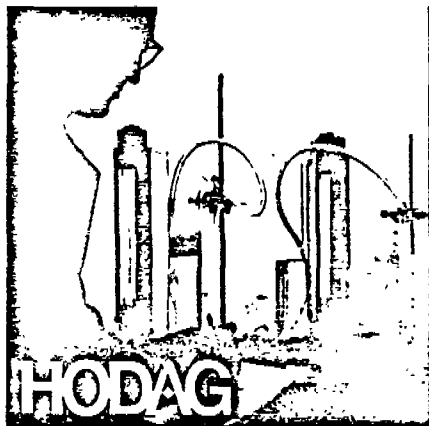




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Withholding of vinyl chloride data hinted

European and U.S. chemical firms, together with the Manufacturing Chemists Association, a U.S. trade group, held in confidence for at least a year preliminary, albeit significant, scientific findings on vinyl chloride as an agent causing liver cancer in rats, C&EN learned early last week. U.S. chemical industry sources say they were bound by an agreement under which four European firms controlled any release of animal test data obtained by Prof. Cesare Maltoni, director, Istituto Di Oncologia, Bologna, Italy.

The first public disclosure of Prof. Maltoni's findings came on Feb. 15, 1974, in the U.S. The disclosure came after B. F. Goodrich's announcement on Jan. 22, 1974, of three deaths due to angiosarcoma of the liver since 1971, among workers at its polyvinyl chloride plant in Louisville, Ky. Subsequently, the number of confirmed cases of angiosarcoma at the BFG plant, at other U.S. PVC plants, and at plants abroad has risen steadily to a total of 19, including 13 U.S. cases. 17 of the workers have died of the liver cancer; two U.S. workers are still living. The U.S. deaths date back to 1961.

Prof. Maltoni's animal data have been a key to much of the regulatory actions taken by the Occupational Safety and Health Administration. In February, the lowest dose level of vinyl chloride in the Italian scientist's study at which liver angiosarcoma developed was 250 p.p.m. Guided, in part, by these findings, OSHA on April 5 set an emergency rule that lowered the permissible OSHA worker exposure level to 50 p.p.m. from the previous ceiling of 500 p.p.m.

Since then, additional animal data have appeared. At a May 10-11 meeting of the New York Academy of Sciences and American Cancer Society, Prof. Maltoni disclosed that he had found one liver angiosarcoma in his rats at 50 p.p.m., together with several other types of tumors. At higher levels of exposure there were more tumors of various types, including liver angiosarcomas, as he reported earlier (C&EN, Feb. 25, page 16).

On April 16, MCA announced that preliminary findings on mice in its own study under way at Industrial Bio-Test Laboratories tended to confirm the Maltoni data then available publicly. And as presented by MCA before the May 10-11 meeting, the data show that under conditions of exposure of seven hours per day, five days per week, for eight months, liver angiosarcomas develop as follows: 2500 p.p.m., 28 liver angiosarcomas; 200 p.p.m., 11; and 50 p.p.m., two. MCA's study also showed other types of tumors. Tests also have just begun at dose levels of 25, 10, and 5 p.p.m.

Besides the animal data there is a

wealth of new medical findings now appearing on vinyl chloride exposure, partly through the May 10-11 meeting. MCA's epidemiological study on 7128 vinyl chloride workers, for example, finds that cancers of the liver (primarily angiosarcoma), respiratory system, brain, and cancers of unknown primary site, as well as lymphosarcoma, "occurred more often than expected in those members of the study population with the greatest exposure," with the caveat added that although these excesses "were not statistically significant, the findings warrant further study." And a major bias in the study is the "discovery"—too late to include it—of 1500 to 2000 workers with the longest exposures, up to 35 years.

In August 1972 Dr. Maltoni found his first angiosarcoma in the first of a series of studies that, according to data available to C&EN, began about Sept. 5, 1971. A key, second experiment at levels of 200, 150, and 100 p.p.m. began about July 8, 1973, when it was observed that the 250-p.p.m. level "was still showing oncogenic effects."

In January 1973 a team of three U.S. chemical industry scientists visited Prof. Maltoni in Bologna to learn of his results and to see his slides. Some months of negotiations with the European company group preceded this visit. The group is made up of Montedison, which first approached Prof. Maltoni to do the study, Imperial Chemical Industries, Solvay, and Rhône-Progil. All four were supporting the work at the time of the visit, U.S. sources say.

Subsequently, the liver angiosarcomas in four U.S. deaths of workers have been judged by OSHA to be "histologically indistinguishable" from the angiosarcoma tumors Prof. Maltoni has found. And he believes that his experiments were "predictive" of what was subsequently recognized in man.

Much remains to be answered in the way the release of the Maltoni data has been handled. There are allegations, unfounded from all that C&EN can learn, that word of early results was passed to U.S. and Italian government officials. A major question mark concerns what was said by MCA to the National Institute for Occupational Safety and Health in July 1973 and earlier. As the trade association testified before OSHA on Feb. 15, 1974, "MCA's first direct contact with NIOSH specifically on vinyl chloride led to a conference between an industry delegation, including a European representative, and Dr. Marcus Key [NIOSH director] and staff on July 17, 1973, at which time the MCA program was presented in some detail, and study protocols, industry statistics, and selected items from the scientific literature were provided." MCA has shed no new light on these contacts.

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