

SUMMARY OF

PROPOSED PLANS FOR EPIDEMIOLOGIC, MEDICAL, AND TOXICOLOGIC
STUDIES PRESENTED AT THE NIOSH/CDC BRIEFING FOR MANAGEMENT
AND LABOR REPRESENTATIVES FROM THE VINYL CHLORIDE AND POLY-
VINYL CHLORIDE MANUFACTURING INDUSTRIES

CLEVELAND, OHIO
FEBRUARY 12, 1974

EPIDEMIOLOGY

It was agreed that:

1. There appears to be a major health problem in the production of PVC from the monomer vinyl chloride (VC);
2. In consideration of the potential scope and seriousness of this problem, NIOSH/CDC take the leadership in the government to investigate the problem, assign it top priority, and immediately to provide or seek the necessary personnel and funds for implementation. This implementation shall include cooperation with interested groups in government, industry, labor, and elsewhere;
3. The Division of Field Studies and Clinical Investigations (DFSCI) within NIOSH/CDC take the lead in undertaking such steps as necessary to determine the full extent of the mortality and morbidity associated with VC exposure among occupational groups.

There appear to be four categories of individuals potentially at risk from exposure to VC and in which exposure and health effects should be evaluated:

1. Production of the monomer VC;
2. The conversion of VC to PVC, both as pure PVC and as polymers containing other substances;
3. The use of PVC in the production of other products; and
4. Consumer uses of PVC products.

In the light of the unusual frequency of angiosarcoma of the liver in a single polymerization facility, first priority should be given to early ascertainment of the disease experience of the foregoing Group 2.

The immediate program should have the following elements:

1. DFSCI/NIOSH in cooperation with the Office of Occupational Health Surveillance and Biometrics (OOHSB) would be involved in:

- a. Assisting Tabershaw/Cooper Associates in any way possible to complete the mortality study of workers at the B. F. Goodrich PVC operations in Louisville.
- b. A governmentally-sponsored epidemiological study of the health hazards associated with the production of PVC.

(1) An attempt will be made to:

- (a) Document the incidence of angiosarcoma of the liver in workers in facilities other than the B. F. Goodrich plant in Louisville;
- (b) Document the incidence of malignant and non-malignant disease in PVC workers;
- (c) Define the real or potential hepatotoxins among the materials used in the production of PVC; and
- (d) Document the state of environmental control in the VC/PVC operations, involving sampling and analysis, work practices, ventilation design, etc.

(2) Five criteria are to be used (listed in descending order of priority) to determine which plants will be studied:

- (a) PVC production history of 15 or more years;

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(2) Five criteria are to be used (listed in descending order of priority) to determine which plants will be studied:

- (a) PVC production history of 15 or more years;

- (b) Size of work force;
- (c) Polymerization involving vinyl chloride with and without vinylidene chloride;
- (d) Location in States where vital statistics information is readily available; and
- (e) In-plant medical program.

Note: Already contact has been made with 18 of the 37 known PVC facilities. Using the above criteria, there is a clustering of plants in the tri-State area of Ohio, Kentucky and Pennsylvania.

- (3) Concurrently, rosters will be developed of both presently employed workers in VC/PVC operations as well as those employees who have moved within or out of the industry.

c. A determination of the extent of use and distribution of PVC among users of the polymer to estimate the exposure to VC or PVC under such circumstances (Contract mechanism).

- 2. CDC will follow through with its surveillance program in the development of a registry for the identification, review, and workup of cases certified as having angiosarcoma, other liver cancers, and other diseases that may appear to be pertinent on death certificates. At the start, this will entail tracing such cases from death certificates recorded for recent years at the National Center for Health Statistics and in vital record departments within individual states. Sufficient detail will be obtained for each confirmed case to permit evaluation of case incidence with respect to geographic distribution, secular trends, and occupation. As the surveillance program develops, additional sources of case ascertainment will be used including contacts with tumor registries, cancer treatment centers, and industry groups.

- 3. NIOSH/CDC will cooperate with other Federal agencies, such as the Food and Drug Administration and the Consumer Product Safety Commission in obtaining information on the use (past and present) and distribution of VC/PVC in aerosol sprays and other household products. NIOSH will also work closely with the National Cancer Institute regarding the state of knowledge of hepatic cancer.

Note: All of the above activities are to proceed apace and concurrently

MEDICAL

A major immediate concern both for VC-related industries and for the government in its projected epidemiologic investigation of the angiosarcoma question will be screening of industrial populations for clinical evidence of disease potentially related to the VC-polymerization process. Such disease encompasses not only angiosarcoma of the liver, but also non-malignant hepatic conditions (cirrhosis), and perhaps other types of cancer and non-hepatic disorders as well. To consider what medical screening procedures are appropriate in this setting, NIOSH/CDC plans in the near future to convene a panel of medical consultants specializing in liver disorders. This panel will review the clinical and pathologic material accumulated to date concerning VC related disease in this country and abroad, and will make specific recommendations to the government with respect to medical screening and followup of potentially at-risk industrial populations.

TOXICOLOGY

NIOSH/CDC will take the lead role in determining needs for experimental animal toxicologic studies. Before developing the protocols, it will be necessary to evaluate the world literature on toxicology and to review the protocol and results of recent and current experiments conducted in the U.S. and Italy. In developing research protocols, NIOSH will work with members of the HEW Committee to Coordinate Toxicology and Related Programs. Many factors and parameters will have to be considered in the development of the experimental design of the study, including species differences, metabolic fate of the inhaled or absorbed VC; dehalogenization of VC, alkalating properties and mechanisms, gas-off products of PVC, toxicology of PVC dust, and effects of low-level exposures to VC. NIOSH does not envision the experiments being done in-house, but rather in one of the other government facilities or by private contractors.