



ALLIED CHEMICAL CORPORATION

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December 3, 1971

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R. N. WHEELER

Mr. R. N. Wheeler
Union Carbide Corporation
437 McCorkle Avenue, S.W.
South Charleston, West Virginia

Dear Nick,

Pursuant to the MCA meeting of November 16 on vinyl chloride, the following are writer's questions and suggestions concerning the proposed manufacturer-sponsored toxicological research.

- (1) After I left the meeting, it suddenly occurred to me to question the diagnosis of the lesions as cancers vs. tumors. I presume the evaluation is conclusive but, if it is not, some part of the proposed protocol should include a recovery period to note whether the lesions regress.
- (2) It is presumed that no human tumor has yet been attributed to VCM, but it would appear to be worthwhile to review the working population that was used by the University of Michigan for study of acroosteolysis. This certainly includes the most highly exposed population and, if no tumors exist here, it can be argued that human experience, if of reasonable magnitude, should take precedence over animal studies. It is conceded that this lesion was not sought in Dr. Dinman's study but, from the available records, it might be easier to review this population than another completely new one. I am thinking of a limited epidemiological study, possibly at a substantially lower cost.
- (3) In the matter of analysis of EDC or acetylene derived samples of VCM, we do not expect to discover known carcinogens. However, it does seem desirable to know whether there are any gross differences in the samples used by Dr. Viola and those to be used here. Certainly the 25 (or 29) impurities mentioned are not all present in equal quantities even if made by the same process, and I suspect that process difference may be substantial. At least we should know the variation which can be expected and be certain that the material used is within limits set by analysis of at least six samples from each process. To be certain that sample impurities do not reveal proprietary process secrets of any manufacturer, MCA could act as a clearing house for analyses. A look at the analyses does not necessarily mean that the

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toxicology project need be delayed. Each manufacturer should be able to report analyses of a few batches within one month and, if no major deviations appear which are of major concern, study could start immediately. Will one sample (single unit tank car) of VCM be used, or will it be used from "one-ton" or smaller cylinders?

- (4) We have no serious objection to the exposure protocol but would prefer one non-rodent species even if numbers of animals (possibly dogs or monkeys) were substantially lower in number. We realize that statistical result will not be as significant, but the opportunity to observe a completely different species where metabolic pathways may be substantially different would appear to justify the statistical sacrifice.
- (5) Mutagenicity and teratogenicity were mentioned briefly at the meeting, but we can recall no decision as to whether such studies would be included. We think tests in this area might be desirable but have no strong feeling that they should be included in this protocol. Dr. Legator of FDA believes that mutagenicity may be predictive of carcinogenicity.

In view of the lack of any similar visible lesion in a substantial exposed human population, we doubt that regulatory agencies in this country will take any precipitous action before confirming the results here. We do believe that samples of food-wrapping films should be tested for migration into solvents simulating food to discover levels which may be expected from reasonably standard PVC formulations.

We will be happy to cooperate with the industry group in this matter of safety and health of employees and public.

Sincerely yours,



W. A. Knapp
Toxicology-Consultant

WAK:pb

cc: Dr. Norman G. White
Shell Chemical Company

Dr. Benjamin M. G. Zwicker
B. F. Goodrich Chemical Company

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its Louisville, Ky. plant.

Dr. Maurice N. Johnson, the Company's director of environmental health, said he had recently received medical reports concerning the death of an employee late in December. A review of medical records uncovered that two other employees had apparently died from the same cause -- one in September, 1971 and one in March, 1973. The reported causes of death are subject to verification, he added.

"Awareness of this grouping," said Dr. Johnson, "warranted a thorough investigation and prompt notification of the two government agencies most directly concerned."

The B.F. Goodrich Company has been conducting programs to reduce exposures to hydrocarbons, particularly vinyl chloride, throughout its operations. While all plants were operating at levels well below those prescribed by Federal government standards, a successful effort has been made to reduce levels in these plants to approximately one-tenth those specified.

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These efforts have included development of the most sophisticated monitoring systems now known; strict rules on procedures where exposure might be increased; a complete checking of all pipes, valves and similar equipment to prevent leaks, and extensive improvements in ventilation systems.

"The death in December, considered in relation to the two previous similar cases, has caused us to initiate intensive investigations throughout the vinyl products operations of the Company," Dr. Johnson said.

"To be sure we get the best independent evaluation and guidance, the Company has engaged Tabershaw-Cooper Associates, Inc. of Berkeley, Calif. Dr. Irving R. Tabershaw, one of the country's foremost experts in the field of public and occupational health and safety, is supervising the work of this consultant firm," Dr. Johnson said.

The Company has instituted a program of explaining the new information and steps the Company is taking to all employees involved in vinyl products production. In addition, the Company has put into action a program to reduce exposures to vinyl chloride and other hydrocarbons to the minimum possible in all vinyl operations. Operations of the plants are continuing under the program of minimum exposure levels.

"We are providing medical examinations to all employees involved in any phase of vinyl chloride or polyvinyl chloride production and reviewing available medical records of any deceased former or retired employees," Dr. Johnson said.

"We have assured officials of NIOSH and the state of Kentucky that we will continue to provide them with any significant new information as it develops," he said.

medical reports concerning the death of an employee in late December. "A review of medical records uncovered that two other employees had apparently died from the same cause—one in September 1971 and one in March 1973," the company said.

It was understood that a fourth death—in 1968—involving a more common form of liver cancer, was considered outside the reasonable bounds of the "grouping" of the three recent deaths, all attributed to angiosarcoma.

Goodrich said it had informed Kentucky health officials and the Federal National Institute of Occupational Safety and Health that the company was investigating the possibility that the deaths might be related to occupational causes.

Will Begin Investigation

Kentucky officials said they had just learned of the situation at the Louisville plant and had asked a medical expert to investigate. In Rockville, Md., a spokesman for NIOSH said a team of experts will arrive in Louisville this morning to begin an investigation.

Dr. Marcus M. Key, director of NIOSH, said the institute also will step up efforts to determine the extent of angiosarcoma in the U.S. and in foreign countries with similar manufacturing processes. A spokesman for the institute said the best information available shows 21 deaths per year in the U.S. attributable to angiosarcoma.

The recent deaths at Louisville, according to Dr. Johnson of Goodrich, involved workers in the company's vinyl products operations. An official of NIOSH said he understood that the workers had an average of 20 years' exposure to various chemicals and agents involved in vinyl operations.

Goodrich said it has been conducting a program to reduce exposure to hydrocarbons, particularly vinyl chloride, throughout its operations. Further steps to limit exposure and to describe the situation to workers in vinyl products production are being taken, the company said.

Goodrich also said it is providing medical examinations to all employees involved in any phase of vinyl chloride or polyvinyl chloride production, and is reviewing all its medical records of former or retired employees.

About 1,200 persons work at the Louisville plant, of whom about 270 are involved in vinyl products operations.

"Crapping of a Bomb"

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U. S. DEPARTMENT OF LABOR

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file

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FOR RELEASE: IMMEDIATE
Thursday, January 24, 1974

OSHA INVESTIGATING GOODRICH CANCER FATALITIES

The U.S. Department of Labor announced today it will hold a public hearing early next month to determine the scope of occupational health problems affecting workers involved in vinyl chloride operations.

The Department also announced it has sent two industrial hygienists from the Occupational Safety and Health Administration (OSHA) to investigate polyvinyl chloride production operations of the B.F. Goodrich plant in Louisville, Ky.

Goodrich announced Wednesday it is investigating whether the cancer deaths of three employees are related to occupational exposure to its polyvinyl chloride production operations. One employee died in September 1971, one in March, 1973, and the most recent one last month.

The OSHA experts will investigate jointly with officials from the state and from the National Institute for Occupational Safety and Health (NIOSH) of the Department of Health, Education, and Welfare.

OSHA's investigation is aimed at determining whether violations exist of federal job safety and health standards on worker exposure to vinyl chloride.

The hearing to be held next month will determine the extent of possible exposure and whether there is a need to amend the OSHA standard.

Under federal limits, workers may not at any time be exposed to vinyl chloride in concentrations greater than 500 parts per mil-

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B. F. GOODRICH COMPANY
POSSIBLE JOB-RELATED CANCER DEATHS

The announcement by B. F. Goodrich Company of three possible job-related cancer deaths at their Louisville, Kentucky Vinyl Chloride Resin Plant is potentially a very serious problem for the PVC resin industry. Our own medical records, along with a preliminary report by Tabershaw-Cooper Associates on the industry-wide epidemiological study indicates that the problem has only occurred at the one plant. The Tabershaw-Cooper study will be completed about the end of first quarter, 1974. This study, covering 6,000 industry employees, will show whether there is a significant occurrence of cancer or other disease in the industry versus a selected control population.

As a result of the announcement, Union Carbide reaffirms its plans in the following areas:

1. We will cooperate with and sponsor through MCA the Tabershaw-Cooper Associates epidemiology study as well as other MCA-Industry sponsored studies on vinyl chloride.
2. Our employee medical surveillance is much more thorough than that of B. F. Goodrich and we will certainly cooperate if the industry proposes additional testing.
3. We have pursued a policy of minimizing employee exposure to vinyl chloride and will continue to reduce exposure levels.
4. We will cooperate fully with the NIOSH and other governmental agencies in their efforts to study the problem.


R. N. Wheeler, Jr.

RNWJr/ra

January 28, 1974

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cc: W. L. LARUMP
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