Exh. 21

PPG INDUSTRIES, INC./ONE GATEWAY CENTER/PITTSBURGH, PENNSYLVANIA 15222/AREA 412/434-2349

ROBERT E. WIDING, Vice President
Manufacturing, Industrial Chemical Division

March 4, 1974

Mr. Gordon J. Myatt
Administrative Law Judge
U. S. Department of Labor
Occupational Health and
Safety Administration
Room 240
1726 M Street N. W.
Washington, D. C. 20210

Dear Mr. Myatt:

Enclosed is a copy (in triplicate) of a statement of PPG Industries, Inc. which we request be included as part of the official record of the Informal Fact-finding Hearing on Possible Hazards of Vinyl Chloride Manufacture and Use, held in Washington, D. C., February 15, 1974.

Very truly yours,

R. E. Widing

R. E. Widing

/kf

cc: Mr. Kenneth D. Johnson
Manufacturing Chemists' Association, Inc.
1825 Connecticut Avenue, N. W.
Washington, D. C. 20009

Enclosures

A Statement by PPG Industries, Inc., for the Official Record
of the OSHA Informal Fact-finding Hearing
on Possible Hazards of Vinyl Chloride Manufacture and Use
February 15, 1974

The information included in this document is intended to inform the Occupational Safety and Health Administration of the practices used by PPG Industries, Inc., to manufacture Vinyl Chloride Monomer (VCM) and the industrial hygiene controls used to minimize worker exposure. This statement is divided into four parts for ease of review:

I) Vinyl chloride monomer manufacturing technology.

II) Vinyl chloride monomer shipping and handling procedures.

III) Employee population and medical surveillance, results and programs.

IV) Summary.

I. Vinyl Chloride Monomer Manufacturing Technology

PPG Industries, Inc., manufactures vinyl chloride monomer at two locations: Lake Charles, Louisiana, and PPG Caribe at Guayanilla, Puerto Rico. The technology for these plants was developed by PPG Industries and has been licensed to firms in Sardinia, Japan and Bulgaria. The process is based on ethylene and chlorine, and a general description and schematic flow sheet was published in Hydrocarbon Processing, November 1971 (attached as Exhibit I). The plants are outdoor operations.

The VCM product from the PPG process has a high purity. A typical purity is 99.99%.

II. Vinyl Chloride Monomer Shipping and Handling Procedures

PPG Industries ships VCM in ocean-going vessels, river-barges, tank cars and tank trucks. These shipments are made from two producing plants: Lake Charles,

Louisiana; Guayanilla, Puerto Rico, and a leased terminal in Paulsboro, New Jersey. PPG published a bulletin "Vinyl Chloride Monomer, Handling and Properties" in May, 1973, which was revised in October, 1973 to reflect a reconsideration for a lower TLV of 50 ppm. The procedures shown in the bulletin represent the best thinking of industry at that time for handling and storage of VCM. Issuance of this bulletin has been temporarily stopped pending review to correspond to OSHA recommended work practices.

III. Employee Population and Medical Surveillance, Results and Programs

PPG has a total of 222 employees involved in VCM production and shipping. The Lake Charles plant has 126 employees, Guayanilla plant has 76 employees and the Paulsboro, New Jersey, terminal has 20 employees.

PPG has taken the position as outlined in our February 8, 1974, (attached as Exhibit II) release as follows:

1. Insist on strict compliance with operating procedures required to prevent exposures to VCM;
2. Instruct each employee to avoid breathing VCM vapors;
3. Instruct each employee to follow safety instructions set forth in operating manuals;
4. Each employee is to report any medical problems or symptoms to an employee's supervisor and/or the plant physician.

You will note that this February 8 release indicates our awareness of this emerging knowledge, our participation in developing more knowledge, our recommendations and programs. Following the Goodrich announcement on January 22, 1974, a further evaluation of worker protection was begun at our operating units in Lake Charles and Puerto Rico.

While the above indicates the extent of our previous, continuing and renewed efforts to prevent personal exposure to VCM vapors, and indicates we are comporting ourselves with an awareness of the present state of the knowledge connecting VCM with angiosarcoma, we believe the standards that apply to VCM in this respect should be developed through NIOSH and OSHA under Section 6 (b) of the Williams-Steiger Act of 1970.

Attached (as Exhibit III) is a statement made by MCA at the February 15 Washington meeting. PPG supported this statement which recommended that OSHA proceed under the provisions of Section 6 (b) of the Act, and PPG continues to recommend that OSHA move forward under Section 6 (b) of the Act. In the interim, PPG has taken and is taking extraordinary measures to outline procedures and practices to prevent VCM exposures of our employees during the manufacture and handling of VCM.

Work records at Lake Charles identify those people who have worked in the VCM plant since its start of operation in 1967. This includes not only those assigned to VCM jobs, but also maintenance workers assigned to the Organics production area for any prolonged period of time.

Since July, 1973, all hourly workers involved in the production of VCM and in the maintenance of the VCM plant at Lake Charles have been identified via a computer program. Time cards and work orders trigger the entry of each name and his VCM work-time into this program, thereby giving us a running record of those potentially exposed. Additionally, we track salaried personnel who have potential exposure--production supervisors, maintenance foremen, process engineers, and laboratory personnel. These records will be subject to the scrutiny of the plant physician, and he will determine when additional medical and laboratory tests should be conducted for those people not normally

in the Organics medical program, but who may be spending a part of their work-time in the VCM plant. Independent contractor personnel are used in the Lake Charles VCM plant only during major outages and equipment is cleared of VCM.

We do not have a similar computerized program at Caribe, however, work records do provide a history of all personnel on VCM jobs since that plant's start-up in 1971. This identification system will be expanded to encompass any other personnel who may spend time in the PPG Caribe VCM plant, including contractor employees who perform the maintenance function for Caribe. The plant physician will determine when there is need for additional medical and laboratory testing of personnel not normally in their VCM medical program.

Similar programs are being initiated at PPG's leased terminal at Paulsboro, New Jersey.

Area monitoring was started and has been performed periodically at Lake Charles since mid-1973, and on a spot basis at Caribe since March, 1973. Frequency and coverage of area monitoring at both plants are being expanded immediately in order to build a better data-base for possible exposure areas. Both time-weighted and ceiling values will be determined. To this end, instruments with a detection range of 1-1000 ppm organics are on order at both plants. Although not specific to VCM vapors, these units should serve to screen organic-free areas, and thus facilitate and speed up the over-all VCM area monitoring program.

Equipment for personal monitoring is now being developed and fabricated, and is expected to be available very soon. Personal monitoring will then be initiated at both plants. More representative time-weighted-average (TWA) data will be gained through this approach.

Annual medical and laboratory testing, including kidney and liver function,

of Organics Area employees at Lake Charles has been in effect since the Organics Area start-up in 1960. This program includes maintenance employees assigned to the Organics Area as well. VCM employees were added to the medical program in 1967 when the VCM plant began operation. A similar medical program has been in effect for all PPG employees since the Caribe start-up in 1971.

Further, we are ready to expand or alter our medical programs if recommendations of medical experts so indicate.

PPG began concerted efforts towards further exposure control shortly after the late January announcements by B. F. Goodrich. Meetings were held at both Lake Charles and Caribe with their operating managements to outline and target the control programs required. Similarly, a survey of the terminal was made. Even though a prior survey had just been made in July, 1973, this follow-up was deemed necessary; and further control recommendations were made.

At all locations, where required, engineering changes in the process are already being implemented, and employees are required to use respiratory protection during certain procedures to prevent exposures. Operating manuals are being revised to prevent worker exposure through procedural instruction. All facets of sampling and testing are being reviewed because of their particular exposure potential. This includes frequency needs, methods, handling, testing procedures, and sample disposal.

Preliminary precautionary information was conveyed to employees in the month of February through regular and special safety meetings. Letters from our Works Managers at Caribe and Lake Charles were more recently sent to all their employees. Accompanying these letters was the PPG information statement dated February 8, 1974 (Exhibit II). This statement was also transmitted to

all Regional Sales Offices on February 11 and was conveyed to customers thereafter. We intend to provide additional information as it develops, such as results and recommendations of MCA task groups, PPG statements to governmental agencies, and any other new material of significance as it arises.

IV. Summary

Although PPG Industries manufactures and ships only vinyl chloride monomer (VCM), and does not manufacture PVC, PPG has initiated strict precautions for the manufacture and shipping of this important chemical. PPG feels that the intent of the Occupational Safety and Health Act would be best served to protect worker safety by recommending that work practices be established under Section 6 (b) of the Act. PPG has informed its employees and customers of the possible human carcinogenic hazard associated with VCM and has re-emphasized its comprehensive medical and operational programs to prevent worker exposure to VCM in its facilities.

Robert E. Widing
Vice President Manufacturing
Industrial Chemical Division

Vinyl chloride — PPG INDUSTRIES

Application: A process to produce vinyl chloride monomer from ethylene, oxygen, chlorine and hydrogen chloride.

Description: The process as presented here is for a "balanced-integrated" vinyl chloride plant wherein vinyl chloride monomer (VCM) is the sole product, and all of the hydrogen chloride (HCl) produced from the cracking of ethylene dichloride (EDC) is recycled to the oxychlorination unit and no externally produced hydrogen chloride is used as feed. Under other circumstances, the process can be arranged to produce either or both EDC and HCl as co-products. The process also is well able to receive externally produced hydrogen chloride as a feed.

In the "balanced-integrated" arrangement, EDC is produced in both direct chlorination and oxychlorination units.

In the direct chlorination unit, chlorine is combined with ethylene in the liquid phase by the addition reaction to produce EDC.

$$C_2H_4 + Cl_2 \rightarrow C_2H_4Cl_2$$

In the oxychlorination unit ethylene, oxygen and HCl are reacted in the vapor phase over a PPG-developed catalyst to produce EDC.

$$C_2H_4 + 2HCl + 1/2\ O_2 \rightarrow C_2H_4Cl_2 + H_2O$$

The heat of reaction is recovered as high pressure steam and used in other portions of the process.

Due to the use of oxygen and the judicious choice of design and materials, the oxychlorination unit operates at a high onstream factor, under moderate pressure employing a simplified condensation system to provide high yields and essentially corrosion free operation.

The crude EDC from the oxychlorination and direct chlorination units is combined with the EDC recycled from the cracking unit and purified by distillation. The small quantity of lights and heavies removed from the EDC are usable feedstocks for other PPG processes.

Vinyl chloride monomer is produced by thermally cracking the purified EDC at high temperature.

$$C_2H_4Cl_2 \rightarrow C_2H_3Cl + HCl$$

The cracker effluent is quenched and the HCl separated and recycled to the oxychlorination unit. High purity polymer grade VCM is separated from the unreacted EDC. The unreacted EDC is recycled to the purification unit.

The process has been designed and automated for safe, low manpower, high yield and high stream factor operation over a broad range of turndown. In addition to producing high purity polymerization grade VCM, the process enjoys essentially corrosion free operation, low catalyst cost, infrequent decoking and low maintenance cost.

Commercial installations: PPG holds more than 400 domestic and foreign patents on the subjects of oxychlorination and vinyl chloride. PPG's oxychlorination and VCM technology was developed in the early 1950s and commercialized in the early 1960s. Polymer grade VCM and EDC are produced by the PPG processes in plants in the United States, Japan and Europe. The combined capacity of the plants now in operation and under construction is more than 2.5 billion pounds per year of EDC and 1.1 billion pounds per year of VCM.

Reprinted from HYDROCARBON PROCESSING, November, 1971
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EXHIBIT II

February 8, 1974

The recent news release by B. F. Goodrich that appeared in the Wall Street Journal on January 24, 1974, that they were investigating cancer deaths of workers in their polyvinyl chloride operations at Louisville, Kentucky, that might be related to occupational exposure is of concern to PPG and the polyvinyl chloride (PVC) - vinyl chloride monomer (VCM) industry.

The American Conference of Governmental Industrial Hygienists (ACGIH), an organization comprised of various governmental and university experts, has for many years adopted Threshold Limit Values (TLV) for numerous chemicals including vinyl chloride monomer. A TLV refers to airborne concentrations of a specific chemical and represents conditions under which it is believed nearly all workers may be repeatedly exposed, day after day, without adverse effects.

Up until 1962 the time-weighted average (TWA) TLV adopted by the ACGIH for VCM was 500 ppm. In 1963, the TLV was revised to include a ceiling value of 500 ppm (without regard to time). This remained unchanged until 1970 when the ACGIH further lowered the TLV level to 200 ppm but removed the ceiling value restriction.

With the passage by Congress of the Williams-Steiger Occupational Safety and Health Act in 1970, the Department of Labor published in the Federal Register its startup standards for various chemicals. This standard established a 500 ppm ceiling value for vinyl chloride monomer.

Dr. P. Luigi Viola, an Italian physician, performed animal studies in attempts to simulate finger bone deterioration experienced by PVC autoclave cleaners in Europe. As a result of this work, published in the U.S. in 1971, he reported finding some cancers in animals exposed to very high concentrations of VCM vapors (20,000 - 30,000 ppm), but his test procedures were subject to numerous questions and criticisms. This new information that high concentrations of VCM may cause cancer in animals was not heretofore appreciated by the industry. This was certainly a cause for concern by PPG, although none of our employees have been exposed to concentrations and times of exposures that were used in Dr. Viola's tests.

PPG and other PVC-VCM producers met in late 1971 under the auspices of the Manufacturing Chemists Association and formed a research coordinators' committee to review all of the available toxicological information and to develop data where the committee felt voids in our knowledge existed. In 1972, this committee commenced the development of protocols for animal exposure and epidemiological studies. The Industry commenced in 1973 a long-term chronic vinyl chloride monomer inhalation study employing hundreds of animals at exposure levels well below those reported by Dr. Viola. This study is currently in progress at the Industrial Biotest Laboratory in Decatur, Illinois.

A contract was awarded to Tabershaw-Cooper and Associates to perform an epidemiological survey to determine the general causes of death among long-term PVC-VCM industry workers. The Tabershaw-Cooper and Associates'

survey was started in the summer of 1973, and will cover approximately 6,000 employees in this industry.

In 1973, European data involving exposure of VCM to rats revealed that cancers were formed at or near the current threshold limit value. PPG revised VCM Bulletin No. 115A to suggest that although the TLV of 200 ppm agreed with the then recommended ACGIH level, PPG recommended that vapor concentrations should not exceed 50 ppm as a time-weighted average atmospheric concentration for an eight-hour day until ongoing toxicological studies are concluded. This bulletin was mailed to all of our VCM customers and PPG facilities.

In view of the latest information that the formation of rare liver-cancers (angiosarcoma) may be related to a segment of the PVC production, PPG has initiated a comprehensive review of its operations to further reduce employee exposures to VCM to the minimum achievable. Some engineering changes in the process are already being implemented and employees will be required to use respiratory protection during certain procedures to prevent exposures. In addition, more elaborate and expanded air monitoring programs are being incorporated to determine the extent of workers' VCM exposures. This will include new instrumentation for detecting very low levels of VCM and a personal monitoring system, in addition to increased area sampling. The PPG facilities are taking immediate action to revise operating manuals to prevent worker exposure in all phases of VCM operations.

At PPG's Lake Charles, La., and Guayanilla, Puerto Rico, plants, employees have been given annual physical examinations and laboratory tests for kidney and liver function since the startup of these VCM operations. Whenever an abnormality is found, the employee is so informed and counseled to seek further medical evaluations from the employee's family physician. PPG has again reviewed all of its vinyl chloride employees' medical records and, to date, there are no indications of any such findings among PPG employees. Although PPG feels, after a review of its medical records and exposure data, that this recently reported angiosarcoma among polyvinyl chloride workers will not develop among PPG employees, the latent period for development of angiosarcoma precludes us from establishing with certainty that no one will develop this cancer in the future.

A team of industry medical experts have been assembled by MCA to review the adequacy of the previous medical tests, and based on their findings, PPG's medical program will be altered if necessary. If any employee desires consultation to discuss his medical history or symptoms, an arrangement will be made to schedule a meeting with the plant physician.

Because of these events, PPG insists on strict compliance with operating procedures required to prevent exposures to VCM. Therefore, each employee is instructed to avoid breathing VCM vapors, to follow safety instructions set forth in operating manuals, and to report any problems or symptoms to his supervisor and/or the plant physician.

EXHIBIT III

copy

MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126

ALBERT C. CLARK
VICE PRESIDENT
TECHNICAL DIRECTOR

February 15, 1974

To the Management Contacts of Companies Sponsoring
the Vinyl Chloride Research Program
and the
Technical Task Group on Vinyl Chloride Research

Subject: February 15, 1974 Hearings
Occupational Safety and
Health Administration

Gentlemen:

Herewith for your information is a copy of the Manufacturing Chemists Association statement (without attachments) submitted at subject hearings. If any attachments are of special interest to you, please do not hesitate to get in touch with us and we will try to provide any except the reprint (A) on the List of Attachments.

Sincerely,

A. C. Clark

ACC:tp

Enclosure

cc: Dr. D. P. Duffield
Mr. D. M. Elliott
Dr. Tiziano Garlanda
Dr. K. D. Johnson

BOR 011346

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MFG. DEPT.

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),

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.

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 1970[5], 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 Congress[6], 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 press[7], 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 adequat 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/m^3). 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 Rowe[8] 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 Adams[9], 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 Mutchler[10]. 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/m^3). 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 knowldege 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.

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