

LAW OFFICES

KELLER AND HECKMAN

1150 17TH STREET, N.W.

SUITE 1000

WASHINGTON, D. C. 20036

TELEPHONE

202 296-2700

CABLE ADDRESS "KELMAN"

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

August 12, 1975

No. 1

TO: All Members of VCM/PVC Mailing Lists

Ladies and Gentlemen:

The purpose of this letter, as in the past, is to try to report to you on the latest developments relative to activity at the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA) and, via a separate report, the Environmental Protection Agency (EPA); in addition, we are hereby urging the submission of certain data (described below) to FDA.

We are sure you have noted that, in response to constructive suggestions, the format for our periodic reports to you is changing with this "edition". Specifically, to save space, we have condensed the list of addressees. Further, to help organize your review and filing of these documents, we will number each letter serially with a number located beneath the data, starting with this letter as No. 1.

FDA

Since our July 18, 1975 report to you, a good deal has occurred and we now have some hope (despite what you are reading in the lay press and hearing on the other mass media), although by no means any assurance, that FDA may again modify its thinking in connection with the not-yet-published proposed Regulations dealing with polyvinyl chloride food contact materials. More specifically, we have some reason to feel there is a chance that if manufacturers of compounds for potable water, pipe, food contact rigid and semi-rigid articles such as bottles and sheet material, or the same types of finished products, promptly supply the Food and Drug

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Administration with information regarding the residual monomer content of their present products, FDA may yet be persuaded to propose to reaffirm the prior sanctioned status of PVC resins and compounds based on the evidence that the characteristics of presently available raw materials will assure that there is no reasonable expectation that vinyl chloride will become a component of foods as a result of the use of polyvinyl chloride food contact articles.

In order to put the extremely hectic activity which has been taking place into some framework, a relatively chronological explanation of what has transpired since our last letter may help. Since that letter was sent to you on July 18, I have had a radio "confrontation" with Dr. Sidney Wolfe of the Health Research Group (HRG) on WOR-AM in New York City, and submitted a letter to FDA in connection with further metabolic studies on vinyl chloride conducted by Dow on its own and in cooperation with the Manufacturing Chemists Association (MCA). Excellent articles covering much of what has been happening have appeared in Food Chemical News. (Its August 4 report concerned our July 18 meeting with the Commissioner, et al. and the August 11 issue mentions, among other things, our August 8 meeting with FDA personnel to discuss the toxicology of vinyl chloride). The Editor of FCN has given us permission to reproduce these articles so copies are enclosed with our fervent suggestion that you review the information contained therein; it is, in our opinion, quite accurate unlike the recent Business Week and August 11 Wall Street Journal stories. Finally, and out of chronology, we will report on some visits made to FDA by individual company representatives and are including herewith samples of letters sent by some companies.

Shortly after the HRG Petition was filed (and you will recall a complete copy of this Petition was included with our July 3 mailing), SPI was contacted by the producer of the McCann program which has been a feature of radio station WOR-AM in New York for at least two generations. We were informed that one day of the program, which is generally directed toward health and nutrition matters, was being set up to have Dr. Wolfe

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present the anti-PVC case. This is why we were offered an opportunity to appear to present the pro-PVC case. Although we generally prefer to avoid this kind of situation, we felt it important that the industry not be accused of refusing to appear on the program and that an attempt be made to divert and blunt immediately any unsubstantiated charges by Dr. Wolfe; thus, the invitation for July 22 was accepted by SPI and I was assigned to the debate.

In light of the nature of the forum, it was decided that our best approach would be the reiteration of the facts that (a) even in the past vinyl chloride did not really enter the diet as a result of PVC packaging because any vinyl chloride that might have entered food packaged in old style bottles or otherwise would volatilize rapidly before ingestion could occur, and (b) the new compounds available have such low residual monomer contents that there is no possibility of migration now.

Actually, we had no hope or expectation of convincing Dr. Wolfe of anything. We did hope that the audience might be "de-panicked" and that any unreasonable and unwarranted fears would be forestalled. Another objective was to try to present enough of the industry's view to limit "pickups" from the show by the wire services; I think the issues were left confused enough so this one purpose was achieved. We are enclosing a copy of a transcript of the program so that you can have a record of at least the words. We thought it would be worthwhile to do so simply so you can see what sort of pseudo-rational antagonism is now being faced and is probably influencing FDA public relations concerns. The intensity of Dr. Wolfe's presentation does not come through but, unfortunately, we cannot present the music to go with the words except to those of you who might want to drop by to hear a forty-five minute tape recording.

Turning to more substantive matters, as many of you know, we had planned to meet with FDA toxicologists on August 8 to discuss the protocol for a feeding study being developed by the Ad Hoc PVC Toxicology Committee. Related to this but completely independently, the Manufacturing Chemists Association (MCA) has been sponsoring

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an investigation of the metabolic fate of inhaled vinyl chloride which is being conducted by Dow Chemical, U.S.A. In addition, Dow with its own funds extended the study to include the metabolic fate of ingested VCM. These studies tend to confirm the report made during the OSHA hearings to the effect that there seem to be at least two metabolic pathways whereby the body "handles" vinyl chloride. There seems to be a detoxification process whereby harmless metabolites are formed and excreted when low levels of vinyl chloride enter the body, and a second (toxic) route that becomes effective when the low level mechanism is swamped or saturated. Accordingly, it was deemed desirable to notify FDA of these findings as a possible means of providing even more of a scientific foundation for the acceptance of the SPI position vis-a-vis PVC food packaging, as distinguished from the HRG position. A summary of the Dow findings was submitted to the Food and Drug Administration on July 30; we are enclosing a copy of our transmittal letter and the summary.

Current FDA procedures require the preparation of a summary report available to the public whenever FDA personnel meet with those outside the Agency. Accordingly, Sam Fine, Associate Commissioner for Compliance, prepared a memorandum regarding the emergency July 18 meeting which we held with the Commissioner and members of his staff (and which we reported on to you at the time). Food Chemical News for August 4 used Mr. Fine's memorandum as the basis for its lead article which, as noted above, is enclosed herewith. This article indicates that the FDA understanding of our presentation and position appeared to be full and complete.

On August 8, representatives of SPI--Ad Hoc PVC Toxicology Committee met with representatives of the FDA to discuss a draft protocol for a feeding study submitted earlier by SPI. It was the intent of the Group to obtain an FDA critique of the protocol so that the proposed feeding study could be undertaken with the assurance that the results would be acceptable to FDA. In addition, as a result of the MCA-Dow Chemical, U.S.A. work, the meeting was broadened to include a presentation to FDA of the results of the metabolic study to date.

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The meeting was unusually well attended by FDA personnel. Included among them were Dr. Howard R. Roberts, Acting Director of the Bureau of Foods; R.E. Shapiro, of the Epidemiology Unit, Bureau of Foods; R. Angelotti, Head of the Office of Compliance, Bureau of Foods; H. Blumenthal, C. J. Kokoski and K. P. Mizra of the Division of Toxicology; A. Holtz, N. Weber, T. Fazio of the Division of Chemistry and Physics and J. J. McAuliffe and G. McCowin of the Division of Food and Color Additives.

Present for SPI and MCA in addition to the undersigned were K. Morgareidge, Food and Drug Research Laboratories, Inc.; C. Spiegel, Continental Can; J. Norris, Dow Chemical; W. Rinehart, Ethyl Corp.; A. Lindquist, Stauffer Chemical; P. Watanabe, Dow Chemical; N. Freifeld, MCA; and D. Dixler, Keller and Heckman.

With respect to the metabolic studies, a presentation was made by Dr. Watanabe which demonstrated that ingested (and inhaled) vinyl chloride forms metabolites with sulfhydryl-containing compounds which are then further modified and excreted via the urinary route. When administered at lower concentrations, essentially all the absorbed vinyl chloride is eliminated in this manner. When fed in higher concentrations, there appears to be a significant depletion of the sulfhydryl-containing moities in the liver and at the same time large amounts of the vinyl chloride are eliminated by exhalation. Nevertheless, even when fed at high levels, the same detoxifying metabolites are also found in the urine although as a percentage of the administered dose they are significantly lower.

In other words, it appears that the first physiological response to vinyl chloride is to detoxify it by reaction with non-protein sulfhydryl groups. When the amount of vinyl chloride becomes too large, however, some of the vinyl chloride is eliminated via the lungs, the quantity depending on how much excess vinyl chloride has been absorbed compared to the sulfhydryl reservoir.

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During the ensuing discussion, it was pointed out that the work so far does not yet demonstrate that high level ingestion produces any metabolites different from low level exposures; nor is there evidence that high level metabolites are carcinogenic.

With respect to the feeding study protocol submitted by SPI, Dr. Rinehart pointed out that the purpose of the study was to provide data on the dietary effects of vinyl chloride when it was administered in a realistic way, i.e. as a part of the total diet rather than as large daily "slugs" as is the case when it is fed by gavage. Other purposes of the study were to demonstrate the effects of lifetime feeding instead of the one year feeding conducted by Maltoni and to use sufficient animals (100 rats per sex per dose) so as to provide better statistical conclusions. Finally, the study proposed to do extensive pathology whereas Maltoni and his co-workers looked only for tumors.

The major FDA criticism from a technical point of view was the absence of what it considered to be a positive control. FDA recommended that some animals be fed by gavage at a level high enough to cause cancer as judged by inhalation and Maltoni feeding study results. The purpose here was to demonstrate that the rats used were susceptible so that if no cancers developed, it could not be stated that the result was due to insensitive animals, i.e. the wrong strain or species.

On a more general level, FDA raised the question as to whether the feeding study would accomplish results commensurate with its cost; since Maltoni has already demonstrated that orally ingested vinyl chloride does cause cancer at some level, a demonstration that it does not cause cancer when administered by a more realistic procedure cannot obliterate his positive findings. Only if the protocol were modified so as to feed the same dose by gavage and by the drinking water route, and the results demonstrated that cancer was induced by gavage and not by PVC in drinking water, could this study negate the evidence already in the record.

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FDA did indicate that there might be some limited value to a study that provided enough animals fed at low levels to demonstrate, with good statistical data, that a criterion of no migration with a specified analytical procedure would provide sound assurance of the public health.

Based upon the FDA comments, the Toxicology Working Group of the Ad Hoc Toxicology Committee will meet early in September to consider revising the protocol or other alternatives.

You will recall that we relayed to you a request that residual monomer and migration data be submitted to FDA. This request was reaffirmed in private conversations between FDA and several PVC producers and during the course of the August 8 toxicology meeting reported above. More specifically and urgently, it now appears that there is some hope for inducing FDA to change the direction along which it is presently going toward a proposed Regulation that would place PVC potable water pipe under an Interim Regulation and PVC food contact bottles and sheet under the necessity for clearance by Food Additive Petitions. This hope is that manufacturers of PVC compounds and finished articles in the foregoing classifications can provide evidence that currently sold products have far lower residual monomer contents than those which originally gave rise to the problem. Accordingly, we are requesting data be supplied by individual producers concerning the following:

1. The residual vinyl chloride content of food contact compounds or finished articles (potable water pipe, food packaging sheet and bottles) before the industry became aware of the residual monomer problem.
2. The present levels of residual monomer in the products you are now supplying for these markets.
3. Your residual monomer goals for these products, and when is it anticipated that they will be reached.

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It is our hope that with such factual data in its file FDA can be induced to once again consider re-affirming the prior sanction status of PVC for all applications subject to a "no-detectable" monomer migration limit. Such data should be sent to:

Dr. Alexander Schmidt
Commissioner, Food and Drugs
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852
(with copies to)

Mr. Sam Fine
Associate Commissioner for Compliance
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20852;

Dr. Howard Roberts
Acting Director, Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204;

Dr. Robert Angelotti
Associate Director for Compliance
Bureau of Foods
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204; and

Mr. Richard J. Ronk
Director, Division of Food and
Color Additives
Food and Drug Administration
200 C Street, S.W.
Washington, D. C. 20204

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Again as indicated above, and in connection with company contacts with FDA, we are enclosing a reproduction of the August 11 Food Chemical News article describing a Tenneco visit to FDA. As an example of some of the letters that various producers are sending to the Food and Drug Administration, we are enclosing copies of letters sent by B. F. Goodrich, and by Ethyl Corporation. In addition, residual monomer levels on new type compounds or finished products are being provided by Hooker, Air Products, and others. We urge that all who can do so. Moreover, in the absence of some special reason for not so doing, we would appreciate your supplying us with copies of anything sent to FDA.

OSHA

First of all, the Petition filed by Air Products and Chemicals, Inc. and mentioned in our July 18 letter but inadvertently not attached, is enclosed for your information.

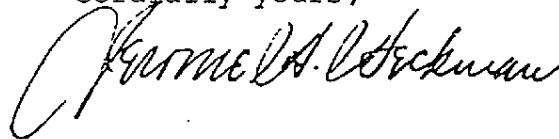
Over the last several weeks (and perhaps we can attribute this in part to the fact that many people are taking July and August vacations this year) virtually no substantive activity related to the Vinyl Chloride Standard has occurred at OSHA. As to the cases where Notices of Contest have been filed, no changes in their status has occurred.

EPA

Following our now usual practice, we are enclosing a copy of a letter received from our Associate Counsel for EPA activities. We believe this report is self-explanatory and will serve to bring you completely up-to-date in this area.

As we have in the past, we shall continue to inform you as fully and promptly as we can with respect to the various phases of the VC/PVC matter. Additionally, we hope that our revised format will make your filing and referencing somewhat easier.

Cordially yours,



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