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JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. RILL
MARTIN W. BERCOVICI
PETER M. NEMKOV
JOSEPH E. HADLEY
CAROLE C. HARRIS
WILLIAM W. PUGH
PETER THOMAS SMITH

LAW OFFICES
KELLER AND HECKMAN
450 17TH STREET, N. W.
SUITE 1000
WASHINGTON, D. C. 20036

TELEPHONE
202 296-2100
CABLE ADDRESS "KELMAN"

March 17, 1975

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;
VC and PVC Producers Committee

Ladies and Gentlemen:

Following up on our last general report letter of March 4, 1975 sent out during my absence from the office for a short vacation, the purpose of this communication is to try to provide you with another overall "round-up" on exactly where we stand as regards vinyl chloride monomer and polyvinyl chloride problems as far as the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Environmental Protection Agency (EPA) are concerned. The most dramatic new developments have been with respect to the Food and Drug Administration and the Environmental Protection Agency areas. The FDA problem is apt to prove the most vexing now because of an interim report released orally by Dr. Maltoni on ingestion studies he has been conducting. Not unexpectedly, these studies have led to the discovery of angiosarcoma in test animals. At least for now, we believe the Food and Drug Administration is taking an enlightened view of the problem presented so there should not be undue alarm but we are discussing the matter at some length below.

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As far as the Environmental Protection Agency work is concerned, as you are all aware, the major responsibility for efforts in this area is now the charge of Associate Counsel, Ruckelshaus, Beveridge & Fairbanks. However, during what is amounting to something of a transition period, Joe Hadley of our offices has been working very closely with Mr. Ruckelshaus and his partners, as well as the VCM/PVC Producer's Committee's Subcommittee on the EPA problem. Thus, a report on this activity, which we also consider to be going rather well under the circumstances, is set forth below.

FDA

As we imagine many of you will have heard by now, verbal reports we received from Europe via Ralph Harding on Monday, March 10, 1975, and immediately relayed to FDA and NIOSH (we have not seen any written formal reports), indicate that Professor Cesare Maltoni has now found preliminary indications that rats fed vinyl chloride by intubation at very high dietary levels roughly equivalent to the inhalation exposures in his previous experiments developed the same types of cancer. In other words, if the reports ultimately prove to be accurate, it would appear that the mode of action of vinyl chloride as a carcinogen for rats is independent of the route of administration, at least as far as comparing inhalation with ingestion. The significance of this type of experiment is hard to assess at this point since the force-feeding levels involved are so grossly above any level of monomer that could conceivably appear in food.

We are attaching a statement which I prepared as a guide for my responses to inquiries posed by the press; this memorandum was not issued as a press release. Before using the statement, however, I sent copies to the Food and Drug Administration where it was reviewed by members of the Division of Food and Color Additives and the Division of Toxicology, at least. Naturally, FDA could not and did not "approve" this document nor would its spokesmen even say that FDA "agreed" with any of my conclusions. Nevertheless, I think I can confidently say that the FDA Staff is not

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disturbed by, nor would it feel compelled to publicly refute anything contained therein.

Based upon our contacts with FDA personnel and others, we believe it is also fair to state that FDA is taking a very clam, considered, "wait and see" approach thus far. It has received nothing in the way of a formal report so that it cannot study in any meaningful way the work done so far by Dr. Maltoni and, thus, cannot comment definitively on the work's significance. Furthermore, at least one knowledgeable FDA spokesman appears to think that the present draft Interim Regulation still going the rounds within FDA needs no change in significant detail as a result of this "information," if that is what it is; nor is any extensive revision of the proposed Interim Regulation going on at this time. In other words, it would appear that FDA is moving very deliberately and responsibly, as it has been doing all along, in dealing with the question of controlling and limiting the possible migration of vinyl chloride monomer to food as a result of the use of PVC packaging materials.

Finally, to give you as much in the way of background on this matter as possible, as well as some additional reassurance about FDA's attitude, we have received permission to reproduce and are enclosing herewith copies of pages 46, 47 and 48 from this week's edition of Food Chemical News.

OSHA

As all of you are aware, the OSHA situation is what might be termed in something of a state of limbo although, as matters now stand, the Vinyl Chloride Standard will become effective on April 1, 1975 unless certain actions presently underway shift the course of events.

More specifically, in accordance with the duly taken votes and instructions given us by the VCM/PVC Producer's Committee, we have been cooperating with counsel for Firestone and Union Carbide with a view towards the filing of (1) a Petition for a Writ of Certiorari to contest the January 31, 1975 decision

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of the United States Court of Appeals for the Second Circuit, and (2) an accompanying "Application to Recall and Stay Mandate of the United States Court of Appeals for the Second Circuit and to Stay Effective Date of the Final Standard Regulating Occupational Exposure to Vinyl Chloride Pending this Court's Disposition of the Petition for Writ of Certiorari and its Final Disposition of this Cause". The latter pleading will be filed because the Court of Appeals denied a Petition for Stay of its Mandate as reported to you in our March 4 letter.

Both the Petition for Writ of Certiorari and the referenced "Application to Recall and Stay Mandate" are scheduled to be submitted this week, undoubtedly by the time you receive this letter. The Application will then be in the hands of Justice Thurgood Marshall who will probably make a reasonably prompt decision on whether to grant any type of further Stay or not. Ultimately, the Petition for Certiorari will be considered by the full Bench of the Supreme Court with four votes required if the Court is to entertain the Appeal on its merits, i.e. is to grant the Petition for a Writ. Incidentally, we have been asked for and have granted permission to the National Association of Manufacturers to file an Amicus Curia Brief vis-a-vis the Petition for Certiorari.

For obvious reasons, and although we have reviewed and commented on both of the documents to go to the Supreme Court carefully, copies thereof are not being sent with this letter since this would place an undue burden on our reproduction facilities and the mails. If any of you have an uncontrollable interest in seeing the pleadings, it would appear that the only practical way to handle this would be for you to go to the Clerk's Office at the Supreme Court at your convenience or, in the alternative, we can probably make copies available for review in our office given sufficient notice.

While the judicial process is being employed in these ways, OSHA is holding up publication of a "Program Directive" we understand it has prepared to guide its

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employees on the enforcement of the new Standard. Likewise, the word we have informally--and this should definitely be taken as wholly unconfirmed since, while we are litigating with OSHA, we are not in a good position to ask about its enforcement policies--is that those of you who have Variance Petitions of various types pending need not be concerned about vigorous enforcement efforts until such Petitions are handled definitively. The basis for this view is the indication given in Secretary's Stender's letter of December 10, 1974 wherein you will recall his advice that OSHA would not plan to be unreasonable about enforcement as to those who have requested Variances so long as the Variance request is pending. The precise words on this subject were: "Until such interim orders [variance orders responsive to requests] are granted or denied, no applying employer will be cited for failing to comply with the Permanent Standard's respirator requirements unless exposure levels are above 50 ppm."

One other point of interest might be mentioned here. Sources at OSHA have advised that at least one Petition or letter has been filed requesting that a company or companies be relieved from the requirement for complying with the transportation, and perhaps the other labeling provisions of the Standard with respect to shipments of materials containing less than 1 part per million residual monomer. The same source indicated that OSHA may be looking favorably on a possible amendment of the Standard as a way of accommodating this position across-the-board. Again, however, it appears unlikely that any action of this type will be taken while the Court proceedings remain active.

EPA

In our last several letters we have tried to keep you abreast of the rapidly developing situation with regard to the Environmental Protection Agency's (EPA) investigations into and findings about air emissions of vinyl chloride. Of late, the Steering Committee of the Vinyl Chloride and Polyvinyl Chloride Resin Producers' EPA Subcommittee has met with the Agency's Standards Development Team assigned to vinyl chloride,

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provided follow-up information and held an additional smaller scale follow-up meeting with the EPA personnel involved. It has now begun to review the extensive support documentation EPA has provided to it. The EPA Subcommittee has distributed these documents, about three inches thick, to each company represented in the Producers Group for comment.

At this juncture, the support documents represent current EPA thinking with regard to the technological basis and justification for setting an air emissions standard; they are also the papers EPA will present to the National Air Pollution Control Techniques Advisory Committee (NAPCTAC) at the end of this month for that group's comment and review. Through arrangements made as a result of the EPA Subcommittee's continuing contact with the Standards Development Team in Research Triangle Park, time has been set aside at the NAPCTAC meetings on March 25 and 26 for the presentation by our Committee of industry comments on the support documents.

Preparations are already underway to develop a suitable presentation. In so doing, it should be noted that, while much of the EPA technical data appears sound, one of the main points to be made will concern its apparent misunderstanding of the manufacturing process for dispersion resins. This topic was discussed in detail with the EPA Staff at a meeting last week but, by the time of the NAPCTAC meeting, additional information, some specifically requested by EPA, will have been prepared in an effort to get more accurate information into the standards development documents concerning the special problems confronting dispersion resin manufacturers.

The up-coming NAPCTAC meeting is just one of the first of many steps EPA must take in developing an air emissions standard for vinyl chloride. Nevertheless, EPA intends to publish a proposed Regulation in the Federal Register about June 20, 1975. The proposal will then be followed by public hearings and further study of comments submitted thereon. Publication of a final Regulation is now scheduled for shortly before Christmas, 1975. This final Regulation, as we have previously reported, would apply only to vinyl chloride and polyvinyl

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chloride resin producers--it will not apply to fabricators. Although considering the possibility, EPA has not yet decided if a Standard for the fabricator segment of the industry is necessary.

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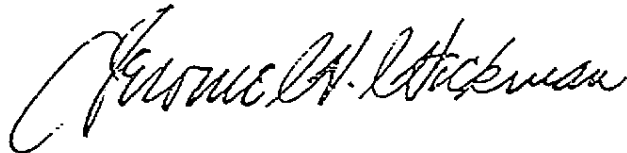
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Summarizing, it is our current view that the agencies responsible for the ultimate regulations that will come out regarding food, drug and cosmetic packaging materials, and air emissions are proceeding very rationally. We do not believe they are likely to be stampeded into inappropriate action but, as one official so aptly put it at a meeting I attended last week, the degree of overreaction can easily depend upon and be in direct ratio to the amount of public hysteria created by press reports.

In any case, we shall continue to do our best to keep you fully posted on what is taking place. If you have any questions or comments in the meantime, by all means let us know.

Cordially yours,



Enclosures

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