

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEEHAN
WILLIAM H. BORGHESE, JR.
ROBERT R. TIERNAN
WAYNE V. BLACK
DAVID L. HILL
MARTIN W. BERCOVICI
EDWIN B. SPIEVACK
PETER M. NEMKOV
JOSEPH E. 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"

May 21, 1974

File
Vinyl Chloride
OS 77

J. B. M.
MAY 22 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;
VC and PVC Producers Ad Hoc
Committee

Ladies and Gentlemen:

In accordance with our now regular practice, we are reporting again on the current status of federal regulatory activities and related matters affecting the vinyl chloride and polyvinyl chloride problem.

As has been true for several weeks now, the major news concerns activity on the Occupational Safety and Health Administration (OSHA) front, although we are also including an update on activities at the Environmental Protection Agency (EPA) and the Food and Drug Administration (FDA). Although none of the items we are reporting this week require specific responses by any of you, we are sure you will recognize that matters previously reported upon do carry continuing responsibilities.

Following the publication by OSHA of its Notice of Intent to File an Environmental Impact Statement in connection with its proposed permanent

May 21, 1974
Page Two

standard for occupational exposure to vinyl chloride, which contained an invitation to provide information, we filed Comments on behalf of SPI on May 16, 1974. These Comments were substantially in the form previously circulated to you so we are not including additional copies at this time. The major purpose of the Comments was to inform OSHA in a formal manner of the work undertaken by the VC and PVC Producers Committee and present a rough timetable as to when the Committee's reports could be expected.

In addition, responsive to the publication of the proposed permanent standard on May 10, we are now drafting a request to extend the time for Comments for an additional 30 days, although we have been informally told by OSHA that it probably will not grant such an extension. In addition, we are preparing Comments on the proposed standard and are drafting a request for a Hearing. In connection with the Hearing which we intend to request, our contacts at OSHA have indicated that it is "mentally scheduling" such a Hearing for "about August 1, 1974."

As we understand it, it is OSHA's intent to keep the Hearing very much "on the track" and will keep presentations to very specific issues. It is expected that the Hearing record will be kept open for perhaps as much as 10 days after the Hearing closes. Then, it is OSHA's intent to try to have the permanent standard published in the Federal Register on September 5, 1974 to take effect (as required by statute) on October 5, 1974.

The VC and PVC Producers Committee is presently at work gathering information that will be used in preliminary form in the Comments which will be filed before the closing date (presumably June 10, 1974). It is anticipated that the maximum amount of information that can be gathered will be presented by various experts at the Hearing.

Among the type of peripheral activities that put pressures on the Agencies and that affect their

May 21, 1974

Page Three

actions is the charge of "withholding significant scientific findings" which appeared in the Washington Post on May 20, 1974. As many of you may recognize, and as the article acknowledges, the same story was originally reported in the May 20 edition of Chemical and Engineering News. We are enclosing copies of the C&EN article and the Washington Post story.

The Chairman of the EPA's task force studying various aspects of the vinyl chloride matter, Mr. G.E. Schweitzer, Director of EPA's Office of Toxic Substances, reported on EPA's present activities at the Toxicology Working Group Conference on May 11 at the New York Academy of Sciences. At that time, Mr. Schweitzer announced that EPA was making available for Comment the preliminary analytical methods it is using which were reported to be sensitive to approximately 60 parts per billion. Because of the length of the procedures, we are not including them with this letter but those interested can obtain a copy from Dr. R.B. Medz, Chief, Standardization Branch, Q.A. Division (RD-687), U.S. Environmental Protection Agency, Washington, D.C. 20460.

EPA has submitted a rather elaborate list of questions that it would like SPI and anyone else interested to assist in answering. These questions have been turned over to a task group of the VC and PVC Committee. However, we are enclosing a copy of the list for your information.

As you know, FDA is working on the problem of an interim Food Additive Regulation applicable to polyvinyl chloride packaging materials. Although it sounds familiar, our latest report as to when the Interim Regulation can be expected is still "in one to two weeks."

In response to FDA's request for extraction data and analytical methodology, results have been submitted to us for transmission to FDA by a number of parties and we understand more information is on

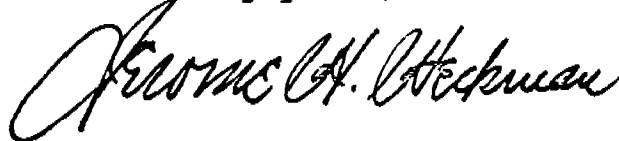
May 21, 1974
Page Four

its way. Once again, we urge that those who have such information forward it to the Food and Drug Administration (to either Mr. G. McCowin, Assistant to the Director of Food and Color Additives, or to the Hearing Clerk). In the alternative, those who wish can send the information to us and we will continue to forward it for them.

With respect to medical uses of PVC, we have received no direct information but we understand information regarding monomer content of medical tubing and sheet material is being gathered and that some may already have been presented to the Food and Drug Administration. In this area, too, interested parties are again urged to submit whatever information they may have.

We shall continue to try to keep in as close touch with the various aspects of these problems as we can and will continue to report them by means of this weekly letter. Naturally, if any fast-breaking matter should arise, we will notify you sooner; but in any event, we shall certainly be in touch with you next week.

Cordially yours,

A handwritten signature in dark ink, appearing to read "Jerome H. Hedeman". The signature is fluid and cursive, with the first name "Jerome" being the most prominent part.

Enclosures

Vinyl Chloride Linked to Cancer**Chemical Hazard Kept Quiet**

By Morton Mintz

Washington Post Staff Writer

For at least a year, chemical firms in the United States and Europe withheld significant scientific findings linking liver cancer to gas used to make one of the commonest plastics, the American Chemical Society's weekly news magazine reports today.

The gas is vinyl chloride, used to make the plastic polyvinyl chloride.

The trade association of the American chemical industry, the Manufacturing Chemists Association, joined in holding the findings in confidence, Chemical and Engineering News reports in its May 20 issue.

The Italian scientist who made the findings said that although preliminary, they were "predictive" of the fatal cancers recently recognized in several workers employed in converting the gas into polyvinyl chloride.

The scientist is Prof. Cesare Maltoni, director of the Istituto di Oncologia in Bologna. In a study initiated in September, 1971, by one of the European firms, Montedison, he discovered a rare form of cancer, angiosarcoma, in the liv-

ers of rats breathing vinyl chloride in a ratio of 250 parts per million (ppm).

That was in August, 1972. At that time, the permissible level for workers allowed by the Occupational Health and Safety Administration (OSHA) was 500 ppm, or twice as much.

In January, 1973, five months after Maltoni found the first rat angiosarcoma, a team of three U.S. chemical industry scientists visited him in Bologna to learn about his work.

The visit was preceded by months of negotiations with the European firms in addition to Montedison that had joined in sponsoring his studies: Imperial Chemical Industries, Solvay and Rhone-Progil.

But "U.S. chemical industry sources say they were bound by an agreement under which [the] four European firms controlled any release of animal test data obtained by Prof. Maltoni," Chemical and Engineering News says. It did not name any of the American firms.

A key second experiment at levels of 200, 150, and 100 ppm began about July 8, 1973, when

Maltoni observed that tumors were continuing to occur in rats at 250 ppm, the trade magazine says.

The first public disclosure of his findings came on Feb. 15, 1974. This was 24 days after B.F. Goodrich Co. announced that since 1971 three workers at its polyvinyl plant in Louisville had died of angiosarcoma of the liver.

Since then, the total of confirmed victims of angiosarcoma at the Goodrich facility and at other polyvinyl chloride plants in the United States has increased to 13 and in other countries to six. Two of the American workers survive. All of the others have died.

On April 5, OSHA announced an emergency rule drastically lowering the permissible concentration of vinyl chloride from 500 ppm to 50 ppm. Workers engaged in manufacturing vinyl chloride and polyvinyl chloride number 6,500 in the United States and 26,000 elsewhere.

Even the 50 ppm level may be hazardous, Maltoni told a meeting of the New York Academy of Sciences and the American Cancer Society on

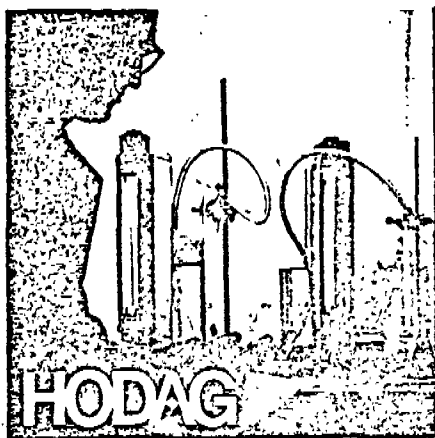
May 10. He disclosed that in rats he had found one liver angiosarcoma at only 50 ppm, along with other types of tumors.

For some nine months, a House-Senate conference committee has had a bill before it that would require manufacturers to test new chemicals under rules laid down by the Environmental Protection Agency (EPA).

The stalled legislation is the proposed toxic substances control bill. Senate conferees have been waiting for Rep. Harley O. Staggers (D-W. Va.), chairman of the House conferees, to announce his readiness to meet, Senate sources say.

The House bill would require pre-production testing of only those new chemicals that are listed as potentially dangerous, with results to be reported to the EPA 90 days before production is to begin.

The stronger Senate version would require in addition that companies notify the agency of all new chemicals considered for production, so that the EPA could order testing of chemicals that are not on the list but that may be suspect



Foam Is No Problem

Fight foam with this Hodag combination—a complete line of antifoam products and the technical knowledge to apply them effectively.

Superior Products

FDA-approved and industrial antifoams developed over many years to meet the toughest foaming conditions.

Technology

Special knowledge of surface activity helps many industries abate unique processing foams.

Technical Facilities

Equipped and staffed to develop just the antifoam you need.

Let us help solve your foaming problems. Use this coupon to get the Hodag combination of products and technical service.

☐ Please send me information on Hodag antifoam agents for _____

☐ Please send sample for this purpose.

☐ Please have representative contact me.

Firm name

Address **ASI-PR 0003338**

City

State

Zip

Name

Title

HODAG CHEMICAL CORPORATION
7247 N. Central Park Avenue
Skokie, Illinois 60076

Withholding of vinyl chloride data hinted

European and U.S. chemical firms, together with the Manufacturing Chemists Association, a U.S. trade group, held in confidence for at least a year preliminary, albeit significant, scientific findings on vinyl chloride as an agent causing liver cancer in rats, C&EN learned early last week. U.S. chemical industry sources say they were bound by an agreement under which four European firms controlled any release of animal test data obtained by Prof. Cesare Maltoni, director, Istituto Di Oncologia, Bologna, Italy.

The first public disclosure of Prof. Maltoni's findings came on Feb. 15, 1974, in the U.S. The disclosure came after B. F. Goodrich's announcement on Jan. 22, 1974, of three deaths due to angiosarcoma of the liver since 1971, among workers at its polyvinyl chloride plant in Louisville, Ky. Subsequently, the number of confirmed cases of angiosarcoma at the BFG plant, at other U.S. PVC plants, and at plants abroad has risen steadily to a total of 19, including 13 U.S. cases. 17 of the workers have died of the liver cancer; two U.S. workers are still living. The U.S. deaths date back to 1961.

Prof. Maltoni's animal data have been a key to much of the regulatory actions taken by the Occupational Safety and Health Administration. In February, the lowest dose level of vinyl chloride in the Italian scientist's study at which liver angiosarcoma developed was 250 p.p.m. Guided, in part, by these findings, OSHA on April 5 set an emergency rule that lowered the permissible OSHA worker exposure level to 50 p.p.m. from the previous ceiling of 500 p.p.m.

Since then, additional animal data have appeared. At a May 10-11 meeting of the New York Academy of Sciences and American Cancer Society, Prof. Maltoni disclosed that he had found one liver angiosarcoma in his rats at 50 p.p.m., together with several other types of tumors. At higher levels of exposure there were more tumors of various types, including liver angiosarcomas, as he reported earlier (C&EN, Feb. 25, page 16).

On April 16, MCA announced that preliminary findings on mice in its own study under way at Industrial Bio-Test Laboratories tended to confirm the Maltoni data then available publicly. And as presented by MCA before the May 10-11 meeting, the data show that under conditions of exposure of seven hours per day, five days per week, for eight months, liver angiosarcomas develop as follows: 2500 p.p.m., 23 liver angiosarcomas; 200 p.p.m., 11; and 50 p.p.m., two. MCA's study also showed other types of tumors. Tests also have just begun at dose levels of 25, 10, and 5 p.p.m.

wealth of new medical findings now appearing on vinyl chloride exposure, partly through the May 10-11 meeting. MCA's epidemiological study on 7128 vinyl chloride workers, for example, finds that cancers of the liver (primarily angiosarcoma), respiratory system, brain, and cancers of unknown primary site, as well as lymphosarcoma, "occurred more often than expected in those members of the study population with the greatest exposure," with the caveat added that although these excesses "were not statistically significant, the findings warrant further study." And a major bias in the study is the "discovery"—too late to include it—of 1500 to 2000 workers with the longest exposures, up to 35 years.

In August 1972 Dr. Maltoni found his first angiosarcoma in the first of a series of studies that, according to data available to C&EN, began about Sept. 5, 1971. A key, second experiment at levels of 200, 150, and 100 p.p.m. began about July 8, 1973, when it was observed that the 250-p.p.m. level "was still showing oncogenic effects."

In January 1973 a team of three U.S. chemical industry scientists visited Prof. Maltoni in Bologna to learn of his results and to see his slides. Some months of negotiations with the European company group preceded this visit. The group is made up of Montedison, which first approached Prof. Maltoni to do the study, Imperial Chemical Industries, Solvay, and Rhône-Progil. All four were supporting the work at the time of the visit, U.S. sources say.

Subsequently, the liver angiosarcomas in four U.S. deaths of workers have been judged by OSHA to be "histologically indistinguishable" from the angiosarcoma tumors Prof. Maltoni has found. And he believes that his experiments were "predictive" of what was subsequently recognized in man.

Much remains to be answered in the way the release of the Maltoni data has been handled. There are allegations, unfounded from all that C&EN can learn, that word of early results was passed to U.S. and Italian government officials. A major question mark concerns what was said by MCA to the National Institute for Occupational Safety and Health in July 1973 and earlier. As the trade association testified before OSHA on Feb. 15, 1974, "MCA's first direct contact with NIOSH specifically on vinyl chloride led to a conference between an industry delegation, including a European representative, and Dr. Marcus Key [NIOSH director] and staff on July 17, 1973, at which time the MCA program was presented in some detail, and study protocols, industry statistics, and selected items from the scientific literature were provided." MCA has shed

EPA QUESTIONS FOR SPI (SOCIETY OF PLASTICS INDUSTRY)

1. list of top 50-100 PVC products by sales volume
2. list of top 50-100 PVC products by volume of plastic in product
3. amounts of unreacted monomer in above products
4. list of PVC compounding plants by name, location, # employees, polymer used, products line, quantities produced
5. list of PVC fabrication plants by name, location, # employees, polymer used, fabrication methods utilized, quantities produced
6. levels of VCM in plants in 4. and 5. by plant area and detection method utilized
7. levels of VCM beyond the plants and detection method(s) used
8. levels of VCM in water effluents
9. decomposition products from various incineration conditions for PVC and quantities of PVC involved
10. amounts of VC leaching out of landfills and total amount PVC buried to date
11. toxicity of PVC resin and products
12. epidemiology studies of workers
13. population within square mile of plants
14. substitutes for VC and PVC
15. Future PVC markets
 - New products
 - New workers for old products
16. Additives used in PVC products