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June 4, 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;
VC and PVC Producers Committee

Ladies and Gentlemen:

This week's report concerns mainly Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA) activities.

With respect to the previously announced "informal" Hearing to be held by OSHA beginning on June 25, 1974, the Vinyl Chloride and Polyvinyl Chloride Producers Committee is meeting this week to settle on positions and, hopefully, select witnesses to present an overall industry posture at the Hearing. However, all parties who will be affected by the permanent standard for occupational exposure to vinyl chloride may well wish to present their own views, arguments, and information at the Hearing; indeed, the Society is of the opinion that such action is to be encouraged. Those who do plan to present a statement through a witness or witnesses are reminded that a Notice of Intention to Appear should be filed with OSHA on or before June 17.

RSV 0002418

As you know, various subcommittees of the VC and PVC Producers Committee have been gathering information and preparing interim reports regarding the various aspects of the vinyl chloride problem. It had been intended to use these reports as the basis for draft Comments which were originally required to be filed as a response to OSHA's proposed permanent standard. In light of OSHA's setting a Hearing date for June 25, it became unnecessary to file Comments, and the various subcommittee reports are now being used to help formulate testimony for presentation at the Hearing. At a meeting to be held this week by the VC and PVC Producers Committee, it is intended to critically review the industry position with a view to recommending and selecting expert witnesses to provide testimony on all phases of the proposed standard.

With respect to the general problem of work-place levels of vinyl chloride, Chemical and Engineering News for May 27, 1974 published a report about moves in the United Kingdom to coordinate research into possible health risks involving vinyl chloride monomer and to recommend ways of avoiding them. We are enclosing a copy of the C and EN report for those of you who may have missed it.

The Environmental Protection Agency action of special interest relates to its having written to major vinyl chloride and polyvinyl chloride producers requesting considerable information regarding air emissions. The Office of Air Quality Planning and Standards of EPA located in Research Triangle Park, N.E. sent individual letters to all the major VC and PVC producers directing that the required information be submitted to the EPA by June 14. We are enclosing a copy of the EPA press release and a typical letter (with the identity of the addressee deleted) for your general information although only those addressed individually have been required to respond.

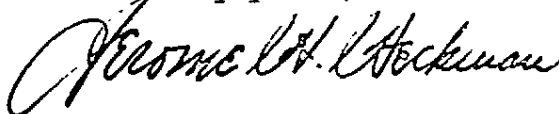
Two points should be noted in connection with this letter. Firstly, although the tone of the letter appears to be quite authoritarian, it is our understanding that the EPA group involved considers that industry has been most cooperative with it. It, in turn, states that it is ready and anxious to cooperate with industry to obtain and exchange all necessary information that can lead to reasonable and responsible standards.

Secondly, the extremely short time allowed for answer was set because EPA is trying to reach a decision early in July regarding the type of regulatory approach it should follow in connection with vinyl chloride emissions. It is EPA's hope that the various companies affected can combine the compliance needs of OSHA and EPA in one over-all engineering concept. For this to occur, the EPA requirements must be enunciated in a time frame that is compatible with OSHA's. Despite this intention, it is our present understanding that no definitive EPA action can be expected before late fall or early winter.

With respect to Food and Drug Administration (FDA) activities, we are once again reminding you that FDA is still requesting information regarding residual monomer levels in PVC plastics used for packaging foods, cosmetics, and drugs, and migration data from such plastics. In addition, it is requesting the submission of analytical methodology along with the actual residual monomer and migration reports. With respect to the anticipated FDA interim regulations, nothing new can be reported except that the regulation is anticipated to be published "in the near future".

We hope this letter with its enclosures will be useful in keeping you as fully informed as possible regarding the governmental and related aspects of the vinyl chloride problem; you can be sure we will continue to stay in touch with you.

Cordially yours,

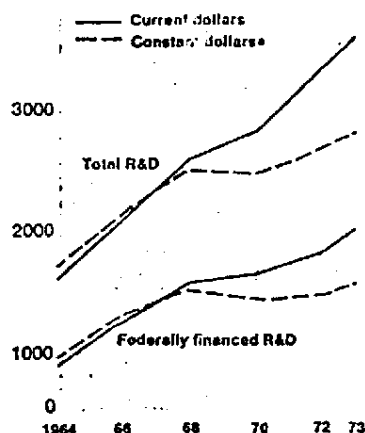


Enclosures

Academic R&D spending has doubled in past eight years

University R&D spending, \$ millions

4000



a Base year 1967, based on gross national product implicit price deflator. Source: National Science Foundation

Further, this group received \$96 million or 9% more R&D monies in 1973 than in 1972. Federal funds accounted for \$85 million or 89% of the increase. NSF adds that the 20 largest institutions accounted for "41% of federally financed R&D performed by all academic institutions in both 1972 and 1973." And, NSF says, that "almost one half, or \$56 million of the support from foundations and voluntary health agencies was concentrated in these 20 institutions in 1973."

High court eases pollution inspection

The Supreme Court has ruled that government air pollution inspectors do not need a search warrant or other permission to enter a company's unrestricted grounds to visually monitor the smoke being emitted from its chimneys. An Environmental Protection Agency spokesman says that the agency is very satisfied with the court's decision since it makes the job of monitoring air quality easier.

The unanimous ruling overturned two lower court decisions that held that conducting such tests without either a warrant or the company's consent constituted an unreasonable search within the meaning of the Fourth Amendment.

The air pollution decision stemmed from a June 1969 inspection made on the grounds of Western Alfalfa Corp. by a Colorado

state health inspector. The inspector entered the company's yard to take an opacity reading on the smoke coming from Western Alfalfa's chimneys during a drying operation. Subsequently the company was told that its emissions violated state standards and was ordered to cease and desist.

Writing the court's opinion Justice William O. Douglas said that Fourth Amendment protection does not extend to sights seen in "the open fields." Further, he observed that the field inspector did not enter the company's plant or offices, or inspect either its equipment or its files and papers. "He had sighted what anyone in the city who was near the plant could see in the sky—plumes of smoke," Justice Douglas said. He also noted that although the inspector was on company property, "We are not advised that he was on premises from which the public was excluded." Hence invasion of privacy, if it can be said to exist, is "abstract and theoretical."

Argentina plans huge chemical program

Argentina is launching a massive \$1 billion investment program to develop its chemical and petrochemical industry. Some of the plans were unveiled last week in Buenos Aires, when president Juan Peron was on hand at the signing ceremony involving members of his government and senior officials of Italy's Montedison. Montedison will act as general consultant to Argentina for the development.

Though full details are not yet available, Argentina wants to set up a variety of projects during the coming eight years. These include plants for making polyolefins; basic organic chemicals such as ethylene oxide and acetic acid; and man-made fibers and fertilizers.

Montedison will be directly involved in the first stage of the plan, which will cost an estimated \$400 million and includes a major petrochemicals center to be sited at Bahia Blanca, about 350 miles southwest of Buenos Aires. The Italian company also will invest in an aluminum plant that Italmipi-anti, a major Italian construction firm, will help build at Puerto Madryn, 325 miles farther south.

Other West European chemical firms are expected to take part in the overall plans. Like Montedison, they will have a financial stake in the new plants.

Vinyl chloride issue focus of U.K. group

Reflecting growing international concern about vinyl chloride, the U.K.'s Chemical Industries Association has set up a committee to coordinate research into possible health risks involving the monomer and to recommend ways of avoiding them.

On the committee are representatives of the four U.K. polyvinyl chloride makers—British Industrial Plastics, BP Chemicals International, Imperial Chemical Industries, and Vinatex, a subsidiary of Continental Oil—which can produce a total of 410,000 metric tons of PVC annually. Also represented are the British Chemical Industry Safety Council, the British Plastics Federation, and the Chemical Industries Association itself. The companies have agreed to spend about \$10 million for detailed studies on in-plant safety conditions, for reducing the atmospheric vinyl chloride vapor levels in their plants to 50 p.p.m. or less, and for developing improved monitoring systems. The funds also will be used for animal experiments and epidemiological studies.

Committee chairman A. W. Barry Barnes of ICI's plastics division, stresses that the move is a positive one on industry's part to counter a recently recognized industrial problem head-on. He also strenuously denies that the industry has been responsible for keeping the lid on release of research results of Italy's Prof. Cesare Maltoni, who has shown that vinyl chloride vapor at concentrations down to 50 p.p.m. induces onset of angiosarcoma, a liver cancer, in rats (C&EN, May 20, page 16).

Focal point of the committee's attention is the polymerization process, where workers run the greatest risk of vinyl chloride exposure. Mr. Barnes points out that atmospheric concentrations of the monomer in U.K. plants already have dropped dramatically from a level of about 1000 p.p.m. 20 years ago to 150 p.p.m. by the middle of last year. Improvements in operating conditions and the installation of leak-proof valves and the like have brought the level to 50 p.p.m. today, he adds.

"The ultimate for most existing plants is 10 p.p.m.," Mr. Barnes claims. "New plants with the most modern technology might achieve 5 p.p.m." But amounts below this "are not conceivable," in Mr. Barnes' view.

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April 23, 1974

TO: All Members of:

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Mailing List;
Ad Hoc Liquor Bottle Committee;
Plastic Pipe Institute
(Executive Board);
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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.

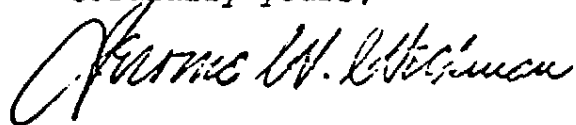
We shall continue to keep in as close touch as we can with all aspects of the current crises. As we have been doing, we shall post you by means of these

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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. McGowan". The signature is written in dark ink and is positioned below the typed name.

Enclosures

RSV 0002561