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VCM

April 15, 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 Rulemaking

Gentlemen:

To put it mildly, the past week has seen a continuing and somewhat intensifying concern over the entire vinyl chloride monomer and polyvinyl chloride resins problem. Again, it is difficult to encapsulate everything that is taking place but we shall try to continue to post you in as telegraphic a style as possible with a weekly letter. In this instance, we are actually sending two letters for reasons hereinafter explained. As far as indicated action is concerned, we ask that you pay particular attention to the separate letter being sent herewith. The reason for the separate letter is so that copies could be sent to the Food and Drug Administration thereby enabling us to comply with a request that we circulate all known contacts in an attempt to see that FDA gets information it believes needed as promptly as possible.

Taking the FDA situation first, although it may not really be the most critical in some respects, we are now seeing what amounts to something of a developing panic in bureaucratic circles. We can imagine how much pressure the Food and Drug Administration Staff is experiencing because we spent the better part of last week taking your PVC telephone calls ourselves. In addition, we know from our sources at FDA that it is receiving a multitude of calls from all sorts of industry representatives advising it about the ubiquitousness of the use of PVC, and the fact that any unduly restrictive action could create chaos. Just for example, we were told that one trade association chief executive advised the agency that if its regulatory efforts were not carefully considered, the entire country could begin suffering a protein shortage due to the shortage of appropriate alternative materials for the packaging of meat and other food products.

What all of this expression of concern has led to is an increase (perhaps not really necessary since the situation has been recognized as critical for some time) in FDA's feeling that it needs more information and should proceed as responsibly as possible. Nevertheless, the pressure from so-called consumer interests is intense.

In any event, the week's events led to our receiving something of a startling telephone call late Friday afternoon requesting that a select group of technical personnel from companies representing some sort of cross-section of interests in the use of PVC be called together for a meeting on Friday, April 19. A number of telephone conversations took place immediately thereafter. The fact is that we advised the FDA Staff we were anxious to cooperate but certainly could not select a group of no more than 40 persons for a meeting intended to develop broad-based technical data about the resins; food, drug and cosmetic packaging; and devices areas. Indeed, I informed our contacts on the Staff that were such a meeting called, we would need to have considerable additional notice, would be required by our

obligations to inform all of you, and that this would probably lead to FDA's being literally swamped with requests to attend any session held.

The net result was that Dr. Schaffner of the Office of Technology who is playing a leading role in overseeing the PVC question from the food, drug, cosmetic and device point of view has at least temporarily withdrawn from the meeting idea in favor of our sending out the enclosed letter. This is why you will note that copies of the letter have been directed to Dr. Schaffner, and Messrs. Ronk and McCowin who continue to have the assignment of trying to resolve the Food and Drug Administration situation.

Finally, I might point out that Mr. Ronk advises that FDA is still hopeful of publishing a Proposed Regulation in the Federal Register "in the next two or three weeks." The only other bit of information relating to FDA activity which might interest you is included in the attached reproduction of an HEW News Release dated April 3, but received here in the middle of last week.

Turning to the other PVC "fronts," as of now we consider the Occupational Safety and Health Administration (OSHA) problem the most critical. As you know from last week's letter, the temporary OSHA standards allow for a 50 ppm upper limit in the vinyl monomer and polyvinyl chloride production environments. There is now reason to believe that the ultimate limits will more closely follow the recommendations of the National Institute for Occupational Safety and Health (NIOSH) which call for a virtually zero tolerance. Some of you may not have seen the NIOSH recommendations so a copy of the March 11, 1974 version is enclosed.

During the course of this week meetings of vinyl monomer and PVC producers are scheduled so there will probably be more to report in this area in due course. Meanwhile, there is some concern that OSHA will be moving more promptly than had originally been anticipated with respect to final and much more stringent regulations. We would

prefer not to speculate unduly in this regard so we hope you will await further word from us on the subject without calling for our "guesstimates" as to what might happen.

In the realm of "in case you didn't see the items" and "for your information" reports, we are enclosing (1) a Washington Post article dated April 10 entitled "'Killer Chemicals' In Hair Spray?" and (2) a copy of a letter and extract of proceedings in Parliament graciously and alertly supplied to me by our associate counsel in the United Kingdom. These enclosures will probably be of some interest.

The Post article does not really contain anything new but will demonstrate the kind of publicity which is bound to give rise to increasing pressures.

The report from Mr. Gamon will simply indicate to you that the British, as might be anticipated, are being a good bit more calm about the problem than are some officials here and elsewhere in the world. You might even find the excerpt from the Parliamentary report helpful in providing some reassurance to your contacts.

It should again be recalled that, as of now, PVC remains prior sanctioned for all uses in this country and is likely to remain so during the time it takes for the Food and Drug Administration to issue its expected proposal, receive comments and data thereon, perhaps even hold a legislative-type hearing (another suggestion that came up when the idea of a "select group" meeting was thrust upon us suddenly last Friday evening), and finalized Rule-making is adopted.

We will continue to be in touch as matters proceed and will also do our best to be responsive to your inquiries in the meantime. We do want to urge that as many of you as can possibly do so respond to the call for help set forth in our separate letter, and that if you do send

data directly to FDA, you supply us with copies of anything submitted to the extent that this is feasible.

Cordially yours,

Jerome H. Stackman

Enclosures