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TO: All Members of VCM/PVC Mailing List

Ladies and Gentlemen:

The purpose of this letter is to update you once again on the latest developments relative to the Food and Drug Administration (FDA) Proposed Rulemaking and to transmit the latest report we have on the Environmental Protection Agency (EPA) anticipated proposed Standard. We are sorry not to have been in closer touch with some of you recently but preparation of the FDA case, and liaison work with Ruckelshaus, Beveridge, Fairbanks and Diamond on the various phases of EPA activity, has been unusually preemptive of our time.

FDA

As we hope you recall from our last general letter (No. 7, dated October 31, 1975), because only 60 days were originally allowed for Comment on the FDA proposals relative to vinyl chloride and polyvinyl chloride (VCM and PVC), a request for an extension of time was filed. On October 27, FDA granted our request in part and extended the time for filing Comments from the original November 3 deadline until December 12, 1975. Since the preparation of some of the data to support the Comments was still not complete and in our hands, on December 3 a second extension of seven more days was sought from FDA. On December 4, additional time was allowed by an informal extension; thus, the final deadline for filing these Comments was set for Friday, December 19, 1975.

SPI-24555

As you might expect, many have worked diligently to help us prepare the SPI filing. Several drafts were completed and we received constructive criticism on the same. In fact, our last meeting with the committee designated to review our draft Comments was on Thursday, December 11. Prior to that meeting we had made available our quasi-final Comments, including a summary of all the data then in hand. Thus, at our December 11 meeting, we received the industry's final instructions.

The SPI Comments have now been filed in a timely manner. As to the substance of the filing, SPI is urging FDA to take full cognizance of the way polyvinyl chloride end products have been dramatically changed since significant parts of the data base for the FDA proposal were acquired; to study closely the extensive scientific evidence which is the essence of the Comments; and to reassess its proposals on the basis of the far more current information presented, such reassessment to include a thorough analysis of the important jurisdictional issues discussed. The Society's position is that, on the strength of the new evidence at hand, the type of regulatory actions proposed on September 3 are inappropriate and should be abandoned. Specifically, on the basis of the scientific evidence, manufacturing information and legal arguments presented, the SPI posture will be that objectivity compels the conclusion that it would be unsound to ban any PVC product complying with the regulatory parameters recommended.

In lieu of the FDA proposals, SPI has recommended that the following regulatory actions be taken:

1. Section 121.2500 of the Food Additive Regulations--generally referred to as the "Good Manufacturing Practices" section governing all of the incidental food additives regulated under Subpart F--should be supplemented by addition of a new paragraph (a)(3) which would require that any food contact article made in whole or in part of a vinyl chloride-based plastic would have to be manufactured so that no vinyl chloride monomer could reasonably be expected to become a component of any food under the intended conditions of use for such article.

2. The proposed new Section 121.2009, properly conceived of as a "prior sanction" reaffirmation regulation, should be revised to cover all uses of polyvinyl chloride resins when finished articles made therefrom (a) are properly tested under specified test methods and (b) it is thereby shown that such articles present no reasonable expectation of vinyl monomer migration to foods or food simulating solvents. We have explicitly indicated SPI's view that the test methodology developed and widely circulated by FDA is appropriate and should be set out in the Regulations as a sort of an "official method."

3. The proposed Section 121.4009 is, in essence, beyond the statutory authority of FDA; even if it were not, the regulation of pipe for potable water by FDA would be redundant. Nonetheless, we have also urged that should FDA still feel it must promulgate regulations in this area, such action should only be taken provided it is made clear that the interim rule will be deleted permanently once FDA is properly satisfied that PVC potable water piping systems present no public health problem.

4. Finally, SPI is urging that, with the above listed regulatory change recommendations, all the other proposed changes, including the array of proposals that would affect PVC adjuvants, can and should be abandoned in order to avoid the creation of unnecessary confusion.

In sum, our Comments are designed to inform FDA that PVC resin, compound and end product manufacturing have changed to the extent that VCM content in food contact articles is so

low that such articles will meet FDA's requirement that the use of vinyl chloride polymers be limited to where either no vinyl chloride or very low levels would be expected to be present as a residual. What we are actually saying is that vinyl chloride monomer will not really be a food additive as a result of the use of PVC food contact articles because there is no reasonable expectation that the monomer will become a component of food.

As to the plastic pipe issue, FDA proposed to put plastic potable water pipe under an Interim Food Additive Regulation because it did not have enough data upon which to make a decision relative to PVC pipe safety. In our opinion, a serious jurisdictional issue was raised when FDA proposed to regulate PVC potable water pipe. Specifically, the question is whether FDA, the Environmental Protection Agency, or both should exercise authority over the safety of the public water supply. Our latest information received just today is that EPA, after much soul searching on how to proceed, will make an argument for essentially exclusive jurisdiction vis-a-vis the safety of the public water supply and the various means used to transmit water; however, since it has decided its statutory power probably is not applicable to very localized water systems, e.g. well-to-home situations, that apparently serve an estimated 41 million people, we hope it will take the position that local authorities can and should handle this matter since no "interstate commerce" basis exists for FDA jurisdiction.

EPA is expected to raise the issue of its jurisdiction in a direct meeting of the responsible officials from both FDA and EPA. In advance of this meeting, however, EPA has, in the form of Comments on the FDA Proposals, provided FDA with information it obtained as a result of experiments and studies it has been conducting on drinking water pursuant to fulfilling its responsibilities under the Safe Drinking Water Act of 1974. A copy of the EPA statement is attached for your information.

Although we believe you will find it self-explanatory, it should be noted that no statement concerning the jurisdictional issues, nor the authority under which the tests were conducted is included in the letter. Frankly, we had expected EPA to take a more definitive position in general, but we are still hopeful the agency will more vigorously

defend its jurisdictional exclusivity, and the favorable conclusions we know some of the EPA Staff has reached about the safety of PVC pipe, in the confines of the meeting room when the session with FDA takes place.

Incidentally, until just last week, we had hoped that by the time we sent you this Report, the EPA meeting with FDA would have been held. The latest word, however, is that the meeting scheduled for last week has been postponed until early in January so we are now very much "up-in-the-air" as to what EPA will do, and how FDA will react. All we can promise is to keep you as fully posted as possible.

As to distribution of the Comments as filed, we are sure you will realize that, due to the bulk of the filing (about 900 pages), we were only able to reproduce a few copies immediately. Copies without all of the technical data Appendices have thus far been given to the SPI Food, Drug and Cosmetic Packaging Materials Committee members at their meeting in Washington, D.C. on December 17, and to the VCM/PVC Resin Producers Group members present at their meeting in New York City yesterday, December 18. We do have a small supply of the Comments without appendices I through Q here and will send them upon request while the supply lasts. For those who need the complete document, you should contact John R. Lawrence at the SPI office in New York (212-537-9400). John is making arrangements for reproductions and is the party who can most easily advise you as to when such copies will be available and what the approximate cost will be.

Today's filing with FDA is not likely to be our last. FDA has already announced that it will also be publishing proposals for non-food PVC applications such as for cosmetics packaging. FDA is known to have been in contact with PVC user groups to obtain data regarding these areas of potential concern. To the maximum extent possible, of course, SPI will be supportive of the efforts made by other groups to assure FDA that all products packaged in PVC are safe.

EPA

With nothing new to report relative to the Occupational Safety and Health Administration Standard, for the

sake of some brevity we shall just note that, following our past practice, we are enclosing a copy of a letter received from our Associate Counsel for EPA activities, Ruckelshaus, Beveridge, Fairbanks & Diamond. We believe this report is self-explanatory and will serve to bring you completely up-to-date in this area.

Finally, we would like to take this opportunity to wish you all a merry Christmas and a hope-fulfilled New Year.

Cordially yours,

Frederic W. Heckman

Enclosures

Enclosed for the Bureau are two copies of a letterhead memorandum dated and captioned as above. The letterhead memorandum is being furnished to the Bureau for its information and for its use in the Bureau's continuing review of the activities of the Environmental Protection Agency. The letterhead memorandum is being furnished to the Bureau for its information and for its use in the Bureau's continuing review of the activities of the Environmental Protection Agency.

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Very truly yours,