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STATEMENT
OF THE
MANUFACTURING CHEMISTS ASSOCIATION
BEFORE THE
OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION
ON
POSSIBLE HAZARDS OF VINYL CHLORIDE
MANUFACTURE AND USE
FEBRUARY 15, 1974

The Manufacturing Chemists Association (MCA) is a non-profit trade association having 174 United States member companies representing more than 90 percent of the production capacity of basic industrial chemicals within this country. With respect to vinyl chloride, the subject of this hearing, over 97 percent of the production capacity reported by Chemical and Engineering News in May 1973 was in our members' plants. For the polymer plants, the corresponding figure was then nearly 88 percent.

Vinyl chloride (VC) is a chemical derived ultimately from petrochemical feedstocks and chlorine. Of the 5.2 billion pounds of the monomer produced by U. S. industry in 1972, all but a small fraction -- less than one percent -- was used in the production of various plastics -- primarily polyvinyl chloride (PVC),

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but including a wide variety of co-polymers with other monomers. Among the plastics, only the production of polyethylene exceeds that of PVC.

The importance of PVC production is not measured just by the value of the unprocessed polymer, but more properly by the almost universal dependence of nearly every branch of industrial and commercial activity upon products and components fabricated from this plastic.

With this statement, we are submitting a description of the industry and its products that appeared in the December 1973 issue of Plastics Engineering, and we ask that this reprint be made a portion of the record of this hearing. This report makes it clear that the VC/PVC industry involves a wide variety of chemicals -- initiators, catalysts, plasticizers, stabilizers, antistatic agents, fillers, pigments, and a host of other specialized, but generally very minor, additives. Under such circumstances, the identification of any adverse health effects among the employees of a vertically-integrated VC/PVC plant with a specific causative agent becomes complex.

A few more statistics concerning the industry may be helpful. The U. S. VC/PVC industry has been operating over forty years, and over the past five years has shown an annually compounded

growth rate of 14 percent -- a rate of growth that is expected to taper off only moderately in the next few years, to about 11 percent. U. S. production now represents about one-fourth of the world total.

Synthesis of the monomer is conducted in fourteen U. S. plants, and thirty-seven plants are engaged in polymerization. It is estimated that about 1,500 workers are employed in monomer synthesis, and an additional 5,000 in polymerization operations.

It is difficult to estimate the number of workers employed in converting, molding, and fabricating these polymers, but they are numbered in the tens of thousands, working in thousands of plants. It has been estimated the wholesale value of the annual output of fabricated products is over three billion dollars.

MCA, as a regular and continuing service to its members, has long had active programs in occupational health and safety. Its past and current activities with respect to vinyl chloride are a natural outgrowth of these programs. MCA's Safety and Fire Protection Committee is now in its twenty-eighth year. Among its other activities, it has prepared MCA's highly-respected series of Chemical Safety Data Sheets for commodity chemicals throughout this

period. One on vinyl chloride -- SD-56 -- was first issued in 1954, and was last revised in 1972.

A Medical Advisory Committee was formed in 1946, later reconstituted with the addition of industrial hygiene engineers, toxicologists, statisticians and other specialists in employee health, and renamed the Occupational Health Committee.

Additionally, MCA is prepared to administer special programs on behalf of groups of interested companies, in instances where only a limited number are directly involved.

Thus, in 1966, when companies were alerted by the European reports of an occupational disease among PVC polymerization kettle cleaners, a project was established at the University of Michigan's School of Public Health to determine the nature, extent, and etiology of the condition known as occupational acroosteolysis. The results of this study have been published by Drs. Harold J. Magnuson, Bertram D. Dinman and others, in a series of three papers^{2,3,4} in the Archives of Environmental Health (January 1971). Although the role, if any, of vinyl chloride in the causation of this condition could not be defined, the industrial hygiene controls and improved work practices adopted by the industry have led to a decline to almost zero in the number of new cases of even very mild forms of this disease.

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It was in an effort to develop an animal model of this condition that the first observations of possible carcinogenesis by vinyl chloride were made. Dr. P. L. Viola, in a report published in March, 1970⁵, reported that rats exposed to 30,000 ppm vinyl chloride vapors for four hours per day, five days per week for a year, showed "degeneration of the skeleton and connective tissue with histopathological pictures similar to those observed in human acroosteolysis of the hands." In his paper, no mention is made of the appearance of any malignant tumors.

A few months later, however, at the Tenth International Cancer Congress⁶, Dr. Viola briefly described observations of malignant tumors in the ear canals of rats subjected to an exposure protocol almost identical with that in his earlier paper. He also reported tumors in the lungs and bones of these rats, but closed his abstract with the specific disclaimer: "No implications to human pathology can be extrapolated from the experimental model reported in this paper."

MCA invited Dr. Viola to come to the United States as a guest of the industry, for a discussion with U. S. occupational health experts. On May 5 and 6, 1971, at a meeting with MCA's Occupational Health Committee, he discussed his more detailed

report then in press⁷, and referred to other studies completed or underway. Dr. Viola spoke of these unreported studies only in rather general terms, and declined to reveal details. He acknowledged that his vinyl chloride was of low purity, but expressed his personal opinion that it was the vinyl chloride, per se, and not any impurities, that was responsible for the pathology he was observing. He claimed to have seen tumors in rats exposed to 5,000 ppm, but expected the results would be negative at half that level. In his opinion, the 500 ppm TLV provided an adequate margin of safety of employees from the tumor induction he had seen in rats at the higher levels. We are not aware of any further publications by Dr. Viola on this subject.

The disparity between Dr. Viola's findings and the relatively low toxicity reported by earlier researchers was immediately recognized. For many years, vinyl chloride monomer was considered to be very low in toxicity, both from single and repeated exposure. Because of its volatility, inhalation was considered the only important route of exposure for workmen. The high flammability of VCM has been considered to be a more serious hazard than inhalation.

From the earliest lists until 1962, the American Conference of Governmental Industrial Hygienists (ACGIH) recommended that the time-weighted average, long-term, 7-8 hour daily exposure

of workmen to vinyl chloride not exceed 500 ppm v/v (1270 mg/m³). This recommendation was based on single exposure studies on animals and on human experience. Recommended time-weighted average concentrations are published by the ACGIH in an annual list of "Threshold Limit Values" (TLV). A TLV was considered by this group to "represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, without adverse effect."

In 1963, the ACGIH modified their recommendation so that 500 ppm was to be a maximum concentration (or ceiling) rather than a time-weighted average. It is this standard that is in the 1970 TLV list promulgated by OSHA on May 29, 1971, as a national consensus standard.

The change from a time-weighted to a ceiling standard was, in part, due to the publication by Torkelson, Oyen and Rowe⁸ of the results of six-month repeated inhalation studies on laboratory animals. These authors reported slight reversible liver injury in rats exposed seven hours per day to 100 ppm, and recommended that the time-weighted average exposure of workers not exceed 50 ppm. This recommendation was not deemed appropriate by Lester, Greenberg, and Adams⁹, however, who did not consider significant injury to have resulted in rats which they had repeatedly exposed to 500 ppm.

In 1970, the ACGIH proposed reduction of their recommended TLV to a time-weighted average of 200 ppm primarily on the basis of work reported by Kramer and Mutchler¹⁰. The authors reported evidence of clinical findings in workers exposed to time-weighted average concentrations of 300 ppm vinyl chloride for many years.

In 1972, the ACGIH took vinyl chloride from the list of Intended Changes and revised the value in their regular list to 200 ppm (510 mg/m³). This value remains the recommended value in the 1973 list. A copy of the documentation for the ACGIH TLV for vinyl chloride is provided as an attachment to this statement.

In view of these developments, it was recommended that MCA convene a conference of vinyl chloride manufacturers to discuss the prospect and feasibility of establishing an industry-supported research program. This meeting, attended by representatives of U. S., Canadian and European firms, took place on November 16, 1971. On the initiative of companies attending, a research project was formed with MCA participating in an administrative role.

A contract with the Industrial BIO-TEST Laboratories, Inc., of Northbrook, Illinois, was signed on February 1, 1973. The complete experimental protocol is submitted as an attachment to this statement. The specific goals in mind were:

1. to attempt to duplicate the European observations with vinyl chloride of a source and quality characteristic of the U. S. industrial product;

2. to extend these studies to two other species of laboratory rodents -- mice and hamsters, to determine whether the responses of rats might be species-specific;

3. to develop dose-response relationships with higher limits of statistical confidence, to permit estimation of potential risks at occupational levels of exposure with greater precision; and

4. to determine what the no-response level is.

In these studies on rats, mice and hamsters, groups of 100 male and 100 female of each species (600 animals at each exposure level) are being exposed to either 0 (control), 2,500 ppm, 200 ppm, or 50 ppm of vinyl chloride monomer, seven hours per day, five days per week, for twelve months. They will then be observed for an additional twelve months (six months for mice). These animals will not have food and water during exposure.

This "lifetime" study is designed primarily as a cancer study and will include only a limited amount of other observations. Because Viola's studies involved simultaneous exposure of food, water, and bedding, a separate group of 100 rats of one on sex is being

posed to 2,500 ppm along with their food, water, and bedding. This has been included because of the possibility that a reaction of the vinyl chloride monomer with either the food, water, or bedding may result in a toxic reaction product.

Although animal exposures started in July 1973, equipment problems gave rise to a number of uncertainties that might have compromised the validity of the results, hence the initial group of animals was discarded and a new set procured. The new exposures got underway on September 10, 1973.

Up to this time, no significant results have been observed in this study, nor would the appearance of any tumors be expected in so short a time. We will keep both OSHA and NIOSH informed as this study progresses.

Recognizing that there must always exist a substantial degree of uncertainty in extrapolating the results of animal studies to the evaluation of workplace hazards, MCA has contracted with Tabershaw-Cooper Associates, (TCA) of Berkeley, California, to conduct a study of the causes of death in vinyl chloride and polyvinyl chloride production workers. The objectives are:

1. to compare the mortality of individuals who have worked in vinyl chloride plants with that of the general population, corrected for area, age, and sex;

2. to compare mortality patterns within the population of vinyl chloride workers, based upon estimated occupational exposure; and

3. to compare mortality among vinyl chloride workers with the mortality of other occupational groups which TCA has studied.

This study is now in its eighth month, and a final report is expected to be issued in April. A copy of the protocol is submitted with this statement.

Although the mortality statistics are as yet incomplete, and have not been analyzed, a preliminary review of the current data from all plants, other than the one concerning which the B. F. Goodrich Chemical Company has made a public disclosure, fails to show any obvious departure from the pattern and incidence of the deaths that would be expected among a population of the kind that has been the subject of this survey.

We will, of course, provide OSHA and NIOSH with the final report and alert them promptly should any significant evidence of occupationally-related deaths appear earlier.

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 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.

Under these circumstances, the VC producing and consuming companies participating in the MCA-administered program were understandably greatly concerned when informed on January 22 by the B. F. Goodrich Chemical Company of the events that have led to the hearing now in progress. A meeting of the representatives of these companies was held on January 25 under MCA auspices to receive a comprehensive report from Goodrich, and to plan and implement any necessary steps not only for the protection of their workers, but also to hasten the resolution of remaining uncertainties.

MCA then immediately contacted NIOSH and, both by telephone and by confirming letter, gave assurance of full cooperation and support in their investigation and development of recommendations for the control of hazards from this source.

MCA publicly announced that it is temporarily withdrawing its Chemical Safety Data Sheet for vinyl chloride, which recognized Dr. Viola's work, but stated that "... many years of industrial experience with human exposures to concentrations

frequently far above current standards have not demonstrated any carcinogenicity to humans." MCA will expedite the reissue of this data sheet, revised as necessary to reflect new knowledge concerning possible hazards of vinyl chloride exposures. A copy of a February 6, 1974, news release on the withdrawal is attached.

As discussed herein, manufacturers are aware of the potential hazard of vinyl chloride and, we are informed, are voluntarily taking steps to reduce employee exposure. Substantial research is now in progress, the results of which they believe will provide a firm basis for any standard applicable to VC/PVC manufacture. Therefore, it is their recommendation that OSHA proceed under the provisions of Section 6(b) of the Act.

On behalf of its producer members, MCA pledges full cooperation with both NIOSH and OSHA as they attempt to define the hazards now tentatively identified with vinyl chloride, and develop standards that will assure the safety of workers in this industry.

LIST OF REFERENCES

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3. Cook, W. A.; Giever, P. M.; Dinman, B. D.; Magnuson, H. J.: Occupational Acroosteolysis - II. An Industrial Hygiene Study. *Arch. Environ. Health*. 22, 74-82 (Jan. 1971).
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5. Viola, P. L.: Pathology of Vinyl Chloride. *Medicina del Lavoro*. 61, 174-179 (March 1970).
6. Viola, P. L.: Cancerogenic Effect of Vinyl Chloride. Presented at the Tenth International Cancer Congress. Houston, Texas (May 22-29, 1970).
7. Viola, P. L.; Bigotti, A.; Caputo, A.: Oncogenic Response of Rat Skin, Lungs, and Bones to Vinyl Chloride. *Cancer Research*. 31, 516-522 (May 1971).
8. Torkelson, T. R.; Oyen, F.; Rowe, V. K.: *Am. Ind. Hyg. Assn. J.* 22, 354 (1961).
9. Lester, D.; Greenberg, L. A.; Adams, W. R.: *Am. Ind. Hyg. Assn. J.* 24, 265 (1963).
10. Mutchler, J. E.; Kramer, C. G.: Report on Relation of Exposure to State of Health of Dow Chemical Workers, Gordon Conf., Tilton, N. H. (August 1968).

LIST OF ATTACHMENTS

- A) PLASTICS ENGINEERING PRIMER/PVC
Reprint from December 1973 Plastics Engineering
- B) Viola, P. L. - Pathology of Vinyl Chloride
- C) Viola, P. L. - Cancerogenic Effect of Vinyl Chloride
- D) Documentation for ACGIH TLV for Vinyl Chloride
- E) MCA News Release #3791
- F) Revised Protocol for Animal Exposure Studies
Industrial BIO-TEST Laboratories, Inc.
- G) MCA News Release #3814
- H) Protocol for Epidemiology Study
Tabershaw-Cooper Associates, Inc.
- I) MCA News Release #3835

MCA Statement at OSHA Hearings/Vinyl Chloride
February 15, 1974

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