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Record of Meeting

VINYL CHLORIDE RESEARCH COORDINATORS

MCA Headquarters

Washington, D.C.

January 11, 1978

Dr. T. R. Torkelson, Chairman, presided and opened the meeting at 9:30 a.m. The following members and guests were present:

MEMBERS PRESENT

T. R. Torkelson, Chairman	The Dow Chemical Company
Z. G. Bell	PPG Industries, Inc.
W. D. Harris	Uniroyal, Inc.
M. N. Johnson	The BFGoodrich Company, Chemical Division
C. D. Kary	Shell Oil Company
W. M. Smith	Air Products & Chemicals, Inc.
G. Ter Haar	Ethyl Corporation
R. N. Wheeler	Union Carbide Corporation
J. T. Seawell	MCA Staff

GUESTS PRESENT

G. K. Hatfield	Diamond Shamrock Corporation
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1.0 Approval of the Record of the Last Meeting

The record of the November 30, 1976 meeting was approved as recorded.

2.0 Review by the Chairman of Time Spans Required for Completion of Action by the Vinyl Chloride Research Coordinators

The Chairman presented a summary of time spans required for completion of action on important matters requiring the prompt

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attention of the Vinyl Chloride Research Coordinators. A few of the examples cited were as follows:

- 1) Recommendation of extended work pertinent to the Equitable Environmental Health study.
- 2) Balloting on final reports covering the metabolic studies.
- 3) Acceptance of the three research reports from the University of Louisville.

The Chairman concluded his summation with a request that future action, especially on matters affecting the continuation of research programs operating under critical fiscal requirements, be more prompt.

3.0 Discussion of Environmental Protection Agency (EPA) National Emission Standards for Hazardous Air Pollutants as They Concern Vinyl Chloride Emission Standards

The Chairman reviewed the efforts conducted to date toward the establishment of realistic emission standards.

The current most pressing matter in this overall area concerns a Notice of Public Hearing to Consider Establishment of State Ambient Air Quality Standards for Vinyl Chloride as announced by the Air Resources Board of the State of California. The Air Resources Board requests evidence and testimony relating to the "effects of vinyl chloride exposures on health, illness, and irritation to the senses". The Board also seeks information relating to the appropriateness of a twenty-four hour or other averaging period, and the appropriate test method.

If one or more new state ambient air quality standards for vinyl chloride are established, the Board will make appropriate amendments to its regulation in Section 70200, Title 17, California Administrative Code, Relating to Ambient Air Quality Standards.

The time and place for public hearing on this matter are as follows:

Date: January 25, 1978

Time: 10 a.m.

Place: Ambassador Hotel
Embassy Row
2400 Wilshire Boulevard
Los Angeles, California

Copies of the staff report on this matter will be available for inspection at or may be obtained from the Headquarters of the Air Resources Board, 1102 Q Street (P. O. Box 2815), Sacramento California, 95812, Attention: Public Information Office.

Notice has also been given that any interested person may present oral or written statements at the public hearing referred to above. The Board requests that interested persons who have written statements to submit on this matter, submit ten copies at least seven days prior to the scheduled hearing date.

4.0 University of Louisville
Acceptance of Research Reports

4.1 Initial Progress Report, April 11, 1977

4.2 Second Progress Report, June 6, 1977

4.3 Annual Report, September 8, 1977

The above-mentioned reports were unanimously accepted by the Vinyl Chloride Research Coordinators.

5.0 University of Louisville
Research Proposals

5.1 Discussion of Research Proposals Submitted for the
Second Year of Research (1977-1978) and Third Year
(1978-1979)

The Research Coordinators reiterated their acceptance of the University of Louisville Research Proposals for both fiscal years (1977-1978 and 1978-1979).

A report was presented by the Chairman and the Project

Manager on the current status of sponsorship for the 1977-1978 research program. This report concluded with a request from the Chairman that all necessary liaison with Management Contacts be carried out in an effort to accelerate action on invoices which have already been mailed.

Under this agenda item, the main topic of discussion was concerned with the nature of this research program, i.e., its concern with (1) "the human aspects" of this research effort on vinyl chloride and, (2) the breadth of the investigations which pertain not only to vinyl chloride but to other chemicals as well. The following component studies of the overall program are illustrative of this second point:

- 1) Immunological systems for the detection of vinyl chloride and other chemical injury.
- 2) Biochemical enzymatic systems for the detection of vinyl chloride and other chemical injury as a potential means of detection of cancer in humans.
- 3) Electron microscopic evaluation of liver injury from chemical workers.
- 4) Assays for identification of the carcinogenic potential of industrial chemicals.
- 5) Tissue antigenic systems for detection of chemical-induced carcinogenesis.

In the opinion of the Vinyl Chloride Research Coordinators, these component studies amply show the breadth of this research and emphasize their opinion that consideration should be given to the sponsorship of this program by an appropriate MCA function concerned with a broad-based approach to research on chemicals in general. It is their further opinion that such broad-based sponsorship may be required for the third fiscal year of research and, in all probability, will be required for any research program conducted after fiscal year 1978-1979.

5.2 Recommendations to Dr. C. H. Tamburro

A research update meeting is planned for May or June 1978 at the School of Medicine, University of Louisville for

the purpose of having each of the directors of component research projects present a review of his findings to date to Panel members.

It will be recommended to Dr. Tamburro that at the time of the research update presentations, plans for each of the 1978-1979 component research studies be reviewed as concluding parts of the individual research summaries or as a separate entity.

5.3 Companies in Arrears on Their Pro Rata Payments for 1976-1977 University of Louisville Research Program

The motion was made, seconded, and carried on a request that MCA take appropriate follow-up action on an attempt to secure pro rata payments overdue for the 1976-1977 University of Louisville research program. These payment deficiencies which are properly reflected in sections 4 and 5 of the financial statement on the vinyl chloride research program dated December 1, 1977 were the sources of the only comments made on the financial statement. The financial statement was accepted as recorded.

6.0 Recommendation Concerning Funding of Research and Matters Relating Thereto within the Framework of the Research Budget

Arising out of discussions under section 5.3 above was the motion, submitted by the Research Coordinators for Panel action, that the necessary commitment be secured from the Management Contacts whereby in the future the Panel can authorize appropriate expenditures for research and ancillary operations (e.g., the upcoming in-depth audit of the chronic inhalation study) within the budget framework approved by the Management Contacts.

7.0 Status Report on Chronic Vapor Inhalation Study and Recommendations on In-Depth Audit

The Chairman began his status summary by citing the fact that the last report received from Industrial BIO-TEST Laboratories, (IBT), Northbrook concerning the subject study was September 23, 1975. Since that date, numerous attempts have been made to accelerate completion of the final report, especially the reading and analyses of slides evolving from the histopathological phases of this overall research program, and, more importantly, definitive information on possible liver lesions, mammary tumors, and lung tumors.

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As of January 5, 1978 representatives of IBT, Northbrook would not project when the final report will be written. Two events have contributed to further delays in completion of the final report, i.e., (1) the resignation of certain key computer personnel immediately prior to computer analyses of histopathological data, and (2) the transfer of records from IBT, Northbrook to IBT, Decatur - the site of future IBT research. At this point, a member of the Research Coordinators called attention to the results of seven audits of the trichloroethylene (TCE) research program being conducted by IBT, Decatur. The audits of the TCE program have clearly shown high levels of technical competence and integrity in research administrative and operating personnel at IBT, Decatur.

At the conclusion of the status summary and the ensuing discussions, a motion was made, seconded, and carried to recommend to the Technical Panel that at the earliest possible time a Vinyl Chloride Audit Task Group conduct in-depth audits of all phases of the chronic inhalation study beginning with the initial exposures and extending through confirmatory slide checks by a competent pathologist to be selected by the Audit Task Group. Particular consideration will be given during the audit to the current status of data summaries on histopathological findings.

The Research Coordinators recommended to the Panel that the Audit Task Group be comprised of:

Dr. Z. G. Bell, Chairman	PPG Industries, Inc.
Dr. T. Benya	Ethyl Corporation
Dr. G. K. Hatfield	Diamond Shamrock Corporation
Dr. R. K. Hinderer	The BFGoodrich Company, Chemical Division
Dr. C. D. Kary	Shell Oil Company
Dr. T. R. Torkelson or Dr. K. Olson	The Dow Chemical Company
Consulting Pathologist	To be selected by the Task Group
Mr. J. T. Seawell	MCA Staff

During the progress of the meeting a telephone call was placed to Dr. John W. Goode, IBT, Decatur to establish a date by which all records, sections, and possibly statistical analyses of histopathological data would be available for auditing. Dr. Goode agreed that the audit would be conducted during the week beginning February 20, 1978. The Research Coordinators estimated that four

or five days will be required for the audit in view of the fact that exposures were initiated September 10, 1973 and in further view of the fact that three animal species were involved at each of the exposure levels.

8.0 Equitable Environmental Health, Inc. (EEH)

8.1 Final Report on Epidemiological Study on Vinyl Chloride Workers

Under the provisos that modified pages of the text, i.e., pages 19, 20, 23 and Table V, are incorporated as replacements for the same numbered pages and table in the second of two "final reports" (both of which were dated August, 1977), a motion was made, seconded, and carried that the Research Coordinators accept the report and recommend that the Panel also accept it.

8.2 Long Range Planning for an Update Epidemiological Study to Be Conducted Five Years Hence

A recommendation was made that five years from the date of the present study that consideration be given to follow-up studies of the cohorts investigated during the original study. It is projected that the update will continue to follow the form of a historical prospective mortality study of workers exposed to vinyl chloride and its polymers.

9.0 Discussion of and Action on Continuation of Cooperative Effort on Continuing Updating of the International Registry Of Reported Cases Of Angiosarcoma Of The Liver Among Vinyl Chloride Polymerization Workers

The Chairman reviewed the excellent work being conducted by Mr. John Stafford of Imperial Chemical Industries Limited on the maintenance of an International Registry of Reported Cases of Angiosarcoma.

Dr. Torkelson concluded his discussion of Mr. Stafford's work by urging that all companies which can possibly contribute to Mr. Stafford's International Registry do so by addressing reports to:

Mr. John Stafford
Imperial Chemical Industries Limited
Plastic Division
P. O. Box 6
Bessemer Road
Welwyn Garden City
Hertfordshire AL7 1HD England

He further requested that copies of all material mailed to Dr. Stafford be sent to him.

10.0 Marshfield Clinic, Marshfield, Wisconsin
Reported Cases of Angiosarcoma of the Liver

Drs. Justus J. Fiechtner and Cesar N. Reyes, physicians at the Marshfield Clinic in Marshfield, Wisconsin described cases of angiosarcoma in the JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION. The Marshfield Clinic treated four individuals for angiosarcoma over a twenty-nine month period between 1973 and 1975. In their report the doctors said the only common thread among the four patients was a past history of farming or farm labor. Arsenic-based pesticides, the most common of which was called copper acetoarsenite, were routinely used years ago to control insects in dairy barns and potato patches. Farmers abandoned these pesticides about ten years ago. Because cancer may not develop until twenty-five or thirty years after exposure to a carcinogenic agent, the physicians expressed the worry that they may have observed only the beginning of a series of such cases.

Insecticides containing higher arsenic levels than copper acetoarsenite were tied to eight cases of angiosarcoma among German vineyard workers during the late 1950's.

In his most recent communication to Dr. Torkelson, Dr. Fiechtner reported that the "casual relationship of arsenic and exposure at an early age" appears to be the most likely lead they have at present.

11.0 Chemical Safety Data Sheet SD-56 on Vinyl Chloride

After general comments on possible conflict between SD-56 and pertinent government publications on vinyl chloride, the motion was made, seconded, and carried to accept the current draft of SD-56 in its present form. The Research Coordinators

recommended that the document in its final form bear the same date as when circulated to the entire Panel for comment, i.e., April 1977.

The Research Coordinators further recommended that the final deadline for all comments to be submitted by either the Research Coordinators or the members of the Technical Panel be set at three weeks after receipt of the Record of the January 11 and 12 meetings of these respective groups.

12.0 Data Information Service on Vinyl Chloride

Dr. Christina D. Kary, Toxicologist, Health, Safety and Environment, Shell Oil Company submitted for the consideration of the Research Coordinators, and ultimately the members of the Technical Panel, a proposal on a compilation, worldwide in scope, to contain all literature references, on both published and unpublished material, on vinyl chloride with the provisions for continuing update and evaluation.

Dr. Torkelson responded to this proposal by recommending that action on it be deferred since the Society of the Plastics Industry (SPI) already has in operation a worldwide interest in searching the literature on vinyl chloride and has been coordinating its efforts with work already in progress on a worldwide literature review on vinyl chloride being conducted by the Office of Occupational Health of The World Health Organization, 1211 Geneva, Switzerland under the direction of Dr. E. J. Fairchild, II.

Dr. Torkelson suggested that should anyone have contributions to make to this overall effort that they be sent to him. He, as Chairman of SPI's Subcommittee on Toxicology, is in frequent communication with Dr. Fairchild and will forward such contributions to Dr. Fairchild as promptly as possible.

13.0 Monograph on Vinyl Chloride

Dr. Thomas H. Milby, President of Environmental Health Associates, Inc. will publish during the near future a monograph on vinyl chloride. This project is being sponsored by the National Cancer Institute (NCI) and Dr. Milby's work will be published as an NCI monograph.

JTS:ec
Record Subject to Approval
February 3, 1978


J. T. Seawell
Project Manager
Vinyl Chloride Research

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