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E. F. Wheeler

TELEPHONE
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CABLE ADDRESS "KELMAN"

April 23, 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 Rule Making

Gentlemen:

The purpose of this letter is, once again, to update you on the status of our polyvinyl chloride resins and products crises vis-a-vis Federal regulatory activity during the past week. The Occupational Safety and Health Administration (OSHA) situation has commanded most of our attention in the last six or seven days but we have also remained in close touch with the Food and Drug Administration (FDA). Please read all parts of this letter and the enclosures since many of them may indicate the need for a variety of actions by your company depending on your specific interests; the situation is simply too complex for us to follow the policy we prefer to use which is to indicate the "need for action" areas in our opening paragraphs.

With respect to OSHA problems firstly--this now being the area we consider most critical--all vinyl chloride monomer and polymer producers, as well as fabricators, are now expected to be in compliance with the Emergency Temporary Standards (50 ppm in the atmosphere) which we sent to you as one of the enclosures in our April 8 mailing.

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With regard to the industrial hygiene (OSHA) aspects of the VCM-PVC matter, under the auspices of SPI, and at the request of the leading companies in the field, on Tuesday, April 16, 1974 what has now been constituted as the SPI Vinyl Chloride and Polyvinyl Chloride Producers Ad Hoc Committee met in Washington for the purpose of considering the industry-wide problems associated with the Emergency Temporary Standards set by OSHA for VCM and PVC facilities. Working committees were set up to gather data regarding levels of exposure in VCM and PVC plants, as well as VCM residual levels in various polymer products shipped by the polymerization plants. In addition, a working group is also investigating the nature of any vinyl monomer problem that might exist in the plants of vinyl processors; if any problem should be found to exist in such plants, an attempt will be made to isolate the sites within the plants that might require special attention. Still further, another working group is investigating the likely economic impact if the Emergency Temporary Standards should be significantly lowered to a level where polymerization plants could no longer remain in production, or if permanent standards should be set (as recommended by NIOSH) at a "no detectable" or 1 ppm monomer level in the air, using methods sensitive to 1 ppm.

Special urgency prompting the requests that SPI call the April 16 meeting and the formation of this Committee was generated by two related developments. Firstly, the Manufacturing Chemists Association (MCA) which is sponsoring inhalation toxicology studies has reported preliminary findings that a level of 50 ppm in air appeared to have induced liver cancer in mice although rats and hamsters were not affected at the same level for the same period of time. A copy of the MCA news release in this respect is attached. Secondly, the Manufacturing Chemists Association informed those of its members that were vinyl chloride or polyvinyl chloride producers that it (MCA) could not represent a segment of the chemical industry in its dealings with regulatory agencies so these companies requested that the Ad Hoc Committee be set up under SPI.

Although the current OSHA regulations indicate that vinyl processors are included in the coverage,

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conflicting statements as to the extent of coverage have been issued by OSHA. More important, there does not appear to be a firm factual base for OSHA to decide whether vinyl monomer problems exist in processing plants at all and if they do exist, where in processor's operations such problems are isolated. It is to obtain such information on behalf of PVC processors and, hopefully, to limit their need to be concerned, that an important part of the Ad Hoc Committee's efforts are being directed.

Yesterday a meeting was held at the OSHA offices between Dr. Van Atta and others on the OSHA Staff and members of our Staff. The major purpose was to explain SPI's intended participation in what had formerly been an area expected to be handled by others. Another purpose was to inform OSHA, before it had progressed too far with the preparation of a proposed permanent standard, of the plans to obtain data which had been formalized by the Society's new VC and PVC Producers Ad Hoc Committee.

During this meeting, it became evident that the OSHA Staff people are anxious to propose a permanent standard that strikes a fair balance between the need to protect workers in PVC plants on the one hand without making it economically impossible for the industry to continue on the other hand. Despite their obvious awareness of the magnitude of the economic impact problem, (and, by the way, we have been in contact with organizations like those representing the food chains which are bending all efforts to impress OSHA and FDA with the need for avoiding precipitous action that might even cut off the food supply of the country), the OSHA people advised that, in the absence of data on which to fix a "safe working level," and in light of the MCA-sponsored data casting doubt on the safety of the 50 ppm level set in the presently effective Emergency Temporary Standard, OSHA will propose a 1 part per million peak exposure limit combined with a 40 ppm-hour limit per week. Regardless of the final figure proposed, it is now anticipated that a proposal will be in the Federal Register on or about April 30. The present thinking on timing is unclear. We were told yesterday that the proposal will allow only 30 days for comment but today we heard there is a chance that 60 or even 90 days may be permitted.

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The main timing problem to which OSHA is acutely sensitive is that it is required to have a permanent standard "on the books" six months after the promulgation of the Emergency Temporary Standard. Since the latter was promulgated on April 5, OSHA must have a permanent standard promulgated and in effect by October 5. It is required to allow a one month lead time between the appearance of a regulation in the Federal Register and the date that it takes effect so OSHA plans to have the permanent standard published by September 5, 1974.

This extremely tight schedule to which OSHA is committed means that either within the Comment period, or during such additional time as is permitted to hold a hearing on the matter should one be requested (and it is certainly our present plan to so request), all the data that can be generated must be available. This means that all interested parties must respond very promptly to the various calls for information that may be forthcoming.

Turning now to the FDA area, the request for information which we transmitted to you last week has been reinforced by two Notices published in the Federal Register on April 22. We are enclosing copies of these Notices for your consideration. Together, they request from all interested parties the submission of VCM residue and migration information, and direct all Registered Drug Manufacturers to supply certain information regarding the use of VCM or PVC containers.

The substance of the Notice of Proposed Rule Making states the intention to ban the use of vinyl chloride as an ingredient of drug products and cosmetic products, but the preamble requests the submission of the type of information we previously noted. However, the Notice to Drug Manufacturers, Packers, and Distributors requires the submission of a list of drugs containing vinyl chloride and a list of drug products packaged in PVC or PVC-lined containers. In addition, information regarding possible exposure to VCM is requested.

Finally--and this is about all of the "good news"--we have been informed that FDA is now considering dropping

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from its anticipated PVC food additive rule making all limits on residual monomer in the food contact surfaces while retaining the limitation of "non-detectable" (at 50 ppb sensitivity) in foods and food-simulating solvents. This, of course, is something we have been strongly advocating ever since March 8.

Although our previous notification to you recommended that data be submitted either to us or to the Food and Drug Administration (attention Mr. G. McCowin), the Federal Register Notice requests that the information be submitted to the Hearing Clerk at the Food and Drug Administration. Procedurally, any information submitted to us or to Mr. McCowin will also be transmitted to the Hearing Clerk so you need not be disturbed by the apparent inconsistency in the recommended addressee; it is just part of the general confusion that pervades this entire issue.

You may also recall that we informed you previously that the Health Research Group had filed Petitions with the Consumer Product Safety Commission, EPA and FDA regarding various uses of vinyl chloride, particularly as a propellant in household products, insecticides and drugs and cosmetics. The Notice of Proposed Rule Making by FDA, which we are enclosing, embodies, at least in part, the FDA response to the Petition it received.

EPA has ordered a voluntary recall of all pesticides which may be on the market and which use vinyl chloride as the propellant but has indicated that it will not name all such pesticides so the Health Research Group is suing for the publication of the names of all producers.

Although the Consumer Product Safety Commission has not yet responded to the petition filed with it, it is understood to be planning to ban the use of vinyl chloride as a propellant in all household items.

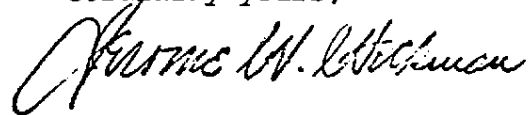
We shall continue to keep in as close touch as we can with all aspects of the current crises. As we have been doing, we shall post you by means of these

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"weekly news letters" so as to keep you as fully and promptly informed as possible.

Cordially yours,

A handwritten signature in cursive script, appearing to read "James W. Littleman".

Enclosures

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VERY IMPORTANT

After this letter was prepared for mailing, word was received that the OSHA proposed Permanent Standard will be published in the May 9 Federal Register. The proposal will be for a zero tolerance with a test method believed to be sensitive to 1 ppm. The Comment deadline date on the proposal will be June 10, 1974. In next week's letter, we shall try to give you full information on the OSHA action and its further implications.

Jerome H. Heckman

*I didn't have this at
the time of our meeting
Monday, May 13.*

*We're trying to arrange
a closer tie-in to the
SPI "Task force" re
exposure in processing plants.
EPA*

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May 6, 1974

TO: All Members of:

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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 Ad Hoc Committee

RE: Polyvinyl Chloride Prior Sanctioned
Status; Proposed Rulemaking

Gentlemen:

The purpose of this letter is, as in each case for the past several weeks, to try to keep you up to date on the status of polyvinyl chloride resins and products from the viewpoint of Federal regulatory activity and related matters during the past week. Although we are not requesting or suggesting new responsive activities in this letter, we do want to remind you of the on-going requests and need for information that has previously been asked of you particularly in connection with the needs of the Occupational Safety and Health Administration (OSHA) and the Food and Drug Administration (FDA).

With respect to activity by OSHA, our most recent contacts have indicated that the soon to be Proposed Permanent Standard is now in the office of the Solicitor of the

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Department of Labor. No firm estimate can yet be given as to when it will be published in the Federal Register; the time of publication is dependent on what changes are required by the Solicitor. Our present information is that the Proposed Permanent Standard would call for a "non-detectable" concentration of vinyl monomer in all plant areas using a method sensitive to 1 ppm and that the proposal will be published anywhere from "within a few days to a few weeks."

As you know, the VC and PVC Producers Ad Hoc Committee has organized a number of task groups. One is to gather information with respect to vinyl monomer concentrations in existing plant facilities and to making technical feasibility estimates as to what lower levels could be achieved in realistic time frames. A second task group is looking into the matter of vinyl chloride concentrations in processors' plants and a third group is gathering medical record information. While it is apparent that the reports from these groups will not be available in time to affect OSHA's plans to propose rulemaking, it is planned to have the information and necessary documentation available in time for filing Comments on the anticipated rulemaking, and for presentation at a Hearing which will be requested.

In the meantime, and as we reported in our last "newsletter", OSHA has indicated its intention to prepare an Environmental Impact Statement (EIS) in connection with the permanent standard for VCM exposure. In that connection we have prepared a set of Comments to be filed which is intended mainly to inform OSHA of what SPI is doing and to provide it with a time-table. These Comments were "cleared" with the Steering Committee of the VC and PVC Producers Ad Hoc Committee at its meeting on May 3, 1974 in Cleveland. We are now circulating a copy of the draft to you so you will be fully informed. It is our intent to file these Comments before May 17, 1974 in substantially the form in which you are receiving them unless substantive suggestions and recommendations for changes are received from any of you by May 14.

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With respect to FDA activities, our most recent information remains that the proposed rulemaking in substantially the form we have previously described is expected to be published in the Federal Register "within a few weeks." Our present understanding is that the proposed rulemaking will not include a requirement limiting the residual monomer content of food contact surfaces (you will recall that this is a change from FDA's original thinking on this matter) but that FDA's questions have not been completely resolved.

We have now begun to receive a trickle of responses to FDA's request for information regarding analytical methodology and extraction results. The Food and Drug Administration also requested that we attempt to obtain samples of PVC bottles so we have now submitted the first group of bottles sent to us. We do hope that all of you who have data will send it along, either directly to the Food and Drug Administration (if possible, with a copy to us) or to us for transmission to the Food and Drug Administration. Regardless of the route you choose, the Food and Drug Administration is anxiously awaiting the requested information.

For your further general information, we are enclosing a copy of a fairly lengthy article on PVC published in the Sunday edition of the Washington Post. The article does make distinctions between facts and alarming predictions, but the alarming predictions or speculations are presented, perhaps more prominently than the facts. Because the article has been published in Washington, and the paper of such special renown since Watergate, the general tone of the story may well generate additional pressure on the regulatory agencies. This reinforces the need for the promptest possible submission of data so all the various agencies involved, especially FDA and OSHA, will have the maximum in the way of reliable facts to draw upon as each develops its regulatory positions.

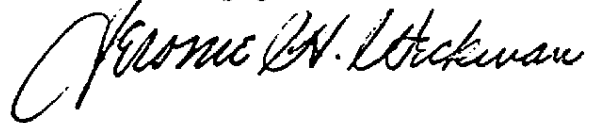
We have no further information regarding the Environmental Protection Agency (EPA) activities at this time. As you know, the EPA has task forces investigating various aspects of the vinyl chloride matter, particularly from the

point of view of emissions and related problems. We have also informed you of its banning of the use of vinyl monomer as an ingredient of pesticides. Although we are continuing to maintain close touch with EPA, we don't really anticipate responsive action on its part in the immediate future.

As many of you already know and as is indicated in the text of the Washington Post enclosure, the New York Academy of Sciences is conducting a meeting of a Working Group on Toxicity of Vinyl Chloride-Polyvinyl Chloride on May 10-11 in New York. We shall be covering this "by invitation only" meeting and will include a summary of what takes place in our next report to you.

We shall continue to keep in as close touch as we can with all the regulatory phases of the current VCM crisis and will keep you posted as we have been doing.

Cordially yours,

A handwritten signature in cursive script, reading "Jerome H. Brickman". The signature is written in dark ink and is positioned to the right of the typed name "Jerome H. Brickman".

Enclosures

D R A F T

Director
Office of Standards Development
Health Administration
1726 M Street, N.W.
Room 500
Washington, D.C. 20210

Re: Standard for Occupational Exposure
to Vinyl Chloride; Environmental
Impact Statement Notice; 39 Fed.
Reg. p. 14522

Dear Sir:

As you know, The Society of the Plastics Industry, Inc. ^{*}/ and many of its members are vitally interested in the proposed standard for occupational exposure to vinyl chloride, and in the environmental and risk-benefit impact that the standard may produce. The subject "Notice of Intent to Prepare an Environmental Impact Statement" invites the submission of pertinent information. Some of these data are currently being gathered for presentation to OSHA by members of SPI. Thus, the prime purpose of this communication is to inform you of what is being done and our estimate as to when more definitive information will be available.

^{*}/ The Society of the Plastics Industry, Inc. (SPI) is a Corporation organized under the Not-for-Profit Corporation Law of the State of New York. It is composed of approximately 1400 member companies and individuals who supply raw materials; process or manufacture plastics or plastics products; engineer or construct molds or similar accessory equipment for the plastics industry; and engage in the manufacture of machinery used to make plastics products or materials of all types. (con't)

RSV 0002387

On April 16, 1974, shortly after the preliminary results were announced of tests wherein mice were exposed to 50 parts per million of vinyl chloride, an organizational meeting of producers of vinyl chloride monomer and polyvinyl chloride resins was held under SPI auspices. This VC and PVC Producers Ad Hoc Committee appointed a Technical Subcommittee and a Risk-Benefit Impact Subcommittee.

The Technical Subcommittee was charged with the responsibility of obtaining as much information as it possibly could in the following areas:

Health and Exposure Records. Here the intent is to obtain to the maximum extent possible health records of long-time employees of VC and PVC plants to supplement the death record survey being conducted by Tabershaw-Cooper under the auspices of the Manufacturing Chemists Association. It is hoped that this

*/ (con't) SPI is the major national trade association of the plastics industry; its membership is responsible for an estimated 75% of the total dollar volume of sales of plastics in this country. Although the Occupational Safety and Health Administration is familiar with SPI and some of its activities as a result of many informal contacts, copies of the SPI constitution, membership directory, organization charts, and other background information can be supplied immediately upon request if this is deemed necessary or desirable.

survey may provide additional information based on long-term human experience to add perspective vis-a-vis the animal exposure tests now continuing. The objective here is to provide OSHA with additional data that should help it in setting realistic exposure standards for vinyl chloride.

Plant Exposure Data. Here the plan is to obtain data regarding present plant levels of vinyl monomer, not only in the VC and PVC producers' plants, but also in processors' plants. This subcommittee plans to evaluate analytical methods and make recommendations in this regard. The subcommittee will also explore and attempt to isolate those particular processes and locations where there is the greatest likelihood of higher concentrations of vinyl chloride in the atmosphere and, concomitantly, may be able to identify those areas that give rise to little concern.

The Subcommittee evaluating economic impact has already contracted with Arthur D. Little, Inc. to conduct a survey of the economic impact of an atmospheric limitation so low that existing plants could not meet the standard and would be forced to close.

The Technical Subcommittee held a working meeting on April 24 and has been charged to submit its reports to the full Committee promptly. Arthur D. Little has undertaken to submit its report within 6 to 8 weeks or sooner.

We believe our client, The Society of the Plastics Industry is moving as rapidly and responsibly as possible in obtaining necessary information to permit the plastics industry to go forward in assuring safe working conditions for its employees. However, it will not be possible to obtain all the information that it plans to gather, much of which is also requested in the subject Notice, before May 17, 1974, the closing date for Comments on the OSHA "Notice of Intent."

Nevertheless, some of the requested information can be presented at this time. It should be particularly noted that the information we are now supplying is that which is not readily available in the published literature and is based on information submitted formally or informally

by interested members of the Society. For ease in reference, the responses are captioned as indicated in the Notice.

a. Medical and toxicological effects.

No new data is available at this time.

b. Current levels of occupational exposure.

This will be discussed in considerable detail and data will be supplied when studies now underway are completed. As of now, it can be reliably stated that most PVC plants now operating show a general average exposure level in the range between 20 and 30 parts per million. Any peak exposures to levels greater than 50 parts per million can be handled by the use of appropriate respirators or gas masks.

Plants operating in the southern parts of the country and constructed with no side walls have, as would be expected, very low--often non-detectable--levels of vinyl chloride in most of the operating areas. Those plants built in colder areas with side walls show measurable levels of VCM in many areas.

Little information is available at this time regarding historical VC levels in the plants. Based upon interviews with long-time employees, it is the consensus that exposures in the past were significantly higher than they are today. Those long involved in the vinyl industry have commented that some of the older plants often smelled of vinyl chloride. Since the threshold for olefactory detection of vinyl monomer is in the range of 250 parts per million, we believe that historical exposures in many areas were probably markedly higher than they are today.

c. Combustibility characteristics.

No non-published data is available to us.

d. Identification of the uses of vinyl chloride or its polymers.

It is expected that a fairly complete exposition of the uses of vinyl chloride polymers will be set forth in the A. D. Little economic impact submission which is currently being prepared.

e. Any information suggesting substitutes.

It would be very difficult to find substitutes for PVC because of its unique properties. Many other materials could be substituted for one or another specific PVC application; but no other substance is presently known that can substitute for all. Furthermore, even where substitute materials are feasible for specific applications, severe shortages exist which would restrict such replacement.

f. Suggested actions which will control the health hazards associated with vinyl chloride or its polymers.

Details regarding such suggestions will be presented as soon as possible. For the present, it can be noted that general good manufacturing practices to minimize and avoid leaks and other obvious procedural changes, including the use of gas masks or respirators when the monomer level becomes excessive, will tend to reduce health hazards. On a longer time scale, engineering studies

are required to redesign equipment and procedures so as to minimize the possibility of escape of vinyl chloride from polymerization processing equipment.

In the near term any hazards associated with PVC processing can be handled by known techniques such as adequate ventilation in selected plant areas. Furthermore, in the long term if PVC resins and/or compounds ultimately can be made with minimal quantities of residual monomer, all conceivable problems associated with further processing of the material will be eliminated.

We hope this information will be helpful to the Occupational Safety and Health Administration as it begins work on an Environmental Impact Statement. Certainly, we shall supply, in as much detail as possible, the data that is gathered by the VC and PVC Producers Ad Hoc Committee as soon as it is available. In the meantime, we will be glad to offer whatever assistance we can in

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providing source information to the extent possible.

Respectfully submitted,

Jerome H. Heckman
General Counsel
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Industry, Inc.

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RSV 0002395