

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210



April 30, 1979

Mr. Robert A. Roland
President
Manufacturing Chemists Association
1825 Connecticut Avenue N.W.
Washington, D.C. 20009

Re: Brain Cancers and Vinyl Chloride Exposure

Dear Mr. Roland:

As part of an Occupational Safety and Health Administration (OSHA) program to evaluate the quality and quantity of epidemiological data bearing on occupational cancer hazards, we have undertaken a review of studies of vinyl chloride-polyvinyl chloride exposed workers. This review has raised several questions regarding the report entitled "Epidemiological Study Of Vinyl Chloride Workers" as conducted by the Equitable Environmental Health Inc. and as transmitted to OSHA on February 23, 1978 by the Manufacturing Chemists Association (MCA) (attachment 1). In an attempt to resolve these questions, OSHA has requested on several occasions, both verbally and in writing, the data underlying the results, interpretations and conclusions of the MCA sponsored study.

Due to the irregular manner in which the MCA results were presented, we initially requested data for the component parts (both observed and expected cause specific deaths) of the Standardized Mortality Ratios as presented in Tables 7-17 of the report. We also requested data supporting the statement on page 24 of the MCA report "Brain tumors were found to be in excess, 12 observed vs. 5.9 expected (significant at the 0.05 level) but the incidence was not related to either duration of exposure or to intensity of exposure to VCM" as no such supportive data were presented in the report (attachments 2-3). Subsequently when we noted that the American Industrial Health Council cited this unpublished study in support of its contention that vinyl chloride was not associated with cancers other than of the liver in humans (attachment 4), a contention not supported by several studies available in the open published literature and not held by the independent scientific community (attachment 5), our request was expanded to include data underlying the entire MCA sponsored study (attachments 6-7). To date, OSHA has neither received the requested data nor satisfactory answers to our questions regarding the MCA sponsored study of vinyl chloride exposed workers.

R&S 142616

In spite of the unavailability of these requested data, OSHA has been able to undertake a matching of brain cancer cases as enumerated in the NIOSH epidemiological study of vinyl chloride exposed workers (attachment 8) with those 12 cases listed in Table 23 of the MCA sponsored study. This effort has indicated that eight cases of brain cancer in the MCA study are primary brain cancers, confirmed either by autopsy, craniotomy or other sources of pathology. In addition 8 cases in the MCA study have been shown to have a pathologic confirmation of glioblastoma multiforme or its equivalent, astrocytoma grades 3-4. Of the remaining 4 cases of brain cancer in the MCA study, no data has been reported which would contravene the diagnosis of primary brain cancer as indicated on the death certificate. These findings are clearly at variance with the MCA report which stated "It is difficult to interpret the significance of this finding of an apparent excess of brain tumors. In the absence of definite confirmation by either autopsy or craniotomy in 8 of the 12 cases, it is quite possible that some might have been secondary brain tumors, with unrecognized primary sites or other non-malignant space-occupying lesions in the cranial cavity."

OSHA's need for the previously requested and additional data regarding the MCA study of vinyl chloride workers recently has been heightened as a result of our investigations of an unusual occurrence of brain cancer cases (11 cases), predominantly glioblastoma multiforme in type, among workers at a Union Carbide Corporation plant in Texas. During our investigation, we were informed that this plant had been included in the MCA epidemiological study of vinyl chloride workers. We also were informed that although some of these brain cancer deaths may have had exposure to vinyl chloride, no cases of brain cancer were reported to have occurred among those vinyl chloride workers selected by the plant for inclusion in the MCA study.

To permit OSHA to properly evaluate the magnitude of multi-site cancer risk, particularly of the brain, among workers exposed to vinyl chloride and to assist us in our investigation of the etiology of an unusual occurrence of brain cancers in one or more plants in Texas City, Texas, we are requesting again that MCA facilitate the release of those data specified in our letters of November 1 and 7, 1978. In addition we are requesting that MCA facilitate the identification of the 35 individual plants which composed the MCA study and those individual plants which were found to have deaths due to brain cancer by way of releasing the names of those corporations which had plants in the study. This information is important to OSHA as we wish to evaluate any differences in chemical processes as they may be associated with the occurrence of brain cancer.

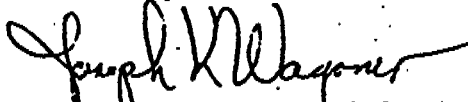
The timely cooperation of MCA in this urgent request will contribute

R&S 142617

to an expeditious and scientifically sound evaluation of the brain cancer risk, both within the vinyl chloride industry and in the plant under current investigation by OSHA and NIOSH.

I look forward to your favorable response.

Sincerely,



JOSEPH K. WAGONER, S.D. Hyg.
Special Assistant for Occupational Carcinogenesis
Office of Assistant Secretary for OSHA

Attachments (8)

cc: Anthony Robbins, NIOSH
Eula Bingham, OSHA, DOL

R&S 142618