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January 25, 1974

Hearing Clerk
U.S. Department of Agriculture
Washington, D.C. 20250

Re: Labeling and Official Marks of
Inspection; Proposed Rule Making,
38 Fed. Reg. 26455, September 21,
1973; Extension of Time for Comments,
38 Fed. Reg. 32813, November 28, 1973.

Dear Sir:

Pursuant to Section 4 of the Administrative Procedure Act as amended, 5 U.S.C. §553(c), and the referenced Animal and Plant Health Inspection Service Notices of Proposed Rule Making and Extension published on September 21 and November 28, 1973 respectively, The Society of the Plastics Industry, Inc. (SPI), ^{1/} by its attorneys, hereby respectfully submits its Comments with regard to the above-designated proposed amendment to Part 381 of the Animal and Plant Health Inspection Services Regulations with respect to the inspection of poultry products. In so doing, SPI is directing its attention solely to the proposed new §381.142 of the proposed rules on containers, since

^{1/} 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. It is composed of approximately 1200 member companies and individuals who supply raw materials;

such containers are often made in whole or in part from plastics materials. SPI concurs with the over-all intent of the proposed rules for poultry containers, that is, to assure that such containers shall not result in the adulteration or misbranding of the product. However, The Society of the Plastics Industry respectfully submits that the aforementioned Section as now written is unduly and perhaps unintentionally restrictive since it would bar the use of many materials as poultry containers, or parts of such containers, which are now presently employed for poultry packaging and which are completely safe and suitable for the purpose.

I.

INTRODUCTION AND STATEMENT OF POSITION

The proposed §381.142 states in pertinent part "Container composition shall comply with Section 409 of the Federal Food, Drug and Cosmetic Act, as amended, and the implementing

1/ (con'd.) 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 and the Department of Agriculture are 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, and the like have been supplied in connection with some of these filings. Any further background information desired can be supplied immediately upon request by the Department of Agriculture.

regulations in 21 CFR 121, Subparts B, E, and F." (Emphasis supplied.) SPI agrees that containers should comply with Section 409 of the Federal Food, Drug and Cosmetic Act, as amended, to the extent that such containers are or contain food additives. However, many containers and/or some of their components, are not food additives as defined by the Act.

Specifically, Section 201(s) of the Food, Drug and Cosmetic Act defines the term "food additive" in pertinent part as "...any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food..., if such substance is not generally recognized, ...to be safe under the conditions of its intended use; except that such term does not include...(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following)..."

In other words, food additives must comply with Section 409 of the Act, but materials which may not reasonably be expected to become components of the food, materials which are generally recognized as safe (GRAS), or materials which have

been the subject of a prior sanction are not food additives under the Federal Food, Drug and Cosmetic Act. Thus, by restricting containers and container materials to substances which comply with Section 409 of the Act and more specifically to those listed in Subparts B, E, and F of the Food Additives Regulations set forth in 21 CFR Part 121, the U.S. Department of Agriculture could be excluding all those materials which are presently used because they do not become components of the packaged food and thus, are not the subject of a Food Additive Regulation in Subpart F, or materials which are "GRAS" and prior sanctioned, but are not listed in Subpart B and Subpart E of the Food Additive Regulations.

The Food and Drug Administration has recognized that packaging materials may be used without their even being classified as "food additives" under the Statute. Thus, Section 121.1(e) of the Food Additive Regulations defines a food additive in pertinent part in the following terms: "A material used in the production of containers and packages is subject to the definition [as set forth in Section 201(s) of the Act] if it may reasonably be expected to become a component, or to affect the characteristics, directly or indirectly, of food packed in the container...[I]f there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive."

The current validity of this statement has been reaffirmed in a letter by Thomas W. Brown, then Director Office of Compliance, Bureau of Foods, Pesticides and Product Safety, of the Food and Drug Administration. This letter dated August 21, 1970, and appended hereto for ready reference, states in pertinent part "it is our position, as regards such substances, that if a food manufacturer, or his food packaging supplier(s) has migration data which establishes that there is no reasonable likelihood of migration to food, he need not seek confirmation of his decision from the Food and Drug Administration that the packaging material is not a food additive." (Emphasis supplied.)

With respect to GRAS substances, it should be noted that Subpart B of the Food Additives Regulation does not list all such substances. Indeed, Section 121.101(a) of Subpart B states in pertinent part "it is impractical to list all substances that are generally recognized as safe for their intended use...the lists in paragraph (d) of this section include additional substances that, when used for the purposes indicated, in accordance with good manufacturing practice, are regarded by the Commission as generally recognized as safe for such uses." It should be noted that these "additional" substances are those which are referred to in the proposed §381.142

as "implementing regulations in 21 CFR 121, Subpart B..."

Furthermore, Section 121.3 of the Food Additives Regulations provides a means for determining the eligibility of a substance to be classified as GRAS and provides in 121.3(b)(1) criteria for substances that will be considered as GRAS and for which publication in the Federal Register is not required. Thus, it is explicitly recognized that some substances are recognized as GRAS even though they are not explicitly listed as such. Still further, Food Additive Regulation 121.40 provides a procedure whereby the GRAS status of materials may be affirmed by the Commissioner, either on his own initiative or on the initiative of a petitioner. It should be noted, however, that this Regulation merely provides a means whereby the Food and Drug Administration can affirm the GRAS status of substances -- the status itself exists independently of whether or not the affirmation of the status has been requested.

With regard to prior sanctioned substances, the Food and Drug Administration and the U.S. Department of Agriculture have provided such approvals to individual companies for specific products. Some of these products, but certainly not all, are generically listed in Subpart E of the Food Additives Regulations. Nevertheless, the Federal Food, Drug and Cosmetic Act explicitly exempts from the definition of food additive, all those substances for which prior sanctions have been granted. The effect of the proposed §381.142 would be to bar

the use of prior sanctioned materials that are not listed in Subpart E of the Food Additive Regulations even though they are explicitly permitted by the Food, Drug and Cosmetic Act. Many more materials are unlisted than are listed. (cf. Food Chemical News Guide, published by Food Chemical News, Inc., Washington, D.C.)

Since the prior sanctions have almost always been addressed to specific products of inquiring companies, many such prior sanctioned materials are not included in Subpart E which lists materials only generically. In this connection it should be noted that §121.2000(a) of Subpart E recognizes the existence and validity of unpublished prior sanctions by stating "...The Commission will publish in this subpart all known prior sanctions. Any interested person may submit to the Commissioner a request for publication of a prior sanction, supported by evidence to show that it falls within section 201(s)(4) of the Act."

II.

RECOMMENDED AMENDMENT TO §381.142

In light of the foregoing discussion, The Society of the Plastics Industry, Inc. respectfully suggests that the proposed §381.142 be amended beginning with the fourth sentence to read as follows:

"Containers shall be composed of materials
which are generally recognized as safe (GRAS),

which are subject to a prior sanction and are used in accordance with such prior sanction, which are not reasonably to be expected to become components of food under the intended conditions of use, or, if they are or contain food additives, are used in accordance with applicable Food Additive Regulations as set forth in 21 CFR 121."

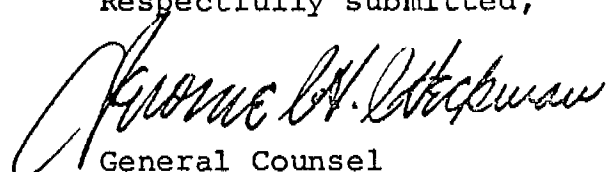
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We respectfully submit that the public health, safety, and economic welfare will be more properly protected by the adoption of Section 381.142 in substantially the form proposed herein. Adoption of the Regulation as presently proposed would create great confusion at least, could necessitate extensive and expensive reformulation of many hitherto acceptable packaging materials for no sound scientific reason, and would provide no additional safeguards vis a vis public health and safety.

Respectfully submitted,


General Counsel
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