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April 23, 1974

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 Institute
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Polyvinyl Chloride Prior-Sanctioned
Status, Proposed Rule Making

Gentlemen:

The purpose of this letter is, once again, to update you on the status of our polyvinyl chloride resins and products crises vis-a-vis Federal regulatory activity during the past week. The Occupational Safety and Health Administration (OSHA) situation has commanded most of our attention in the last six or seven days but we have also remained in close touch with the Food and Drug Administration (FDA). Please read all parts of this letter and the enclosures since many of them may indicate the need for a variety of actions by your company depending on your specific interests; the situation is simply too complex for us to follow the policy we prefer to use which is to indicate the "need for action" areas in our opening paragraphs.

With respect to OSHA problems firstly--this now being the area we consider most critical--all vinyl chloride monomer and polymer producers, as well as fabricators, are now expected to be in compliance with the Emergency Temporary Standards (50 ppm in the atmosphere) which we sent to you as one of the enclosures in our April 8 mailing.

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With regard to the industrial hygiene (OSHA) aspects of the VCM-PVC matter, under the auspices of SPI, and at the request of the leading companies in the field, on Tuesday, April 16, 1974 what has now been constituted as the SPI Vinyl Chloride and Polyvinyl Chloride Producers Ad Hoc Committee met in Washington for the purpose of considering the industry-wide problems associated with the Emergency Temporary Standards set by OSHA for VCM and PVC facilities. Working committees were set up to gather data regarding levels of exposure in VCM and PVC plants, as well as VCM residual levels in various polymer products shipped by the polymerization plants. In addition, a working group is also investigating the nature of any vinyl monomer problem that might exist in the plants of vinyl processors; if any problem should be found to exist in such plants, an attempt will be made to isolate the sites within the plants that might require special attention. Still further, another working group is investigating the likely economic impact if the Emergency Temporary Standards should be significantly lowered to a level where polymerization plants could no longer remain in production, or if permanent standards should be set (as recommended by NIOSH) at a "no detectable" or 1 ppm monomer level in the air, using methods sensitive to 1 ppm.

Special urgency prompting the requests that SPI call the April 16 meeting and the formation of this Committee was generated by two related developments. Firstly, the Manufacturing Chemists Association (MCA) which is sponsoring inhalation toxicology studies has reported preliminary findings that a level of 50 ppm in air appeared to have induced liver cancer in mice although rats and hamsters were not affected at the same level for the same period of time. A copy of the MCA news release in this respect is attached. Secondly, the Manufacturing Chemists Association informed those of its members that were vinyl chloride or polyvinyl chloride producers that it (MCA) could not represent a segment of the chemical industry in its dealings with regulatory agencies so these companies requested that the Ad Hoc Committee be set up under SPI.

Although the current OSHA regulations indicate that vinyl processors are included in the coverage,

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conflicting statements as to the extent of coverage have been issued by OSHA. More important, there does not appear to be a firm factual base for OSHA to decide whether vinyl monomer problems exist in processing plants at all and if they do exist, where in processor's operations such problems are isolated. It is to obtain such information on behalf of PVC processors and, hopefully, to limit their need to be concerned, that an important part of the Ad Hoc Committee's efforts are being directed.

Yesterday a meeting was held at the OSHA offices between Dr. Van Atta and others on the OSHA Staff and members of our Staff. The major purpose was to explain SPI's intended participation in what had formerly been an area expected to be handled by others. Another purpose was to inform OSHA, before it had progressed too far with the preparation of a proposed permanent standard, of the plans to obtain data which had been formalized by the Society's new VC and PVC Producers Ad Hoc Committee.

During this meeting, it became evident that the OSHA Staff people are anxious to propose a permanent standard that strikes a fair balance between the need to protect workers in PVC plants on the one hand without making it economically impossible for the industry to continue on the other hand. Despite their obvious awareness of the magnitude of the economic impact problem, (and, by the way, we have been in contact with organizations like those representing the food chains which are bending all efforts to impress OSHA and FDA with the need for avoiding precipitous action that might even cut off the food supply of the country), the OSHA people advised that, in the absence of data on which to fix a "safe working level," and in light of the MCA-sponsored data casting doubt on the safety of the 50 ppm level set in the presently effective Emergency Temporary Standard, OSHA will propose a 1 part per million peak exposure limit combined with a 40 ppm-hour limit per week. Regardless of the final figure proposed, it is now anticipated that a proposal will be in the Federal Register on or about April 30. The present thinking on timing is unclear. We were told yesterday that the proposal will allow only 30 days for comment but today we heard there is a chance that 60 or even 90 days may be permitted.

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The main timing problem to which OSHA is acutely sensitive is that it is required to have a permanent standard "on the books" six months after the promulgation of the Emergency Temporary Standard. Since the latter was promulgated on April 5, OSHA must have a permanent standard promulgated and in effect by October 5. It is required to allow a one month lead time between the appearance of a regulation in the Federal Register and the date that it takes effect so OSHA plans to have the permanent standard published by September 5, 1974.

This extremely tight schedule to which OSHA is committed means that either within the Comment period, or during such additional time as is permitted to hold a hearing on the matter should one be requested (and it is certainly our present plan to so request), all the data that can be generated must be available. This means that all interested parties must respond very promptly to the various calls for information that may be forthcoming.

Turning now to the FDA area, the request for information which we transmitted to you last week has been reinforced by two Notices published in the Federal Register on April 22. We are enclosing copies of these Notices for your consideration. Together, they request from all interested parties the submission of VCM residue and migration information, and direct all Registered Drug Manufacturers to supply certain information regarding the use of VCM or PVC containers.

The substance of the Notice of Proposed Rule Making states the intention to ban the use of vinyl chloride as an ingredient of drug products and cosmetic products, but the preamble requests the submission of the type of information we previously noted. However, the Notice to Drug Manufacturers, Packers, and Distributors requires the submission of a list of drugs containing vinyl chloride and a list of drug products packaged in PVC or PVC-lined containers. In addition, information regarding possible exposure to VCM is requested.

Finally--and this is about all of the "good news"--we have been informed that FDA is now considering dropping

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from its anticipated PVC food additive rule making all limits on residual monomer in the food contact surfaces while retaining the limitation of "non-detectable" (at 50 ppb sensitivity) in foods and food-simulating solvents. This, of course, is something we have been strongly advocating ever since March 8.

Although our previous notification to you recommended that data be submitted either to us or to the Food and Drug Administration (attention Mr. G. McCowin), the Federal Register Notice requests that the information be submitted to the Hearing Clerk at the Food and Drug Administration. Procedurally, any information submitted to us or to Mr. McCowin will also be transmitted to the Hearing Clerk so you need not be disturbed by the apparent inconsistency in the recommended addressee; it is just part of the general confusion that pervades this entire issue.

You may also recall that we informed you previously that the Health Research Group had filed Petitions with the Consumer Product Safety Commission, EPA and FDA regarding various uses of vinyl chloride, particularly as a propellant in household products, insecticides and drugs and cosmetics. The Notice of Proposed Rule Making by FDA, which we are enclosing, embodies, at least in part, the FDA response to the Petition it received.

EPA has ordered a voluntary recall of all pesticides which may be on the market and which use vinyl chloride as the propellant but has indicated that it will not name all such pesticides so the Health Research Group is suing for the publication of the names of all producers.

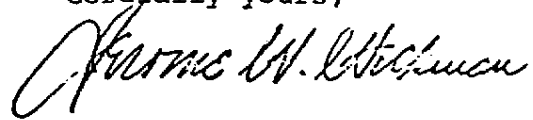
Although the Consumer Product Safety Commission has not yet responded to the petition filed with it, it is understood to be planning to ban the use of vinyl chloride as a propellant in all household items.

We shall continue to keep in as close touch as we can with all aspects of the current crises. As we have been doing, we shall post you by means of these

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"weekly news letters" so as to keep you as fully and promptly informed as possible.

Cordially yours,

A handwritten signature in cursive script, appearing to read "Thomas W. Hutchinson".

Enclosures