

MAR 25 1975

MICA

MANUFACTURING CHEMISTS ASSOCIATION

1625 CONNECTICUT AVENUE N.W. WASHINGTON D.C. 20009 (202) 463-4126

March 21, 1975

TO: Technical Task Group on Vinyl Chloride Research

SUBJECT: Items related to Vinyl Chloride

Attached for your information are the following:

1. A copy of the paper presented by Dr. Gordon of Industrial BIO-TEST Laboratories at the March 5 meeting of the International Academy of Pathology in New Orleans entitled "Comparison of the Morphologic Features of Hepatic Angiosarcoma in Man and Rodents Following Prolonged Exposure to Vinyl Chloride."

2. A news release on the availability of a new book entitled "The Determination of Vinyl Chloride - A Plant Manual," published by the Chemical Industries Association Limited, Albion House, 93 Albert Embankment, London SE1 7TU

Sincerely,

Milton Freifeld

Milton Freifeld, Project Manager

MF/etv

Attachments

RSV 0020465

earlier interim report dated May 9 had been mailed to the Panel prior to the meeting. It covered gross and histopathologic findings in small groups of rats sacrificed after one year.

It was agreed that if the secretary did not receive comments to the contrary by June 7, concurrence would be assumed. In that case these reports would then be made public including distribution to appropriate government agencies.

The secretary relayed a question from Dr. Gordon of IFT regarding the examinations of brain tissues from animals that had died. Dr. Gordon felt such information could be useful in the light of Professor Maltoni's reported correlation of tumors in animal and human brain tissues. Similar work on sacrificed animals is already covered in the MCA agreement with IFT. This is to be resolved by Dr. Torkelson. (Note: it has since been reported by Dr. Torkelson that in the future IFT will attempt to examine brains from all animals, including those found dead.)

6. Review of Dow Studies

6.1. Metabolism

At the meeting, Dr. Torkelson gave the secretary a formal interim report, September 1, 1974 to May 1, 1975, from Dow to be reproduced and distributed to the Panel. Dow is also preparing an article based on this information for publication in a scientific journal which will be distributed to the sponsors.

6.2. Teratology

It is expected that the final report will be completed by the end of this summer per Dr. Torkelson.

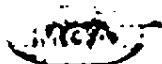
6.3. Mutagenesis

The report is currently in preparation and should be ready within two weeks per Dr. Torkelson.

7. Financial Status

Mr. A. C. Clark summarized the financial data on the project and a copy of his report is attached.

The Panel was also informed that since so many changes had occurred in the industry recently, reported capacities were being updated by questionnaires to management contacts.



MANUFACTURING CHEMISTS ASSOCIATION

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ALBERT C. CLARK
VICE PRESIDENT
MANUFACTURING CHEMISTS ASSOCIATION

June 2, 1975

Philip H. Abelson, Editor
"Science"
1515 Massachusetts Avenue, N. W.
Washington, D.C. 20005

Dear Dr. Abelson:

The Edsall article, "Scientific Freedom and Responsibility" (J. T. Edsall, "Science," May 16, 1975) requires comment. I presume Dr. Edsall is not responsible for the content of the article, but merely prepared it from the AAAS committee report. However, scientific freedom and responsibility are as important for AAAS committees as they are for other scientists. The "case of data suppression concerning the carcinogenicity of vinyl chloride" (pg. 690) is a melange of omissions and untruths inconsistent with scientific freedom and responsibility. Since so much pertinent information has been omitted concerning this matter readers may be misled into believing Dr. Edsall's report.

Edsall states that, "up to that time (May 1970) there had apparently been no research in the plastics industry concerning the possible hazards of vinyl chloride...". This is untrue. In fact, the basic published data on vinyl chloride toxicity came from American industry (references 1-7). The information in references 4, 5, 6, and 7 had been publicly disclosed and presented prior to their publication dates. Furthermore, the investigations of Dr. P. L. Viola and Dr. Maltoni have been supported by European industries.

Edsall correctly states that Manufacturing Chemists Association (MCA) member companies entered into an agreement with the European sponsors of Maltoni's work not to reveal preliminary Italian data. The agreement was not dissimilar to that between American sponsors (Government, Industry, and Academic) and research institutions that new data remain the property of the institution and not be disclosed until the study is completed and evaluated prior to disclosure of final results in proper scientific channels. There was no intention to withhold adverse data. Under MCA rules, all data developed under its auspices must be promptly reported publicly. Without exception, this has been done with all data on vinyl chloride.

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Philip M. Abelson, Editor
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U. S. Government scientists knew of Maltoni's preliminary results early in 1973 but considered it as preliminary as did U. S. industry. At the Second International Symposium on Cancer Detection and Prevention in Bologna, April 9-12, 1973, Dr. Maltoni showed a table of preliminary results linking vinyl chloride with cancer formation⁸ (not published until 1974). Dr. Umberto Saffiotti, Associate Director of Carcinogenesis, National Cancer Institute, was present at the meeting and subsequently discussed the results with Maltoni at his Italian laboratory.⁹ Saffiotti felt that the work needed to be included in "a well documented report" to be assessed by the World Health Organization (Review Panel of the International Agency for Research on Cancer of which the United States is a member). This committee also considered Maltoni's data preliminary at that time and "decided to postpone compilation of the definitive review to the next meeting of the committee."⁹

Following a period in which epidemiological and animal studies were being established, MCA on April 17, 1973 asked the Europeans to jointly make presentations to United States and European Government authorities. The Europeans readily agreed, and on June 15, 1973 MCA called the National Institute for Occupational Safety and Health (NIOSH) and requested an opportunity to bring new information to that agency's attention. The appointment was set by NIOSH for July 17. Five European and American industry representatives presented to NIOSH the information that tumors had been observed at concentrations below that reported by Viola. At that time, human cases had not been reported; therefore, no special significance could be attached to the types of tumors observed by Maltoni.

The MCA suggested label referred to by Edsall was illustrated in the Chemical Safety Data Sheet (SD56) on vinyl chloride, revised April 1972. Section 10.1 on Health Hazards refers to Viola's published studies. The Data Sheet states "Recent research studies reported from Italy indicate that repeated, long-term high level exposures of rats to vinyl chloride monomer vapor can result in the development of malignant tumors. However, many years of industrial experience with human exposures to concentrations frequently far above current standards have not demonstrated any carcinogenicity to humans." Thus the statement by Edsall that MCA "...appears to have deliberately deceived NIOSH regarding the true facts." is inaccurate and misleading.

Sincerely,



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References:

- (1) Torkelson, T. R., F. Oyen, and V. K. Rowe. The toxicity of vinyl chloride as determined by repeated exposure of laboratory animals. American Industrial Hygiene Association Journal, 22(5), 354-361. 1961.
- (2) Wilson, R. H., W. E. McCormick, C. F. Tatum, and J. L. Creech. Occupational Acroosteolysis, report of 31 cases. The Journal of the American Medical Association, 201(8), 577-581. 1967.
- (3) Baretta, E. D., R. D. Stewart, and J. E. Mutchler. Monitoring Exposure to vinyl chloride vapor: breath analysis and continuous air sampling. American Industrial Hygiene Association Journal, 30, 537-544. 1969.
- (4) Dimman, B. D., W. A. Cook, W. M. Whitthouse, H. J. Magnuson, and T. Ditchek. Occupational Acroosteolysis: I. An Epidemiological Study. Archives of Environmental Health, 23, 61-73. 1971.
- (5) Cook, W. A., P. M. Giever, B. D. Dimman, and H. J. Magnuson. Occupational Acroosteolysis: II. An Industrial Hygiene Study. Archives of Environmental Health, 22, 74-82. 1971.
- (6) Dodson, V. H., B. D. Dimman, W. M. Whitthouse, A. E. M. Eber, and H. J. Magnuson. Occupational Acroosteolysis: III. A clinical study. Archives of Environmental Health, 22, 83-91. 1971.
- (7) Kramer, C. G., and J. E. Mutchler. The correlation of clinical and environment measurements for workers exposed to vinyl chloride. American Industrial Hygiene Association Journal, 33(1), 19-36. 1972.
- (8) Maltoni, C. Occupational Carcinogenesis. Proceedings of the Second International Symposium on Cancer Detection and Prevention. Bologna, April 9-12, 1973. Excerpta Medica, Amsterdam. 1974.
- (9) Hearing before the Subcommittee on Environment of the Committee on Commerce, United States Senate, August 21, 1974, (Serial No. 93-110) on Dangers of Vinyl Chloride, pages 54-56.

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Cesare Maltoni*, Adriano Ciliberti*, Luciano Gianni* and Pasquale Chiesco*: The appearance of angiosarcomas in rats following oral administration of vinyl chloride** (Insorgenza di angiosarcomi in ratti, in seguito a somministrazione per via orale di cloruro di vinile)
Ospedali della Vita, 2 (1), 65-66 (1975).

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