

MEMORANDUM

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

KC - 1-10-11-11-11
R. L. Lullin

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 etiologic 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.

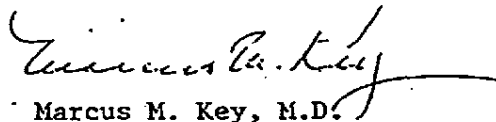
You should be aware that the consultants from industry who worked with us proposed that the recommended standard contain the concept of an allowable "working level" for vinyl chloride gas in the atmosphere, which they identified as a time weighted average of 50 ppm. They recommended that where workers 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 M. Key, M.D.
Assistant Surgeon General

Attachment