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June 10, 1974

Hearing Clerk
Department of Health, Education
and Welfare
Food and Drug Administration
Room 6-86
5600 Fishers Lane
Rockville, Maryland 20852

Re: Substances in Food Contact Articles in the Household, Food Service Establishments, and Food Dispensing Equipment; Food Additive Status (39 Fed. Reg. No. 72, pps. 13285-13287)

Dear Sir:

Responsive to the above-referenced Food and Drug Administration Notice of Proposed Rulemaking published on April 12, 1974, The Society of the Plastics Industry, Inc. (SPI), by its attorneys, and acting through its Food, Drug and Cosmetic Packaging Materials Committee,[1/] hereby respectfully submits its views with

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 1400 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 (cont'd

regard to the proposed amendment to Part 121 of the Food and Drug Administration's Regulations which would add Section 121.14 thereto.

I
Statement of Position

1. It is the position of The Society of the Plastics Industry, Inc. that the instant proposal, the avowed purpose of which is to do away with what has become known colloquially as the "housewares exemption" from the coverage of the Food Additives Amendment of 1958, is:

(1) Ill-conceived and far too broadly framed to accomplish what might otherwise be a worthwhile objective;

(2) Would, if adopted, violate basic precepts of statutory construction and defeat a clearly stated Congressional intent;

(3) Broaden FDA regulatory authority so as to make the law, and particularly the Food Additive Regulations, even

/ (cont'd) 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, 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.

more unenforceable in any way that could remotely be considered clear and even-handed;

(4) Bring within regulatory, and hence, questionable legal status a host of products never intended by Congress to be regulated by FDA; and

(5) Leave wholly unanswered a fundamental question which urgently requires definition and yet has remained unanswered for at least the past thirteen or fourteen years, while making it appear that this question is a simple one that will effectively delimit the application of the instantly proposed rule. [This question, of course, is the one of when FDA will move forthrightly, publicly and definitively to state the premises upon which a potentially affected party can confidently conclude in good faith that, under specified intended conditions of use, a substance may not reasonably be expected to become a component of foods and, hence, is not a Food Additive so that it need not be dealt with through the cumbersome, expensive and inordinately time consuming Food Additive Petition-Regulation Promulgation process.]

2. It should be clearly understood that the Society does not take issue with the Food and Drug Administration's desire to prevent food contamination by substances such as lead or similar known toxic materials. We respectfully submit, however, that this objective can be achieved by much more pin-pointed rulemaking or selective enforcement action than is being proposed here. FDA could easily and effectively accomplish its aims by use of its

considerable voluntary recall or involuntary seizure powers to bar such known toxic substances from use in dinnerware or cooking utensils when occasions so require, rather than cast doubt on the status of a host of materials and products which have never created a problem and are simply not worthy of the kind of government and industry cost and effort that always accompanies full-scale Food Additives Petition treatment.

3. Finally, yet perhaps most significantly, great exception is taken to a wholly misleading inference spread throughout the preamble to the Section 121.14 proposal, and included in the Section itself, this inference being that it is a simple matter to decide when a substance is not subject to FDA regulation because it may not reasonably be expected to become a component of foods. Were it in any realistic sense true that the Food and Drug Administration had some recognized and known criteria which would enable any interested party to determine when a substance may be considered a non-migrant, ergo a non-additive, the instant proposal would still be in direct conflict with our view of Congressional intent but might not be considered of such great consequence, or so unreasonable. The fact is, however, that in actual practice the FDA Staff will seldom agree that

anything which might contact food in any way need not be considered a food additive because it may not reasonably be expected to become a component of food.[2/] So long as this situation remains fluid and undefined, and the persistent nemesis which it has been since at least 1960, it is our view that rulemakings like the instant one should be abandoned in favor of realistically narrow proposals, or enforcement action where a true health hazard is presented.

2/ Indeed, at one time, the then Deputy Commissioner of FDA, John L. Harvey, candidly stated in an address given at Rutgers University on January 18, 1962 that: "...if there [is] enough reason to run extraction studies on packaging or equipment materials, why shouldn't it be concluded that it would be reasonable to expect that the substances involved would, in fact, become a part of the food? Since the law refers to 'reasonably to be expected' we then began to advise those who asked that we were not in a position to give them a letter which would absolve their product from any responsibility from under the Food Additives Amendment but instead suggested that they file petitions. That is the present status of this item." (Emphasis supplied.) Harvey, Food Additives and Regulations, 17 Food, Drug Cosmetic Law Journal 275 (April, 1962.)

In theory this almost unbelievable legal conceptualization has been abrogated by subsequent informal communications such as the so-called "Tom Brown Letter" of August 21, 1970, a copy of which is attached hereto as Appendix A. Despite the existence of this letter and other pronouncements by the Assistant General Counsel, Food, Drugs and Environmental Health Division, of the Department of Health, Education and Welfare, Mr. Peter Barton Hutt, in specific cases, the fact is that there is no clear Food and Drug Administration policy or quantitative guideline to steer those who must make decisions on when a food additive problem is at hand or not.

II

The Food and Drug Administration's Contention That the Legislative History of the Food Additives Amendment of 1958 Does not Support the So-called "Housewares Exemption" is Erroneously Premised, Requires Specious and Circuitous Argumentation, and Ignores Well Accepted Principles of Legislative Interpretation

4. As is conceded in the April 12 notice published in the Federal Register, during the floor debate on the Food Additives Amendment of 1958, the Congressman who chaired essentially all of the hearings leading to the enactment of the law, and the Floor Manager for the Food Additives Bill, H.R. 13254, Mr. John Bell Williams, stated without equivocation that the bill was "not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils." We respectfully submit that it is entirely specious to argue away from Mr. Williams' statement, ignore the emphasis on the terminology "for example" and some 16 years later revise a legislative interpretation so as to expand the Food and Drug Administration's powers over articles of commerce, many of which might present only the remotest possibility of adding any component to foods.

5. In the April 12 notice of proposed rulemaking FDA has set forth various rationales to justify expansion

of its statutory authority; nevertheless its conclusion is in direct contradiction to the legislative intent underlying passage of that part of the 1958 Food Additives Amendment relevant to indirect additives. The fact is that Congressman Williams clearly sought to explain in part what was meant by the implied exclusion in the law as to food contact articles not reasonably expected to become components of food when he said, and we repeat for emphasis:

> "This bill is not intended, for example, to give the Food and Drug Administration authority to regulate the use of components in dinnerware or ordinary eating utensils." [Congressional Record, 104:17418.]

6. In statutory interpretation, it is a well-recognized principle that legislative intent must be recognized. The Supreme Court in U.S. v. Congress of Industrial Organizations, 68 S. Ct. 1349 (1948), held that the purpose of Congress is the dominant factor in determining the meaning of a statute, while another federal court in Gruver v. Commissioner of Internal Revenue, 142 F. 2d 362 (4th Cir. 1944) held that statutory terms of variable meaning must be construed in harmony with legislative purpose. In another case, it was held that in determining whether a situation is within the purview of a

statute, the court is to put itself, so far as it can, in the position of the Congress that enacted it and decide whether or not the Congress would have declared the situation was covered by the statute, Calley v. U.S., 272 F.2nd 443 (2d. Cir. 1960).

7. Further, it is clear that the scope of a statute is not to be expanded by an overly broad interpretation. Thus, in Commissioner of Internal Revenue v. McGuire, 111 F.2d 843, 845[3/] (7th Cir. 1940), the Court stated:

> "...where language is used [in the statute] which admits of more than one meaning, it is to be taken in such sense as will conform to the scope of the act and carry out the purpose of the statute, being mindful, however, that it is not permissible under the pretense for interpretation to make a law, either by extension or restriction, which shall depart from legislative intent. In such a situation, resort to aids outside the language itself is necessary." [Emphasis supplied.]

8. The language of these cases is wholly apt here where a very specific statement made at the time of the law's enactment leaves no real doubt of the intent to exclude housewares and similar articles from the general provisions of the Williams Amendment. In the face of the

3/ Affirmed 61 S.Ct. 789, rehearing denied 61 S.Ct. 936.

patently stated exclusionary intent of Congress, FDA's contrary argument can only be characterized as tortured and specious.

9. It is strangely based in part upon use of the "incidental additives" definition, which includes in the coverage of the Act those substances "which may reasonably be expected to become a component of any food." FDA argues that housewares may be sources of substances that become components of food. It is true that the "incidental additive" definition is directed towards the destination of the additives, i.e. whether they might become a component of food or not, rather than the source of additives. It is also true that the statute is silent as regards the source question generally but it is submitted that the silence in the case of housewares was very effectively and intentionally broken on the Floor of the House. In such situations of statutory silence or ambiguity, resort must be made to clear evidence of legislative intent. Here Congressman Williams' statement in the Congressional Record, which certainly constitutes a firm statement of intent, specifically exempts housewares from coverage.

10. FDA also argues that were it the intention of Congress to exempt housewares, it would have done so by

specifically enumerating housewares in the list of exemptions in Section 201(s) of the Act. However, housewares as an "item" are not in the same vein as the other items excluded under Section 201(s) of the FDA statute. All of the exemptions listed in that Section are either enumerated by allusion to scientific precepts, or covered by another federal statute or by different sections of the Food, Drug and Cosmetic Act. Thus, the exemption list in 201(s) would have been an inappropriate place to list housewares (unless the Consumer Product Safety Act had been law at the time) and FDA's attenuated reliance on the absence of housewares in the 201(s) exemption list is inapt.

III

There is no Need for the Food and Drug Administration to Adopt the Instant Rulemaking Since its Other Considerable Powers Can be Used to Deal With any Public Health Hazard Presented Without Forcing a Preclearance Procedure on Innocuous Substances or Products

11. As is indicated in the preamble to the proposed new Section 121.14, "FDA has for several years conducted a widely publicized regulatory program against... products" like migratory substances in pottery, dinnerware, enamel ware or pewter. To the best of our knowledge,

this program has been or could have been conducted under the virtually plenary powers given FDA under the provisions of Section 402 of the Federal Food, Drug and Cosmetic Act, as amended, to proceed in situations where hazards to public health are concerned. This section makes it quite clear that FDA has the power to seize foods which are adulterated and industry has conceded, as a practical matter, that this power may reasonably be exercised so that FDA can order recalls or seize any food contact materials where there is a valid reason to believe that the same will add a poisonous or deleterious substance to foods.

In light of the general effectiveness of this approach, it is difficult to understand why further authority is now needed. At the very least, if such authority is truly required, taking into account the broad powers given the Consumer Product Safety Commission relative to all types of articles intended for household use, the Food and Drug Administration should seek the authority it believes it requires from Congress instead of arrogating such power in a rulemaking proceeding which is so obviously extra-statutory.

12. On this ground also, it is submitted that the instant proposal is unnecessary, illegal in conception, and should be abandoned forthwith.

IV
The Adoption of the Proposal Will Further Complicate and Confuse Statutory Interpretation, Disrupt Important Commercial Relationships, and Perpetuate a Basic Regulatory Dilemma Which has Been Widely Discussed While Remaining Unresolved Since Shortly After the Enactment of the Food Additives Amendment of 1958

13. Once again, a seemingly straightforward Food and Drug Administration rulemaking proposal has brought into focus the increasingly intolerable burden which industry has been forced to face since Food and Drug officials began in 1960 to cast a cloud over that very important part of the Food Additives Amendment and the Food and Drug Administration's Regulations which state, in effect, that a substance is not a food additive unless it "may reasonably be expected to result, directly or indirectly, in its becoming a component...of any food." Since at least 1966, representatives of industry, including the undersigned, have decried the Food and Drug Administration's unreasonable interpretations of Section 201(s) of

the Act and Section 121.1(e) of the Food Additive Regulations.[4/]

14. Rather than burden this set of Comments with another recital of industry's continuing quandary in this respect, the Food and Drug Administration is asked to consider incorporated by reference herein the voluminous Comments submitted to FDA on November 6, 1967 in response to the then proposed and never subsequently acted upon Food Additives Procedural Regulations (32 Fed. Reg. 152 p. 11443 et seq.). In this document, the checkered history of the varying interpretations afforded the phrase "reasonably...expected to result, directly or indirectly, in its becoming a component...of any food" was discussed at great length, and an urgent plea for definitive action was made.

15. Subsequently, and partly as a result of Congressional inquiries, the Food and Drug Administration called the National Conference on Indirect Food Additives where the entire problem of defining what is an indirect

4/ See American Chemical Society Division of Organic Coatings and Plastics Chemistry Papers Presented at the New York Meeting, September, 1966, Vol. 26, No. 2.

food additive was discussed and recorded in a two-volu transcript presumably resting in the FDA files.[5/]

16. During and after this Conference, the Commissioner of the Food and Drug Administration and the members of its Staff committed FDA to take action which would clarify the question of when a non-food article is or is not to be considered a food additive.

17. Still later, in May of 1969, industry was informally presented with a proposal commonly referred to as the "Ramsey proposal," it being stated in the covering letter executed by the then Assistant Director for Regulatory Programs of the Bureau of Science, L. L. Ramsey, that the informal proposal was intended to be responsive to the importunings of industry prior to and during the National Conference on Indirect Food Additives.[6/] Nonetheless, and for reasons which have never been fully explained or even coherently disclosed, no version of the "Ramsey proposal" has ever been published as a proposed or final rule.

5/ Copies of this transcript, as well as the aforementioned Comments of The Society of the Plastics Industry, Inc. in the Food Additives Procedural Regulations rulemaking are available to FDA immediately upon request should the Agency be unable to locate its own copies conveniently.

6/ In an excellent paper entitled The Food Additive Problem of Plastics Used in Food Packaging, Mr. Ramsey (cont'd)

18. As a result of the Food and Drug Administration's failure to deal with this issue, industry remains in a constant state of uncertainty as to when a food additive problem is presented where food contact surfaces or packages are involved. So long as this situation persists, and so long as food processors understandably demand assurance that a product meets Food and Drug Administration requirements, it is totally inequitable and misleading for FDA to take the position that a rulemaking of the type at hand here will not create virtual havoc in the marketplace because: "Of course, if there is no migration of a substance to food...the substance is not a food additive and no Petition is required."

19. The fact is that the Food and Drug Administration will rarely concur in a no-migration conclusion and, instead, will almost invariably insist on a Food Additive Petition to establish the status of a food contact article or component thereof. This, in

6/ (Con'td.) explained much of the background which led to his proposal and reported on its status in 1969. A complete copy of this paper, delivered at the National Technical Conference of The Society of Plastics Engineers meeting in Dallas, Texas on November 4-6, is attached to this set of Comments as Appendix B.

turn, can impose upon a party manufacturing something as innocuous as doilies, general purpose pails or jars, or ordinary dishes the necessity for spending very substantial amounts of time and money on acquiring and presenting the data for a Food Additive Petition, after which the expectation must be that a Regulation will not be promulgated in less than 184 days[7/] even if the petition is "perfect," which is seldom the case in light of FDA's constantly changing demands for supporting data.

7/ See Transcript of Proceedings, Seminar--Food and Drug Administration/Society of the Plastics Industry, Inc., June 18, 1971. On page 128 of that transcript, Mr. Nathaniel Geary of the Food and Drug Administration Staff candidly reported on an internal FDA study of petition processing and noted, in part, as follows:

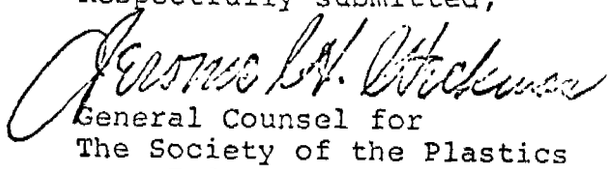
> "Our sample looked at the petitions that were good and sailed through.
>
> "We found the average time of the sample was 184 days to get the thing through the Agency. This is four days over the upper extension of the statutory limit."

It is possible that some improvements may have been made in the Food and Drug Administration's processing of "perfect" incidental food additive petitions since the time of Mr. Geary's statement but, if so, this has not been noticeable. On an average, it has been our experience that almost no petitions are processed within 180 days. We would estimate that since the enactment of the Food Additives Amendment some type of averaging of petition processing time for incidental food additives petitions would probably show a mean of from one to two years, or more.

* * *

The foregoing premises considered, and unless and until such time as definitive action along the lines of that suggested by Mr. Ramsey in his May 6, 1969 letter is taken, we respectfully submit that rulemakings of the type here contemplated should be abandoned or indefinitely delayed.

Respectfully submitted,



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