

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLA. <
DAVID L. HIL
MARTIN W. BELLOVICH
EDWIN B. SPIEVACK
PETER M. NEMKOV
JOSEPH F. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH

LAW OFFICES
KELLER AND HECKMAN
1150 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

April 8, 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 Division
(Voting Representatives);
SPI Executive Committee;
SPI Public Affairs Committee

RE: Polyvinyl Chloride Status; OSHA,
EPA, and FDA

Gentlemen:

In accordance with our practice of the last several weeks, the purpose of this letter is to continue keeping you as well informed as possible regarding changes in the proposed or actual regulatory status of polyvinyl chloride and its copolymers. In so doing, the following paragraphs will deal with the current activities of the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA). The only action required by any of you is essentially the same as requested in last week's letter, i.e. (1) we would still like to receive additional data on PVC potable water pipe extraction, (2) the same is true as regards migration data relative to food packaging materials, particularly film and sheet, and (3) we have not yet received and would still like to have anything you can supply on milk tubing and blood bag extraction.

Actually, the Food and Drug Administration situation has not changed materially from the time of our last letter. All that we can say is that I spoke with Mr. Richard Ronk again today and was advised that FDA is still probably two or three weeks away from proposing the revocation of the existing PVC prior sanction, and the substitution of an Interim Food Additive Regulation. The delay is occasioned in part by the need for additional consideration of the test methodology to be employed. Dan Dixler has been in contact with some of you to help with this problem and we have advised FDA that the data it desires will be forthcoming as soon as possible.

Otherwise, the Agency is still thinking along the lines previously indicated. There is some chance that there may be a swing in FDA philosophy regarding the matter of how explicitly it will deal with the plastic pipe question but, frankly, it would be misleading in our opinion to offer anything other than a remote hope in this connection. We are doing our best to handle this problem, as well as the others many of you have raised; the additional data we have requested would be of aid to us. Nevertheless, as you know, Mr. Ronk continues to be thinking about explicit mention of plastic pipe in some way in the preamble or body of what is published even though it cannot be said with accuracy that anything definitive in the way of a draft is ready as yet.

One other Food and Drug Administration question has been raised by several of you so we thought it might be well to bring it to everyone's attention. In last week's letter we noted that the FDA scientists are considering a 1 ppm residual monomer limitation on flexible film and other items, as contrasted to a 10 ppm limitation on rigid bottles. The reason for this is primarily because FDA has no actual extraction data on flexible film or sheet, whereas it does have data on rigid materials. If it were supplied with migration data concerning the former, its thinking could be shifted since, at the present time, it is based solely on a calculation assuming total migration. Anyone especially interested in this problem, and unfamiliar with the preparation of the type of data needed, should feel free to contact Dan Dixler of our office for advice as to how appropriate extraction work might be done.

On the other hand, there has been a very significant development in one of the other areas of regulatory concern. As anticipated, an Emergency Temporary Standard vis-a-vis exposure to vinyl chloride has been promulgated by the Occupational Safety and Health Administration (OSHA). It applies to all those handling or using vinyl chloride monomer and to PVC processors. Although the regulation itself does not explicitly state that it applies to vinyl plastics processors, the regulation can be read in that light and it is explicitly indicated in the preamble to the regulation that this is the intent. We are enclosing a copy of the Federal Register publication (39 Fed. Reg. 12342 - 12344) so that you can have the full text available for reference.

As you will note, the regulation which became effective on April 5, 1974 requires that no employee be exposed to vinyl chloride monomer at a concentration in excess of 50 ppm. Furthermore, compliance with this requirement should be established by monitoring that begins as soon as possible, but no later than April 22, 1974. Monitoring should be conducted on at least a weekly basis until all results for three consecutive weeks are at or below 50 ppm; thereafter monitoring should be conducted on at least a monthly basis as long as the tests show that the maximum exposure level is not exceeded. Should the exposure level be exceeded, monitoring on at least a weekly basis shall be resumed until again all three successive weekly results are satisfactory.

The regulation also includes requirements regarding the method of monitoring, employee observation and notification, record keeping and rules for compliance.

In particular, the rules for compliance require that whenever the vinyl chloride concentration exceeds 50 ppm or when there is an accident that indicates the likelihood of a greater than usual release of vinyl chloride into the ambient air, all exposed employees should be withdrawn to a safe area unless they wear suitable respirators or self-contained breathing apparatus.

Included in the Federal Register notice, but perhaps of little direct concern to most of you is the amendment to §1910.19 of the OSHA Regulations which has the effect of

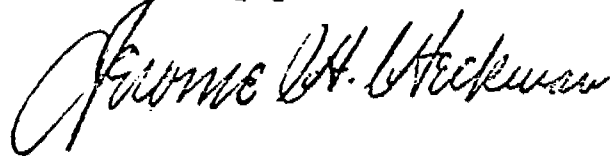
assuring the application of the vinyl chloride regulations to certain specific industries: construction, ship building, shipping and longshore operations.

Finally, we are also advised that the Environmental Protection Agency has indicated that it is considering the environmental aspects of the entire VC-PVC problem and expects to issue a report by early summer. EPA held a briefing for the press and environmental groups on vinyl chloride last Thursday. The major piece of information disclosed was that an EPA Vinyl Chloride Task Force is studying the problems raised by the recognition of special problems associated with vinyl chloride and expects to have a report soon. It was also noted that both EPA and the Food and Drug Administration have taken steps to effect recalls of aerosol products in connection with which vinyl chloride may have been used as a propellant ingredient. Attached to this letter is an EPA release of last Thursday, and a wire service report from last Wednesday dealing with the FDA recall action.

Little of direct concern to the plastics industry, per se, was noted at the EPA briefing except a report that the Solid Waste Office foresaw no rising problems of PVC containers in trash. To offset this "plus" was a report that the vinyl chloride monomer loss in a plant making PVC by the suspension process was 6 - 6 1/2% and that EPA is going to stop this loss by making it more costly to pollute.

Once again we want to assure you that we are doing our best to follow the many governmental activities bearing on this complex problem and will continue to try to keep you as up to date as possible.

Cordially yours,



Enclosures