since the safety of these non-migratory colorants when used in food contact plastics is not in doubt.

In summary, and merely clarifying the statement set forth in the next-to-last paragraph of the SPI's August 4, 1972 Comments, if the Food and Drug Administration does not adopt the recommendations set forth on pages 6 and 7 of the said filing, the Society recommends that the limitations set forth in the proposed regulation be amended to omit all mention of the specific plastic materials in which the colorants may be used, and to provide only such limitations on the amount extracted by a suitable test procedure as is required to assure the safe use of these materials.

Respectfully submitted,

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

Of Counsel:

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