

Manufacturing Chemists Association

Minutes of Meeting

VINYL CHLORIDE RESEARCH COORDINATORS

MCA Conference Room

Washington, D. C.

January 30, 1973

MEMBERS PRESENT:

T. R. Torkelson, CHAIRMAN	The Dow Chemical Company
Z. G. Bell, Jr.	PPG Industries, Inc.
W. D. Harris	UNIROYAL, Inc.
R. L. Maycock	Shell Chemical Company
W. E. McCormick	B. F. Goodrich Chemical Company
W. E. Rinehart	Ethyl Corporation
R. N. Wheeler, Jr.	Union Carbide Corporation

GUESTS PRESENT:

D. P. Duffield	ICI
N. V. Hendricks	Exxon Corporation
C. A. Johnson, M.D.	The Goodyear Tire & Rubber Company
M. G. Ott	The Dow Chemical Company

MCA STAFF PRESENT:

G. E. Best	MCA
A. C. Clark	MCA
K. D. Johnson	MCA

1. Minutes of Meeting of November 14, 1972

The minutes, as distributed, failed to record the presence of Dr. W. D. Harris, a member representing UNIROYAL, Inc.

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2. Report of Conference with European Group

Dr. Torkelson presented a highly favorable report on the conference attended by the delegation from the U.S. group (Drs. T. R. Torkelson, Mac Roy Gasque, and R. J. Kociba, Research Pathologist from The Dow Chemical Company). He expressed his appreciation of the quality of the research work and its documentation, and of the frankness with which the findings of the project were presented and discussed.

A copy of a CONFIDENTIAL summary of the findings to date, with brief interpretative comments, as received from Montedison, is attached to these minutes.

The animals were housed throughout the experiment in cages within the exposure chamber. Food and bedding (sterilized wood chips) were thus exposed to the vinyl chloride vapors. The possibility of a significant effect from adsorption-desorption of the vapors, or of chemical interaction between the vapors and/or the food or bedding is considered unlikely, but remains a possibility as a contribution to the observed animal reactions.

The observed excess animal mortality, not associated with tumors, was ascribed to lung infections secondary to pulmonary irritation from the chemical vapors.

The Coordinators voted to authorize MCA to disburse up to \$2,500 of the project's contingency funds to defray the expenses incurred by its delegation to the Bologna conference.

3. Liaison with European Group

All communications from MCA or its members to the European group are to be addressed, in parallel, to:

Mr. D. M. Elliott
General Manager - Production
Solvents and Monomers Group
Mond Division
Imperial Chemical Industries Limited
P. O. Box No. 13, The Heath
Runcorn, Cheshire, ENGLAND

and to

Dr. Tiziano Garlanda
Protezione Ambientale E Sicurezza
Montedison
Via Appiani, 12 - Milano
ITALY

Any such communications not channeled through MCA should be provided, as information copies, to MCA, attention of Dr. Kenneth D. Johnson.

4. Selection of Protocol for MCA Project

As a result of discussions between Dr. Keplinger of Industrial Bio-Test Laboratories, Inc. and Dr. Torkelson, Dr. Keplinger, under date of December 11, 1972, submitted a letter to MCA outlining several options open to MCA and the costs for each. These options are stated as modifications to their letter proposal of August 17, 1972.

In order that the contract can be executed without delay, the Coordinators voted to begin the project with an authorization for option 6(b), at a cost of \$149,000. This option provides that the two test groups to be exposed to acetylene-derived monomer be dropped, and that a third species (hamsters, 100 male and 100 female per group) be added to each of the three exposure groups and the control group. Exposures of the animals to the test atmospheres would be initially contracted for one year only, with the animals then to be maintained in stock cages for the remainder of the study.

Additional funding, as required to provide for the originally anticipated plan of continuing exposures throughout the experiment, and for possible mutagenesis and/or teratogenesis studies, will be recommended to the project sponsors. It was the judgment of the Coordinators that at least \$200,000 in total funding should be requested at this time. Such funding is to be sought promptly before Industrial Bio-Test Laboratories, Inc. has committed the exposure facilities to other studies for the second project year.

Exposure levels are to be 5,000, 500, and 50 ppm as tentatively agreed upon at the November 14, 1972 meeting.

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The Coordinators voted to approve the request of The Dow Chemical Company to negotiate with Industrial Bio-Test Laboratories, Inc. to collect and deliver to Dow, at Dow's expense, selected tissues for cytogenetic studies.

5. Epidemiology

Dr. M. G. Ott, of The Dow Chemical Company, described the epidemiology studies they are now conducting on their vinyl chloride workers. A copy of their protocol is enclosed. Preliminary results at one of the four plants to be surveyed fail to indicate any excess cases in this group.

Dr. D. P. Duffield, of ICI, described the epidemiological studies planned by the European group, which is searching the death certificates of deceased plant employees with a history of industrial vinyl chloride exposure, and comparing the incidence of neoplasms with that in a control group without such exposure. He expressed the hope that any studies conducted by the U.S. group would provide statistics suitable for statistical evaluation in conjunction with the data from their study.

The quantity and quality of American data that might be available to an epidemiological study of employees of American firms was discussed at some length. It was agreed that MCA should distribute, through the members of the Technical Task Group, a questionnaire eliciting their estimates of what might be available in their company records.

It was voted to invite the organizations listed in the minutes of the November 14 meeting to attend a prospective contractors briefing at MCA offices on February 20. The Coordinators are to meet at 9:00 AM that morning to review the returns from the questionnaire referred to in the preceding paragraph, with the briefing session scheduled for 1:00 PM that afternoon. Prospective contractors are to be asked to treat data revealed at this meeting as confidential, and to be alerted to the need for meeting project schedules.

Did not attend - Conoco data is less than
10 year exposure at Aberdeen, less than 5 year
elsewhere

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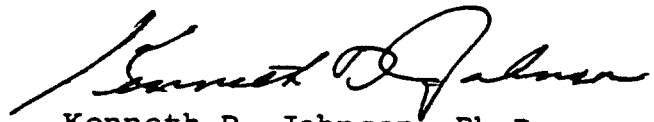
6. Information Release

The need to exercise discretion in the handling of information about, or to be developed by, this project was stressed. It was the consensus of those present that, when MCA negotiated a research contract with Industrial Bio-Test Laboratories, Inc., it would be appropriate to release such information to the press. There will be no reference to the European studies and the nature of the project is to be referred to as a chronic inhalation study without reference to the question of carcinogenesis.

The question was raised as to the position that should be taken by MCA and/or its member companies on (1) probable changes in the Threshold Limit Value for vinyl chloride, and (2) the use of vinyl chloride as an aerosol propellant. With respect to the first, there was general agreement that specific inquiries should be answered with a frank statement that available literature data suggested that an early and significant reduction from the present 200 ppm standard could be anticipated, and that industrial hygiene planning should be designed to keep exposures to a minimum. MCA is to handle inquiries it receives on an ad hoc basis, and no standardized position paper is to be prepared. Each company will have to exercise its individual judgment as to the timing and level of future standards its customers may be told to anticipate.

The limited commercial value of the aerosol propellant market, in contrast with the unlimited potential for product liability claims, was stressed as justification for serious consideration by the manufacturers of withdrawing from this market. All recognized that an insistent discouragement of the use of vinyl chloride as a propellant might focus undue and premature attention on the industrial hygiene aspects of the problem. No MCA position on this question is recommended at this time.

Respectfully submitted,



Kenneth D. Johnson, Ph.D.
Secretary

Minutes Subject to Approval
February 7, 1973

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Attachments
KDJ:mb

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ATTENDEES

JANUARY 17, 1973

MANUFACTURING CHEMISTS ASSOCIATION

- DR. MAC ROY GASQUE, MEDICAL DIRECTOR
OLIN CORPORATION
- DR. RICHARD KOCIBA, PATHOLOGIST
THE DOW CHEMICAL COMPANY
- DR. THEODORE TORKELSON, TOXICOLOGIST
THE DOW CHEMICAL COMPANY

ICI, ENGLAND

- MR. DON ELLIOTT, GENERAL MANAGER - PRODUCTION
SOLVENTS AND MONOMERS GROUP
- DR. DAVID DUFFIELD, MEDICAL DEPARTMENT

MONTEDISON, ITALY

- DR. TIZIANO GARLANDA, PROTEZIONE AMBIENTALE E SICUREZZA
MILANO
- PROF. DOTT EMILIO BARTALINI, HEAD OF MEDICAL SECTION
MILANO

SOLVAY et Cie

- DR. MARCEL-JEAN LEFÈVRE, TOXICOLOGICAL OFFICER
BRUSSELS
- MR. AUGUSTE GOSSELIN, INGÉNIEUR E.E.G.
BRUSSELS

RHONE-PROGIL

- DR. JEAN BERROD, MEDICAL CHIEF
PARIS

UNIVERSITY OF BOLOGNA

- PROF. CESARE MALTONI, ISTITUTO Di ANCOLOGIA

81 WEEK SUMMARY

4 HOURS PER DAY; 5 DAYS PER WEEK FOR 52 WEEKS

EXPOSURE CONCENTRATIONS	ALIVE/STARTED	TUMORS		
		CARCINOMA OF CERUMINAL (ZYMBAL) GLANDS	ENDOTHELIAL* ANGIOSARCOMA OF LIVER	NEPHROBLASTOMA** OF KIDNEY
10000	4/60	13	4	3
6000	14/60	3	6 (50 WEEKS)	1
2500	30/60	2 (26 WEEKS)	1	4
500	31/60	1	1	0
250	27/60	0	1	2

50	40/60	0	0	0
0	42/60	0	0	0
VA 2500	24/96	<u>0</u>	<u>0</u>	<u>0</u>
		19	13	10

() WEEK WHEN FIRST OBSERVED

* METASTASIS TO LUNG

** METASTASIS TO LIVER AND SPLEEN

NO OBSERVED SEX DIFFERENCE IN INCIDENCE

3 OTHER TUMORS OBSERVED BUT NOT CONSIDERED RELATED TO EXPOSURE AT THIS TIME

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CONCLUSIONS FROM EUROPEAN INFORMATION

ANIMAL STUDIES - WELL DONE; LITTLE REASON TO DOUBT

- POSITIVE AT 250 PPM AFTER 82 WEEKS
- NEGATIVE AT 50 PPM AFTER 82 WEEKS
- HAVE ADDED MORE ANIMALS

PRELIMINARY HUMAN - QUESTIONABLE SPUTUM

- QUESTIONABLE EAR (SKIN)
- WILL DO EPIDEMIOLOGY BY COMPANY
USING A COMMON QUESTIONNAIRE

RELATIONS TO U.S. & MCA - EXCELLENT; CONTACTS ESTABLISHED

- WOULD LIKE TO SIT IN WITH MCA
RESEARCH COORDINATORS
- WISH TO MEET BEFORE OCTOBER 1974
- WOULD NOT LIKE CONVERSATIONS BETWEEN
INDUSTRIAL BIO-TEST AND EUROPE OR
MALTONI AND U.S. (UNLESS THEY WERE
PRESENT)
- WOULD LIKE TO HAVE U.S. CO-SPONSOR
ITALIAN WORK

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FUTURE EUROPEAN WORK

1. WILL KEEP SURVIVING ANIMALS FOR THEIR LIFETIME
- OVER 30 WEEKS

2. HAVE STARTED MORE RAT EXPOSURES
250 PPM

(100-125 PPM MAY BE ADDED)
50 PPM
25 PPM

3. EPIDEMIOLOGY BY EACH COMPANY USING A STANDARDIZED FORM
DEVELOPED BY ICI

4. CONSIDERING
 - a) 2 EXPOSURES PER WEEK 1000 PPM OR LESS FOR ONE
YEAR AND HOLD FOR LIFETIME
 - b) 2-3 MONTHS OF 4-HOUR EXPOSURES

5. CONSIDERING
SIMULATING WORKERS' EXPOSURES (DURATION, FREQUENCY,
CONCENTRATION) BY SCALING DOWN TO RATS

6. PROBABLE
COLLECT SPUTUM SAMPLES FOR EVALUATION

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