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September 9, 1974
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TO: All Members of:

SPI Food, Drug and Cosmetic
Packaging Materials Committee;
General Polyvinyl Chloride Interest
Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee;
VCM and PVC Producers Committee

Ladies and Gentlemen:

This latest addition to our set of reports on governmental and related activities covers the period since our rather massive letter of August 26, 1974. We have up-dates on matters concerning the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA), and the Food and Drug Administration (FDA).

Our present information is, of course, that the Occupational Safety and Health Administration is still aiming at a Federal Register publication of the vinyl chloride occupational standard on or about October 5, 1974. In connection with the Standard, OSHA has received a draft of an economic impact study prepared for it by Foster D. Snell Incorporated. Although still in draft stage, copies are available to interested parties through OSHA; the final statement is due to be completed this week. The Hearing

record has been held open for this document, and one company has filed a motion to reopen the Hearing to permit cross-examination of Foster D. Snell representatives.

In addition, the Office of Planning, Evaluation and Research of OSHA has prepared what might be considered a second part of the Economic Impact Survey entitled "An Economic Impact and Technological Feasibility Study for the Compounders, Processors and Fabricators of Polyvinyl Chloride Resins." Here too, copies of the Survey are available to interested parties; we are not including copies of either Study with this letter because of their great bulk.

A review of the latter Study shows that it draws no conclusions. Nevertheless, it clearly points out that exposure in processor's plants tend to be quite low and that the cost of compliance with a "non-detectable" requirement would tend to be quite high, although not readily quantifiable. We are attaching copies of two portions of this report referring to the Study's estimate of the magnitude of the problem, both from the point of view of exposure of workers and the difficulties of procuring whatever equipment may be required.

The VCM and PVC Producers Committee of The Society of the Plastics Industry met last Friday to consider both the Foster D. Snell report and OSHA's "Part Two." After the meeting we prepared Comments on the two reports and submitted the same today. A copy of our filing on behalf of SPI is enclosed herewith.

Our contacts at the Environmental Protection Agency have now indicated that the EPA's Task Force report "should be ready" to be submitted to the Administrator during the early part of the week of September 8. It seems reasonable, therefore, to conclude that EPA will take no formal action until the Administrator has had time to review the report so that our guess is that no EPA publicly announced action can be anticipated before the latter half of September.

With respect to the long anticipated proposed Interim Food Additive Regulation concerning polyvinyl chloride plastics for use in food contact applications, the Regulation has not yet been published in the Federal Register. A recent news release has ascribed some of the delay in promulgating

the Interim Food Additive Regulation to FDA's desire to "clear" it with other interested Agencies. This may well be involved, but it is expected to be published "within a week or two." Our contacts at the Food and Drug Administration can offer no better time estimate.

As we understand it, the delays appear to be the result of minor editorial changes and are not expected to have any substantive effect on the proposed Regulation. In other words, to the best of our present information, the proposed Regulation will still require that food contact polyvinyl chloride plastics contain less than 10 parts per million of residual monomer and that, when tested, the amount of vinyl chloride possibly migrating to food-simulating solvents may not exceed 50 parts per billion.

You may recall that FDA requested information regarding the residual monomer content of PVC packaging materials, and the possible migration of residual monomer to foods. FDA repeated this request in the preamble to a Notice concerning drugs and cosmetics published in the Federal Register on August 26, 1974. We are enclosing a copy of that notice to refresh your recollection.

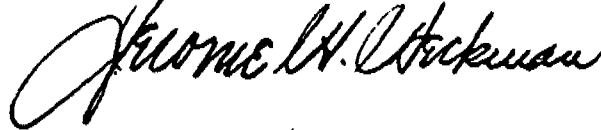
The main reason we thought we would remind you about this matter is because we have reason to believe that, assuming FDA proceeds with its 10 ppm residual monomer in the food contact surface proposition, there could be special problems relative to so called "rigid films" of the type used for "bubble" packaging of food products. This being the case, it occurred to us that it might be worthwhile to remind you of the FDA request for data since we have reason to suspect that very little, if any, information has been supplied on either the residual monomer or extraction characteristics of this class of product. Although it is undoubtedly too late to supply data which might do anything to change the FDA proposal, the availability of such data could be most important as an influence on the final Interim Food Additive Regulation so receipt of the same by the Food and Drug Administration, and our office, would probably be most helpful.

A final FDA-related item relates to a meeting held by the Toxicology Task Group of the Plastic Bottle Institute, the Food, Drug and Cosmetic Packaging Materials Committee, and

the VCM and PVC Producers Committee to review work done by Food and Drug Research Laboratories (FDRL) as the initial phase of a study of the ingestion toxicity of vinyl chloride. The preliminary FDRL study was intended to evaluate possible methods of feeding vinyl chloride monomer in a controlled fashion to rats so that an appropriate feeding study could be conducted to demonstrate the safety of polyvinyl chloride as a food packaging material. A more complete protocol based upon the results of this preliminary study is being prepared for submission to the appropriate groups in the Society.

We will continue to keep you as fully informed as possible.

Cordially yours,

A handwritten signature in cursive script, reading "Jerome H. Hickman". The signature is written in dark ink and is positioned to the right of the typed name "Jerome H. Hickman".

Enclosures