SPI

THE SOCIETY OF THE PLASTICS INDUSTRY, INC.

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U R G E N T M E M O R A N D U M

CONFIDENTIAL

MARCH 12, 1974

THE ATTACHED LETTER FROM SPI COUNSEL, JEROME HECKMAN, REPORTS AN IMMINENT, CRUCIAL FDA ACTION VITAL TO ANYONE CONNECTED IN ANY WAY WITH PVC, ITS PRECURSORS AND COMPONENTS. I URGE YOU TO READ IT IMMEDIATELY AND TO CONSULT WITH ANYONE IN YOUR COMPANY WHO MAY BE AFFECTED.

FURTHER, THIS LETTER IS ADVANCE INFORMATION AND IS NOT APPROPRIATE FOR PUBLICATION. PLANS FOR RESPONSES TO THIS DEVELOPING SITUATION ARE UNDERWAY AT SPI.

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March 12, 1974

TO: All Members of:

SPI Food, Drug and Cosmetic
Packaging Materials Committee;
BATF Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
Plastic Bottle Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Prior Sanctioned PVC Status;
Proposed Rule Making

Gentlemen:

On March 8, 1974 a meeting was held between representatives of the Food and Drug Administration and the representatives of the PVC Task Force mentioned in our letter of last week. The meeting was called at the request of the Food and Drug Administration, ostensibly to learn what actions and plans the Society of the Plastics Industry had to provide responses to the questions raised at the December 20, 1973 meeting as they were set forth in the summary filed with the Hearing Clerk on February 5, 1974. Actually, the Food and Drug Administration used the meeting as a forum to disclose informally its intentions regarding the developing PVC situation.

As soon as we assembled for the conference, it became apparent from the stature of the toxicologists and others present that the Food and Drug Administration considered this to be a major regulatory matter and session. The meeting was held in the office of Dr. Virgil O. Wodicka, Director of the Bureau of Foods. Dr. Wodicka was present

during part of the discussion, but did not actively participate in it. Those present were:

FDA

Division of Food and Color Additives

Mr. Richard J. Ronk, Director
Mr. Louis E. Buckley
Mr. Gerad L. McCowin

Division of Toxicology

Dr. Leo Friedman, Director
Dr. Herbert Blumenthal, Deputy Director
Dr. Charles J. Kokoski
Dr. Krishna P. Mirsa

Division of Chemistry and Physics

Mr. Albert Holtz
Mr. Michael J. Clifford
Mr. George Lakata

Division of Chemical Technology

Dr. Charles F. Jelinek, Director

SPI

Dr. Charles J. Spiegl, Continental Can Co.

Dr. Ivor L. Simmons, M & T Chemicals, Inc.

Dr. Kenneth Morgareidge, Food and Drug Research Laboratories

Jerome H. Heckman, Esq. Keller and Heckman

Dr. Daniel S. Dixler, Keller and Heckman

Invited but not able to attend for SPI was William Rinehart of the Ethyl Corporation.

The major problem as FDA now views it was discussed by everyone at length but was probably best summarized by Dr. Blumenthal. He stated that based upon the experimental work conducted by both Dr. Viola and Dr. Maltoni, combined with recent epidemiological evidence, it must be concluded that vinyl chloride monomer is a carcinogen. Further, he said it must be presumptively considered to be a carcinogen even when taken orally because the cancers that were formed

after inhalation exposure were at a site far removed from the point of contact. In other words, the vinyl monomer had to be absorbed through the lungs and then transported to the liver where the angiosarcoma developed. Furthermore, the liver cancers were not caused by metastasis of cancerous lung tissue. Consequently, the Food and Drug Administration feels it has to assume in the interest of the public safety that the same possibilities exist for vinyl chloride taken via ingestion.

For this reason we were informed that FDA will shortly (within one or two weeks according to Mr. Ronk) publish in the Federal Register a notice regarding polyvinyl chloride. In the Notice it is intended to review the entire problem by means of a preamble. The discussion will conclude that the continued use of polyvinyl chloride for food contact purposes can no longer be considered safe without some restrictions and limitations while the questions regarding its safety are being resolved by further scientific investigation. Consequently, the Notice will propose the following:

1. The prior sanctioned status of polyvinyl chloride resins will be revoked.

2. An "Interim Food Additive Regulation" will be proposed to permit the continued use of polyvinyl chloride resins under conditions that will assure that the public will be exposed to no undue hazards. These conditions may include a limitation on the residual vinyl chloride monomer content in the polyvinyl chloride food contact surface to less than 10 ppm, and assurance that no vinyl monomer will transfer to food using a detection method sensitive to 50 ppb.

3. The Notice will state that a suitable toxicology protocol will have to be submitted within sixty days. Actually, a protocol was submitted on March 5, 1974 (as will be discussed below) and this will be considered as a first step toward compliance with this requirement. In addition to the submission of a protocol, however, the work called for will have to be carried out expeditiously and time limits for its completion and reporting to the Food and Drug Administration will be set.

4. Some system of reporting to the Food and Drug Administration will be required so that the Food and Drug

Administration can be assured that polyvinyl chloride materials used in food contact applications do comply with the interim requirements (the possible less than 10 ppm in the food contact surface and no detectable vinyl monomer in food concepts).

5. Finally, the Notice will state that no present urgent hazard exists so that no recall of presently packaged foods will be necessary.

The Food and Drug Administration also made it explicitly clear that this order is intended to apply not only to packaging materials, but also to potable water pipe, and industrial and farm equipment that is used to transport food during processing, e.g. vinyl tubing used on milking machines. Furthermore, it is altogether likely that this same set of restrictions will be applied to cosmetic containers and drug containers.

[It is because of FDA's explicitly and repeatedly stated intention to include within the scope of the forthcoming order PVC potable water pipe as well as any other PVC equipment that contacts foods or water, we have expanded the mailing list for this letter to add the Executive Board members of the Plastic Pipe Institute.]

We are attaching hereto a copy of an informal letter which was delivered to the Food and Drug Administration on Tuesday, March 5, 1974. This letter, sent at FDA's request, was a point by point discussion of the various questions raised by the Food and Drug Administration during the December 20th meeting. Because of the shortness of time between the FDA's request for the meeting and the date at which it was actually held, we were unable to circulate a draft of the letter, and you will recall you were forwarned of this in our letter of February 27, 1974. Since it was impossible to prepare a more formal presentation and obtain the concurrence of the membership, it was requested that this letter be considered an iternal memorandum and that it not be placed on file at the Hearing Clerk's office. We were assured that this would be so handled.

On Friday the Food and Drug Administration did not give any critique of the protocol that was submitted to it with the March 5th letter. However, since polyvinyl chloride

is to become a regulated material, the toxicology generally required in a Food Additive Petition will be required. These toxicology requirements were discussed generally.

Firstly, it was agreed that rats of the same species that Dr. Maltoni used were sensitive to vinyl chloride monomer, and they should be used for the test for determining whether vinyl chloride monomer when taken orally, would cause cancer. Since these rats are known to be sensitive, a second species will not be required, although two species are generally required to assure that at least one sensitive species has been used. If the feeding study proposed should demonstrate that vinyl chloride monomer, when ingested, causes cancer, the Delaney clause may become operative and no Food Additive Regulation can be written to permit the use of polyvinyl chloride for food contact purposes if any vinyl chloride monomer were to migrate to food. Under these circumstances the test method sensitive to 50 ppb would undoubtedly not be considered sensitive enough; indeed, if carcinogenicity is proven, it is unlikely that FDA would permit any use of PVC in food or water contact surfaces, this being its view of its obligation under the so-called Delaney clause.

On the other hand, if, as some feel it reasonable to anticipate, vinyl chloride monomer is given a "clean bill of health" when ingested then a Food Additive Regulation can be written to permit the use of polyvinyl chloride even though vinyl monomer may possibly migrate to food. If a Regulation is proposed whereby the amount of vinyl monomer migrating to food is not detectable using a method sensitive to 50 ppb, then it is possible that no additional toxicology will be required beyond that included in the two-year rat protocol already submitted.

However, the possibility exists that it will be considered commercially desirable to request that detectable quantities of vinyl monomer be permitted to migrate to food. Under these circumstances, we have been informed that significantly more toxicology will be required, possibly including tests of teratology, mutagenicity, studies on the metabolic fate of vinyl monomer when ingested and multi-generation reproduction studies.

Although it was our original intention and expectation that we would be able to discuss the details of the

analytical procedures in light of the FDA requirements, no time was spent on this aspect of our letter at the meeting. Actually, the meeting began at 1:00 and continued until after FDA closing time. During this time, information was given to the Food and Drug Administration with respect to levels of vinyl monomer that could be expected in all kinds of food when packaged in the "new" compounds. Furthermore, some fragmentary information was given regarding levels of vinyl chloride monomer found in random samples of foods which have been packaged in polyvinyl chloride compounds some time in the past and analyzed recently. The Food and Drug Administration confirmed that it has already been informed by various European regulatory agencies that vinyl chloride monomer has been detected in a variety of foods packaged in Europe.

The levels of VCM in food already packaged combined with the assurance that foods packaged in "new" compounds could be expected to show no vinyl monomer migration detectable with a method sensitive to 50 ppb, apparently encouraged the Food and Drug Administration to conclude that, (a), the present levels of exposure did not require a recall, but that, (b), continued use of polyvinyl chloride food contact materials requires that they be formulated and processed in such a way as to assure that no detectable vinyl monomer will enter foods in the future.

In view of the significance of the actions proposed by the Food and Drug Administration, we wanted to transmit this report as rapidly as possible so you could have maximum lead time before the Food and Drug Administration publishes the new proposed rule making along the lines which we have indicated. Obviously the latest developments we are reporting will require concerted action and, very likely, the bringing into play of parties not heretofore considered directly involved, e.g. suppliers of pipe resins and pipe manufacturers. You can be assured that, very promptly, we, Ralph Harding and/or Tom McGrath, will be discussing the possibilities and means whereby appropriate action and plans can be made with your leadership, including people like Ken Michel, Clarence Neher, Bryce Batzer, and Karl Hochschwender. Thereafter I am sure we will be in touch with you, possibly to call a very large meeting as soon as the anticipated

Food and Drug Administration's Proposed Interim Food Additive Regulation on PVC is published.

In the meantime, we shall continue to keep in as close contact as possible with Food and Drug and will report to you fully as matters proceed.

Cordially yours,

Jerome W. Stockman

Enclosure