JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESANI, JR.
ROBERT E. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH
PETER THOMAS SMITH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2100
CABLE ADDRESS "KELMAN"

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

Ladies and Gentlemen:

It has been some time now since we have been in touch with you on other than PVC problems but we trust you recognize that much of our time in the past months has been preempted by the VC-PVC "emergency." Nevertheless, a number of unrelated matters have come up which we believe should be brought to your attention.

The first item concerns the so-called Housewares Exemption. As you know, some time ago the Food and Drug Administration published a proposal to abolish the Housewares Exemption. In that connection, we filed Comments on behalf of the Society and the Food and Drug Administration is now struggling with the problem of writing a Regulation. We have been reliably informed by our contacts in the Office of the General Counsel that no Regulation can be anticipated in the near future.

This by itself is not unusual, but the original Notice, anticipating that a Regulation would be promulgated in ample time, stated that Petitions would have to be filed before December 31, 1974 to provide for the regulation of such housewares as might be subject to the Regulation. Not only has the Regulation not been promulgated yet, but we have been informed quite reliably that it is altogether unlikely that any Regulation will be promulgated before the end of this year. Consequently, that portion of the Notice that spoke about the need to file Petitions by December 31, 1974 is clearly inapplicable. If and when a Regulation

does issue, there will be ample notice for all affected to take whatever steps may be necessary to comply so that those who have been worried about the need to file Petitions on housewares components before the end of the year can relax, at least temporarily.

Closely related to the housewares matter, if only because housewares are often colored, is the long delayed Colorants for Plastics Regulation. A proposal in this connection was published quite some time ago; Comments were filed on behalf of the Society, but for administrative reasons a final Regulation has never issued. Our most recent check on this elicited the response that this matter is temporarily "on the back burner", and that no final Regulation need be expected before December 31, 1974.

In connection with the entire subject of regulating indirect food additives, and related to the general review of GRAS and prior sanctioned materials, the National Academy of Sciences--National Research Council is making plans to conduct a survey on indirect food additives. This survey is being planned by the Committee on GRAS List Survey, Phase III. At the invitation of the Committee, representatives of SPI (Dr. Dixler and myself) attended a meeting at which approaches to the survey were discussed. We are enclosing a copy of the agenda for the meeting and a copy of a discussion sheet that was offered for comments.

It was apparent that the NAS-NRC Committee was very much aware of the enormous complexity of the indirect food additive regulatory scheme and was anxious for help in devising a procedure whereby a reasonable survey could be undertaken. Most of the invited guests recommended that the entire list of Regulations be carefully reviewed and that those materials which "were not reasonably expected to become components of food," such as all those listed in the adhesive Regulation (§121.2120), should be allocated to secondary status. It was also recommended that the entire concept of a reasonable approach to what constitutes an indirect food additive (e.g. a reaffirmation of the "Ramsey Proposal" approach) be considered.

In a more substantive way it was recommended that a market basket survey be instituted to provide a comprehensive evaluation of what packaging materials are currently being used. From this it might then be possible to approach the various major manufacturers of packaging materials to obtain from them information regarding the composition of the packaging materials which could then lead to a meaningful evaluation of what indirect additives are actually being used and in what quantity. It should be recognized that the purpose of the NAS-NRC survey is to determine how much of what indirect additives are actually being used, and not to assess their safety. It is apparently the intention of the Food and Drug Administration to make such safety evaluations once the identities and quantities of indirect food additives in actual use have been established.

Another matter which we believe requires attention is the Notice of Proposed Rulemaking published in the Federal Register on September 23, 1974 in connection with the General Recognition of Safety and Prior Sanctions for Food Ingredients. This was published at pages 34194 - 34197 of the Federal Register as a part of a fairly extensive Part II of the Federal Register for that date encompassing a large number of food additives and GRAS substances Regulations and proposals. We are enclosing copies of the cited pages for your records.

In the preamble to the Notice of Proposed Rulemaking, the Food and Drug Administration has stated that it is revising some Regulations to clarify the criteria for GRAS status, the differences between GRAS status and food additive status, and the procedures being used to conduct the current review of food ingredients. Throughout the preamble, and indeed specifically in proposed §121.1(m), the FDA is blurring distinctions between foods, food ingredients and food additives. We believe that the Federal Food, Drug and Cosmetic Act distinguishes between foods and food additives; indeed, a pending court case in Massachusetts hinges on this distinction.

If any of you believe that Comments should be filed in connection with this rulemaking on behalf of SPI, please let us know. Alternately or in addition, you may wish to file Comments on behalf of your own companies. Since the closing

date for Comments is December 23, 1974, we would appreciate hearing from you promptly if you feel that SPI Comments are in order.

As you consider the substance of these proposals, you might wish to bear in mind the following:

1. The Federal Food, Drug and Cosmetic Act requires the regulation of food additives but prescribes enforcement procedures only for foods. Consequently, if the distinction between the two is blurred, the Food and Drug Administration could seize an uncleared or unsafe food additive as being an adulterated food. You should know in this connection that one U.S. Attorney has indicated in a trial memorandum submitted to a Federal Judge that even a truck could be considered a food in an enforcement proceeding if deleterious substances from the truck contaminated food that was being shipped.

2. The proposed §121.105(b)(3) indicates that an ingredient can be affirmed as GRAS for specific use as an indirect additive prior to the general evaluation of the GRAS status of that ingredient. This may provide an opportunity for specific GRAS affirmation of food packaging materials if the quantity that might migrate to food is sufficiently low and adequate toxicology is available to permit a GRAS conclusion. This would obviate the need to go the Food Additive Petition route in such cases.

3. It is the intention to ultimately list all known prior sanctions in Subpart E of the Food Additive Regulations. This will be accomplished in connection with the GRAS review as indicated in the proposed §121.14(d). Failure to respond with proof of an applicable prior sanction in response to a proposal will constitute waiver of the right to assert or rely on such sanction at any later time.

One final item, this to be considered as an advance notice. Plans are now being made for a meeting of the Food, Drug and Cosmetic Packaging Materials Committee to be held in Washington, D.C. on the 22nd of January. A meeting notice will be sent soon which will confirm the date. In the meantime, it might be desirable to mark your calendars for this date.

Please let us know if you feel that Comments should be filed in connection with the proposed rulemaking mentioned above, or if you have any questions or comments about any of the items we have discussed. In the unlikely event that we are not in touch with you before January, please accept our sincere wishes for a happy holiday and a prosperous New Year; and we hope to see you all at the meeting in January.

Cordially yours,

Jerome H. Heckman/jm

Enclosures