

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

TO : Assistant Secretary of Labor
Occupational Safety and Health Administration
Department of Labor

DATE: MAR 11 1974

FROM : Director, National Institute for
Occupational Safety and Health

SUBJECT: Recommended Occupational Health Standard for the Manufacture of
Synthetic Polymer from Vinyl Chloride

On January 22, 1974, representatives from the B. F. Goodrich Chemical Company informed NIOSH that the deaths of several employees of their Louisville, Kentucky, plant might have been related to occupational exposures. An immediate industrial hygiene walk-through survey of the facility was conducted by NIOSH and resulted in developing and transmitting to affected companies recommendations for precautionary monitoring and control procedures for polymerization processes involving vinyl chloride. On February 1, 1974, NIOSH/CDC conducted a briefing for other Federal agencies with health research responsibilities at which it was disclosed that four employees of the plant in question had died of angiosarcoma of the liver. Because of the extremely low incidence of this disease, estimated to be on the order of 20 to 30 deaths per year in the United States, the history of four cases in a five-year period in one plant was considered of great importance. It was concluded at the briefing that a new occupational cancer had been discovered: angiosarcoma of the liver. It was further concluded that this disease was associated with the manufacture of polyvinyl chloride and that vinyl chloride was the prime etiological candidate in producing the disease.

NIOSH, with the assistance of expert consultants from both industry and organized labor, began development of a recommended occupational health standard. These and other activities were discussed in more detail at the OSHA Informal Fact-Finding Hearing on Possible Hazards of Vinyl Chloride Manufacture and Use on February 15, 1974. It was also during this Hearing that Professor Cesare Maltoni of Bologna, Italy, presented the preliminary results of his research which showed induction of angiosarcoma of the liver and other organs, as well as the production of other cancers in rats exposed to vinyl chloride. The results of these studies identify vinyl chloride as a carcinogen and further confirm its role in inducing the cancers observed in the B. F. Goodrich workers.

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Since the OSHA Hearing, NIOSH has learned of at least five additional cases of angiosarcoma of the liver. Two of these cases were diagnosed in the current working population at the same Louisville facility, while the other three involved deceased workers, one each from the Louisville facility, Union Carbide's South Charlestown plant, and Goodyear's Niagara plant.

Although vinyl chloride must be considered as a carcinogenic agent, the immediate problem appeared to be concentrated in polymerization facilities. Consequently, the attached NIOSH recommended standard only applies to such operations. This is not to say, however, that appropriate standards should not be developed for other exposures to the basic chemical. NIOSH is implementing further evaluation of the data, coupled with field observations, to determine exposure potentials in pre- and post-polymerization operations. You will be informed as further data and plans are developed.

As previously indicated, NIOSH considers this to be a most serious problem and strongly urges that expedited rulemaking be implemented by OSHA to insure that the health of exposed workers is promptly and adequately safeguarded.

We feel that, except where employers experience problems in obtaining air supplied respirators or environmental monitoring equipment, the attached recommendations can be implemented as soon as a standard is promulgated. The medical surveillance requirements which will be supplied in one to two weeks could also be implemented immediately with the possibility that some employers would need a short period of time for their medical staff or consultants to make arrangements for any special laboratory tests.

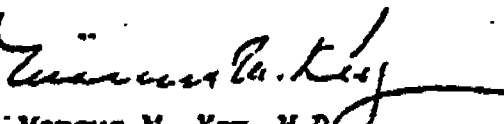
You should be aware that the consultants from industry who worked with us proposed that the recommended standard contain the concept of an allowable "working level" for vinyl chloride gas in the atmosphere, which they identified as a time weighted average of 50 ppm. They recommended that where workers were exposed to concentrations in excess of this level they should wear air-supplied respirators.

This concept of an allowable "working level" might seem justifiable in that Professor Maltoni found no liver tumors at 50 ppm, but there is the possibility that tumors might have been produced if a larger number of animals had been exposed at that concentration. Based on theoretical considerations, there is probably no threshold for carcinogenesis although it is possible that with very low concentrations, the latency period might be extended beyond the life expectancy. In view of these considerations and our inability to describe a safe exposure level as required in section 20(a)(3) of the Occupational Safety and Health Act, we rejected the concept of a threshold limit for vinyl chloride gas in the atmosphere.

Consequently, our recommendations as contained in the attached document are such that where any employee is exposed to measurable concentrations of vinyl chloride, as determined by the recommended sampling and analytical method, he shall wear an air supplied respirator. This recommendation is based on some preliminary information that the standard chemical cartridge respirators are inefficient in protecting against vinyl chloride. NIOSH is implementing a study to evaluate the degree of protection afforded by different types of respirators using vinyl chloride as the test gas. As information becomes available, it will be forwarded to OSHA as recommendations for alternative respirator usage. The employer is also required to develop a Control Plan to reduce airborne concentrations of vinyl chloride to levels not detectable by the recommended method.

As you will note in reviewing the recommended standard, there are references to the "sampling and analytical method recommended by the Director." This method, in the form of a compliance sampling data sheet, will be forwarded to OSHA within a week. We now estimate that the level of sensitivity of our recommended method will be around one part per million, specifically for vinyl chloride.

The Office of Research and Standards Development, which is directed by Mr. Vernon E. Rose, has had lead responsibility in developing this recommended standard. As your professional staff review and evaluate our document, questions or requests for additional information should be directed to Mr. Rose.


Marcus H. Key, M.D.
Assistant Surgeon General

Attachment

Statement

by

Anton Vittone

Division President

B.F. Goodrich Chemical Company*
6100 Oak Tree Boulevard
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Before a Fact-Finding Hearing on The Possible
Hazards of Vinyl Chloride Manufacture and Use
for The Occupational Safety and Health Administration

February 15, 1974

U. S. Department of Labor
Washington, D.C.

*a division of The B.F. Goodrich Company

R&S 158502

TESTIMONY FOR FACT-FINDING HEARING FOR OSHA, CALLED BY OFFICE OF SECRETARY OF LABOR, FEBRUARY 15, 1974, WASHINGTON, D.C.

My name is Anton Vittone. I am president of B.F. Goodrich Chemical Company, a division of The B.F. Goodrich Company. Our headquarters are at 6100 Oak Tree Boulevard, Cleveland, Ohio (44131). I have a prepared statement, from which I will now read and submit for the record of this hearing. With me to assist me in answering questions which may follow this presentation are Maurice N. Johnson, M.D., director of environmental health; Dr. Roger W. Strassburg, director of environmental affairs, and L. B. Crider, senior scientist and specialist in analytical chemistry and monitoring systems — all of B.F. Goodrich. Their biographies are attached to our written paper.

Over the years, our Company has sought to maintain a safe working environment through two basic means — containment of potentially or known toxic materials during the manufacturing process and, secondly, protection of our employees through work practices, education and equipment.

Our efforts to maintain a safe working environment have been in keeping with then known scientific information or data relating to levels of exposure which has resulted in decreasing levels of exposure with time.

Our recent discovery of four deaths from a rare type of liver cancer among employees at our Louisville plant was, to our knowledge, the first evidence indicating a possible relationship between human angiosarcoma and chlorinated hydrocarbons used in the production of polyvinyl chloride resins (PVC). Our confirmation of the significance of this new evidence convinced us that we should report it to our employees and to the Federal and state agencies with primary scientific responsibility for occupational health.

Our statement today will focus on what we have learned about the four deaths at Louisville and our knowledge of previous toxicological data. We will also summarize our program to further safeguard employees now on the job through increased containment of vinyl chloride in processing and reduced worker exposure during all phases of the operation.

The B.F. Goodrich Company began commercial production of polyvinyl chloride resins and compounds in 1937. We currently operate five such plants — at Louisville, Kentucky; Avon Lake, Ohio; Long Beach, California; Henry, Illinois, and Pedricktown, New Jersey, and a vinyl chloride monomer plant at Calvert City, Kentucky. Approximately 1,700 of our employees are engaged directly in these processes. The Louisville, Kentucky plant is the oldest of our operating polyvinyl chloride resin plants having initially started production in 1942. We supply finished resins and compounds to about 2,200 domestic customer plants.

The Technologies Involved in the Production and Use of Vinyl Chloride

There are two types of vinyl chloride monomer processes: acetylene based and ethylene based.

B.F. Goodrich has operated both types. Prior to the early 1960's, our principal process for vinyl chloride involved the reaction of acetylene and hydrogen chloride using a mercuric chloride catalyst deposited on carbon. Starting with a pilot plant at Louisville in 1957 and culminating in a petrochemical complex at Calvert City in 1964, we converted to our present ethylene based vinyl chloride process. This consists of three operations: (1) reaction of ethylene with chlorine to produce ethylene dichloride, (2) thermal cracking of ethylene dichloride to produce vinyl chloride and hydrogen chloride and (3) reaction of hydrogen chloride with more ethylene in the presence of oxygen to produce more ethylene dichloride. The latter process is known as oxychlorination.

Significantly, the vinyl chloride monomer, produced in both processes, is distilled to yield commercial vinyl chloride with 99.9% purity. The purified vinyl chloride is either pipelined as a liquid under pressure to an adjacent consuming plant or transferred to pressurized tank cars for shipment to other polyvinyl chloride resin plants.

There are four types of polyvinyl chloride processes: suspension, emulsion, mass and solution. B.F. Goodrich Chemical uses the first three types with over three quarters of its production being by the suspension process.

The steps in the process for suspension are:

- Vinyl chloride monomer is received at the plant in pressurized tank cars as liquid.
- It is transferred to storage tanks and then piped in a closed system to reactors.
- Water, suspending agents and catalysts are added to the reactors.
- Polymerization is conducted at controlled temperatures.
- Unreacted monomer is recovered and recycled to the process.
- Water is centrifuged from the stripped polymer slurry and the wet polymer cake is dried.
- Dried polymer is bagged or siloed for bulk shipment or transferred to compound operations.

The emulsion PVC process differs only in the types of emulsifiers and catalysts used in the reactor.

- Most emulsion PVC processes in our plants are followed by spray drying of the emulsion.

The mass PVC process differs primarily in that it is anhydrous — no water is used in polymerization. After unreacted monomer is recovered, the dry powder is packaged.

C ompounding

In all of our PVC production plants, we convert part of our resins into compounds in powder or cubed form. This compounding operation is the next step toward the finished products.

- PVC powder is mixed with stabilizers, lubricants and, in some cases, plasticizers in powder mixers of various types.
- The powder mix is fluxed in internal mixers and subsequently diced or pelletized before packaging for shipment.

B.F. Goodrich Toxicity Experience

In connection with these processes, our Company has had some experiences that we want to review with you in order to complete your understanding of certain factors that prompted us to interpret the most recent events as we did.

In mid-1964, Dr. John L. Creech, our Louisville plant physician, reported that an unusual hand problem had developed among a few employees who entered the polymerization reactors to manually remove the buildup of solid PVC from the reactor walls. This was the first time we encountered a problem anything like this. Dr. Creech's observation was found to confirm European published reports of a similar problem.

We called a meeting with other PVC manufacturers to review the situation and participate with them in an extensive research program through the Manufacturing Chemists Association. We then cooperated in a worldwide investigation of what came to be known as the "hand problem" or acroosteolysis. Our employees were advised of the problem and a continuing monitoring system of hand X-rays was established at all our plants. These studies of the hand problem correlated only with manual cleaning of PVC reactors.

Despite the lack of conclusive evidence as to a chemical cause of the hand problem, we initiated an aggressive program to reduce this type of exposure. Goodrich developed a hydraulic reactor cleaning process which is used on all our reactors. The use of hydraulic reactor cleaning reduced substantially the number of entries into reactors, and thus the manual hand effort as well as the exposure to vinyl chloride. In the past several years we have observed no new cases of the hand problem.

In May, 1970 Dr. P. L. Viola, of Rome, reported the appearance of tumors in rats exposed to 30,000 ppm of vinyl chloride vapor in inhalation studies. This level is close to the lower explosive limit of vinyl chloride vapor.

Nevertheless, knowledge of this published information caused the MCA Vinyl Chloride Task Group to initiate a suitable protocol to determine whether tumors could be induced at levels of exposure above or below the 500 ppm maximum standard then in effect.

In conjunction with the development of this protocol, the MCA task force learned of similar animal research which had been initiated by some European PVC manufacturers some time after Dr. Viola's report.

The MCA animal test program began in September, 1973. In addition, the MCA program was expanded to include an industry-wide epidemiology study now under way.

In January, 1973 we intensified air sampling analysis in all our plants to determine more accurately the levels of vinyl chloride monomer exposure. We soon learned that commonly used air sampling techniques were inadequate for fast measurements at low levels for extended periods of time and for determining the cause of any increase in level. Therefore, we investigated all other monitoring techniques, including those being used in other companies, and decided that we needed to develop our own advanced system which would be capable of monitoring at very low levels and over extended periods of time.

While we had been concentrating on reduction of any process loss of vinyl chloride for years, we began a series of special plant manager meetings in mid-1973 to minimize worker exposure to vinyl chloride, to discuss new monitoring systems and to put into effect new work practices. We established an interim goal of 50 ppm maximum exposure and are working toward lower levels.

Louisville Situation

In the spring of 1973, Dr. Creech believed that he was observing among some employees an increasing incidence of symptoms normally associated with possible liver ailments. He discussed his concern with Phillip H. Lawrence, manager of the Louisville plant, and recommended that liver function tests be initiated among certain groups of the plant's PVC employees.

The Company's newly appointed director of environmental health, Dr. Maurice N. Johnson, who is with me today, subsequently went to Louisville and started the testing program involving 271 employees.

The tests, which were completed in early December, 1973, showed that 55 employees had some evidence of slight liver abnormalities. Because of the known limitations of liver tests, these results were not in themselves a major cause for concern.

On December 18, Dr. Johnson again visited the Louisville plant. He consulted with Dr. Creech on these results and they agreed to retest those employees showing any indications of abnormality. These tests have just been completed and are now being evaluated.

In this meeting, Dr. Johnson was informed by Dr. Creech that he had recently learned that an employee died in March, 1973 of angiosarcoma of the liver. Dr. Creech also reported that this rare type of cancer prompted him to review medical records concerning another employee and former patient who died of liver cancer in 1971 and that review confirmed it was an angiosarcoma. Because of Dr. Creech's growing concern and Dr. Johnson's awareness of other pertinent toxicological studies, they reviewed available medical records in the plant and found that another employee had died of an unknown type of liver cancer in 1968. They also learned that another employee was critically ill with a diagnosis of cirrhosis. This man died the following day.

Dr. Johnson returned immediately to Akron for a special meeting with top corporate officers at which the developments at Louisville were reviewed. The decision was made to begin an in-depth investigation with the assistance of outstanding consultants in the field of industrial medicine. Dr. Johnson contacted Tabershaw-Cooper Associates, Inc., of Berkeley, California, because of their reputation and also their involvement in the MCA work that was mentioned earlier. Dr. Johnson met with Dr. Irving R. Tabershaw in California on January 14 and 15 to review all the information then known to the Company. Before returning to Akron, Dr. Johnson learned that the cause of the third death, which had occurred on December 19, was angiosarcoma of the liver.

Another in a series of top management meetings was held on January 18 to discuss these developments. Dr. Tabershaw flew to Akron for a meeting with corporate and divisional officers on Sunday evening, January 20.

Because of the possibility that these deaths from a rare type of liver cancer might be work-related, the decision was made to inform the Occupational Safety and Health Administration (OSHA) through the Kentucky Department of Labor and the National Institute of Occupational Safety and Health (NIOSH), as well as to provide the essential information to our PVC employees, union officials and the public.

The initial meeting with NIOSH took place in Washington on January 22 after Doctors Johnson and Tabershaw returned from a visit to the plant and consultation with Dr. Creech in Louisville on January 21. The notification to OSHA through the Kentucky Department of Labor was made in Louisville by Doctors Johnson and Tabershaw on January 23.

A public statement was also released by the Company on January 23. A second statement was issued to the news media on January 29 immediately after it was learned that a review of autopsy records confirmed the cause of the 1968 death as angiosarcoma of the liver.

During this period, Harry B. Warner, president of B.F. Goodrich; Thomas B. Nantz, executive vice president, and I held private meetings with the families of three of the deceased employees. On the same day, Messrs. Warner, Nantz and I inspected the Louisville plant to observe current work practices and exposure levels. After these observations and consultation with Doctors Johnson and Tabershaw, we concluded that the existing situation warranted continued operation of the polyvinyl chloride facility.

Epidemiological Studies

We have actively supported and participated in both animal and epidemiological studies through the MCA's Vinyl Chloride Task Group of its Occupational Health Committee.

Because of recent developments, we have expanded the scope of our part of the MCA epidemiology study in order to obtain as in-depth a study as possible of employees exposed to vinyl chloride and related chemicals.

The deceased employees had an average exposure of approximately 19 years to vinyl chloride and 10 years to vinylidene chloride. They also had variable exposure times to such volatile organic chemicals as vinyl acetate, methyl acrylate, ethyl acrylate, methanol and chlorinated solvents.

It would be premature to report on the liver activity tests now in process at all our PVC plants or to provide any statistical analysis of the correlation with chemical exposures. We can tell you that no other cases of angiosarcoma have been found in our preliminary review of death records of employees and retirees from Louisville and our other plants. This review is continuing.

Summary

We have attempted to provide information with respect to our findings of four cases of angiosarcoma of the liver of deceased employees of our Louisville, Kentucky, plant which have brought about this hearing. With respect to Item 6 of the agenda, i.e., "whether the available information warrants the issuance of an Emergency Temporary Standard, or the commencement of a regular rule-making under Section 6(b) of the Occupational Safety and Health Act," we recommend that your Agency proceed with the regular rule-making procedure under Section 6(b).

We will do all we can to protect the health and safety of our employees. To help achieve these ends, we have brought exposure levels in all our operations below 50 ppm on a time-weighted average and are working toward lower levels of exposure. Our plant monitoring procedures are reliable and are being improved. We are in the process of providing liver function tests to all exposed employees. We are implementing most of the temporary precautionary procedures recommended by NIOSH on January 31 at all plants as rapidly as possible. Several recommendations will require further clarification and discussion with NIOSH before implementation. Our Medical Department is working closely with government and other medical authorities to specify the best possible medical screening and testing procedures.

In summary, the clinical evidence associated with the deaths of four of our employees identifies the need for scientific inquiry beyond the experience of any one company or industry group.