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No. 12

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

Once again we want to bring you up to date on recent developments regarding PVC. This letter will cover regulatory matters in the Food and Drug Administration (FDA), Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) areas.

FDA

PVC Pipe

As you know, the FDA proposed regulations included proposals concerning PVC pipe. Preparatory to a formal response to some of the questions raised, a draft "discussion" protocol had been prepared by an action task group representing both PPI and Unibell and was submitted to FDA for its informal review and comments. A meeting had been set for January 6 between FDA personnel and representatives of the action task group to obtain FDA's opinion regarding the draft protocol. Then, at almost the last moment, FDA cancelled the meeting on the grounds that it was "premature." The reasons given by FDA were the following:

1. Until the jurisdictional question between EPA and FDA is settled, comments by either agency may lead to a duplicative waste of effort;

2. Until all the Comments in the PVC docket are reviewed and evaluated and until FDA has decided upon the regulatory approach it will take, any suggestions or recommendations with regard to PVC

pipe may turn out to be irrelevant; and

3. In the portion of the proposal that concerned PVC pipe, FDA raised three questions that required answering before the proposed interim regulation could be made final. A preliminary review of the Comments filed suggests that the requisite answers may already be available and that, without the need for any further field studies, a final disposition of the PVC pipe status may be made at the time final regulations are promulgated.

During the course of discussions regarding the cancelled meeting on the draft protocol, a question was raised as to whether the anticipated "housewares exemption" rule-making would consider household installations of plastic pipe. We were informed that present intentions are that no explicit reference to such pipe would be made.

It was also apparent that FDA was sensitive to the criticisms raised by the Council on Wage and Price Stability and did not want to be involved in any, even informal, activity that might lead to the unnecessary expenditure of industry funds. Furthermore, the FDA spokesman referred to a criticism voiced by at least one commentator that FDA and EPA requirements had been different in the past, leading to unnecessary duplication of effort.

Finally, and here we may be responding more to our innate hopes, as a result of these discussions we felt that the FDA staff (at least at the Bureau of Foods level) may now believe that the basic technological and safety problems have been resolved and that the only real problem remaining is one of proper regulatory language so that a scientifically sound position can be "sold" to the Commissioner's office.

At one point during the conference, we were informed that April 1 is now an "informal target date" for

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a final PVC regulation to be published in the Federal Register. To the best of our knowledge, however, this target date has not been administratively programmed. Inasmuch as all the Comments filed have not yet been delivered to the Bureau of Foods and its technical staff has barely started on the review of the scientific data, the April 1 date appears to be a laudable, but perhaps unrealistic, goal. It should be remembered that after the technical review of all the submitted data has been completed, it will then be necessary for Bureau of Foods' personnel to reach a decision as to the proper regulatory stance to take in drafting final regulations that will reflect this position and to prepare a preamble that answers with some specificity every Comment that has been filed.

Cosmetics Packaging

Some of you will recall that Dr. Schaffner of the Food and Drug Administration had earlier indicated that a proposed regulation or policy statement on cosmetics packaging was planned for publication in the Federal Register before the end of December, 1975. No such proposal appeared and we have now learned that the Division of Cosmetics Technology, the division charged with responsibility for drafting such regulations, is waiting to review all the Comments filed in the PVC docket before going forward with any proposed cosmetics position. As we understand it, the Division of Cosmetics Technology is now reasonably assured that present compounds and the products made therefrom pose no significant or urgent safety problems for cosmetics users and feels it can act deliberately, waiting for as much information as can be developed before moving in this area.

OSHA

With regard to the Occupational Safety and Health Administration (OSHA) Standard, you may recall that last spring and summer several companies petitioned OSHA to modify, amend or, at least, explain formally certain portions of the Standard for Occupational Exposure to Vinyl Chloride.

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We had known for some time and, indeed, had so advised you in these letters that it was highly unlikely that OSHA would ever react publicly to alter the Standard. As a result, during the entire interim, companies had been operating on rather impromptu advice received from counsel or some individual at OSHA in many areas where questions existed. Although OSHA has responded in writing from time to time to requests for advisory opinions concerning a particular plant's problem or condition, now, perhaps for the first time, OSHA has responded to a Petition in a general fashion applicable to the industry at large.

In the attached, self-explanatory letter from OSHA directed to Mr. Raymond Schenck of Air Products and Chemicals, Inc., OSHA has taken a formal position running parallel to that which many in industry have been espousing for some time. Specifically, OSHA has decided that the definition of "fabricated product" must be interpreted, in so far as "release of vinyl chloride" is concerned, to mean a release that is at or above the action level.

The import of this interpretation is that many PVC resins and compounds which contain low residual vinyl chloride monomer will be eligible for classification as "fabricated products." The obvious benefit of this is that these products will be exempt from labeling requirements. Additionally, it should be noted that products which are exempt from labeling requirements are those which should be expected to be exempt from the Standard itself because of the fact that the materials are incapable of releasing vinyl chloride monomer in quantities in excess of the action level. Thus, many of the fabricators, compounders and others handling such PVC materials prior to final fabrication would be effectively exempted from the OSHA Standard providing the rudimentary requirements of initial monitoring and the like are performed and show negative results.

EPA

Until such time as Associate Counsel Ruckelshaus, Beveridge, Fairbanks and Diamond have a reasonable opportunity to comment in writing on the myriad activities in

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which they are currently engaged, we are undertaking to advise you--albeit only in the most general terms--about the initial industry response to the Environmental Protection Agency's recently proposed National Emission Standard for Hazardous Air Pollutants--Vinyl Chloride and its declaration that vinyl chloride is a hazardous air pollutant.

On January 7 and 8 the EPA Subcommittee of the Vinyl Chloride and Polyvinyl Chloride Resin Producers' Group met in Washington to conduct a technical critique of the Proposed Standard and to prepare a first draft of Comments for consideration later this month by the Producers' Group.

With regard to the industry's technical response to the Proposed Standard, it would appear that a number of definitional and technical changes will be strongly recommended by the EPA Subcommittee to the Producers' Group for ultimate inclusion in SPI Comments to EPA on its Proposal. Additionally, a number of points about the reporting and record keeping requirements are viewed as unreasonably burdensome. The very lengthy, detailed and often-required reports proposed are also likely to be opposed. A number of other proposed requirements in the Standard which would be redundant--in and of themselves or vis-a-vis the OSHA Standard--and some other items which have no obvious purpose will also be the subject of the EPA Subcommittee draft Comments.

An effort to obtain an extension of time relative to the hearing which EPA has now scheduled for the first week in February is also underway because it would interfere with the preparation of Comments on the Proposed Standard. A copy of the Notice of Public Hearing as it appeared in the Federal Register is attached. Although the purpose of the February hearing would be to discuss the classification of vinyl chloride as a hazardous pollutant and how it should be regulated, and although the publication of the "declaration" and the Proposal simultaneously complicates the timetable mandated by the Clean Air Act, it is customary to hold administrative hearings after the completion of the Comment period. While a response on the extension request is expected from EPA shortly, we decided not to delay this

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letter since we anticipate communicating with you again as early as next week with more information about the EPA Subcommittee's proposed Comments, other details with regard to the up-coming EPA hearing and the like.

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As in the past, we shall continue to inform you as fully and promptly as we are able with respect to all the various aspects of the VCM/PVC matter.

Cordially yours,

Joseph P. Healy

Enclosures