



MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D.C. 20009 (202) 483-6126 W. A. K.

APR 22 1974

April 17, 1974

To: TECHNICAL TASK GROUP ON VINYL CHLORIDE RESEARCH

Subject: Report on Conference with Industrial BIO-
TEST Laboratories, April 15, 1974

Gentlemen:

As a result of the telephoned information received by MCA from Industrial BIO-TEST personnel last week, a conference at the Northbrook, Illinois offices of IBT was set up at which an oral status report on the chronic inhalation studies with vinyl chloride was presented to MCA, industry and federal agency representatives.

Those in attendance, and their affiliations, are shown below:

Z. G. Bell, Jr.	PPG Industries, Inc.
A. S. Cummin	Borden, Inc.
E. J. Fairchild	NIOSH
J. W. Goode	Industrial BIO-TEST Laboratories
D. E. Gordon	Industrial BIO-TEST Laboratories
W. D. Harris	UNIROYAL, Inc.
M. N. Johnson, M.D.	The B. F. Goodrich Company
Flynt Kennedy	Continental Oil Company
M. L. Keplinger	Industrial BIO-TEST Laboratories
R. J. Kociba	The Dow Chemical Company
H. L. Kusnetz	Shell Oil Company
D. V. Lassiter	OSHA
W. E. Rinehart	Ethyl Corporation
W. M. Smith	Air Products & Chemicals, Inc.
J. F. Stara	U. S. Environmental Protection Agency
T. R. Torkelson	The Dow Chemical Company
R. N. Wheeler	Union Carbide Corporation
B. M. G. Zwicker	B. F. Goodrich Chemical Company
R. F. Blewitt	MCA
A. C. Clark	MCA
K. D. Johnson	MCA

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Dr. Goode first presented the mortality data and gross observations, and then Dr. Gordon described the pathology observed in the mice. The data, as presented, are shown in the attached tables. There are apparent discrepancies between the total mortality data and the detailed listing of recent deaths. These will be resolved. No test-related pathology has yet been noted in any animals other than mice.

Dr. Fairchild, of NIOSH, reported that Dr. David Rall, of HEW, had appointed a committee to coordinate departmental toxicology and related programs, and that under this committee there has been named a subcommittee to develop a "white paper" on guidelines for research to determine "socially acceptable" levels of risk. A report from this subcommittee, which will cover both philosophical and statistical considerations, is expected in the next few weeks.

Dr. Stara expressed the view that the vinyl chloride problem presented industry with a unique opportunity to seek to demonstrate a "no effect level" of a human carcinogen with a sensitive animal model of well-documented validity.

Dr. Lassiter expressed a guarded judgment that the mouse data reported by IBT would not lead OSHA to modify the emergency temporary standard, but that it might well cause OSHA to accelerate the rule-making process for the development of a permanent standard.

Dr. Lassiter also reported briefly on the retrospective morbidity and mortality studies being conducted by NIOSH/CDC at nine or ten locations (six companies) around the country. No epidemiological data were presented.

In an afternoon session of the Research Coordinators, it was agreed that the exposure of the mice in the present project should be terminated at nine months, but that exposures of both rats and hamsters should proceed for the initially-planned twelve months.

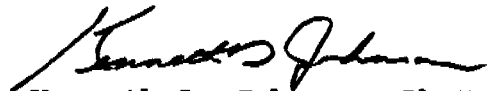
It was further moved, seconded and carried that the chairman appoint a group to begin investigating the cost and availability of facilities of new experiments to be conducted at lower levels of exposure, with larger groups of animals. He was asked specifically to seek to encourage the National Center for Toxicological Research, at Pine

Bluff, Arkansas, to offer to undertake such a program. Details of the test protocol are to be left open until after the Rall committee makes its report available.

The Research Coordinators asked MCA to call a meeting of the Technical Task Group on Vinyl Chloride Research as soon as the report of Tabershaw-Cooper Associates on their epidemiological study reaches them.

A copy of the MCA news release reporting the Industrial BIO-TEST mouse data has been sent to you in this morning's mail.

Sincerely,



Kenneth D. Johnson, Ph.D.
Secretary
Technical Task Group on
Vinyl Chloride Research

KDJ:mb

Tables Attached

cc : Mr. A. W. Barnes
D. P. Duffield, M.D.
Dr. Tiziano Garlanda
Vinyl Chloride Management Contacts

TABLE 3

Mouse Mortality Data

DATE	GROUP							
	<u>Controls</u>		<u>TI</u> ^{1st}		<u>TII</u> ^{2nd}		<u>TIII</u> ^{3rd}	
	<u>F</u>	<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	<u>M</u>	<u>F</u>	<u>M</u>
February 10, 1974	2	8	6	26	2	4	7	8
April 12, 1974	5	11	9	31	13	7	13	18

← Inverse mortality

S. Austral BIO-TEST Laboratories, Inc.

1810 FRONTAGE ROAD

NORTHBROOK, ILLINOIS 60062

Summary of Tumors in Vinyl Chloride Exposed Mice

IBT Number 663-03222-MCA

TABLE II

<u>Group, Animal No., Sex</u>	<u>Histopathologic Findings</u>			<u>Date of Death</u>
	<u>Lung</u>	<u>Liver</u>	<u>Skin</u>	
T-I				
1023 Male	AA (s)*	HS (s)**	***	
1110 Female	AA (s), Metastatic Skin Tumor		EC (para-aural)	3-20-74
1119 Female		HS (s)		3-24-74
1200 Female	Metastatic Skin Tumor		EC & MC+ (Femoral region)	3-30-74
T-II				
1347 Female	Metastatic Skin Tumor		EC (Abdomen)	3-5-74
1309 Female		HS (s)		3-18-74
1889 Male	AA (s)	HS		3-25-74
1382 Female		HS (s)		4-2-74
1350 Female	AA (s)	HS (s)		4-5-74
1299 Female	AA (s)		EC & MC (Inguinal Region)	4-9-74
T-III				
1538 Female	AA (s)	HS (s)		3-6-74
1532 Female	AA (s)		LS⊙	3-7-74
1562 Female	AA (s)	HS (s)		3-8-74
1598 Female	AA (s)	HS (s)		
1405 Male	AA (s)	HS (s)		2-25-74
1494 Male	AA (s)	HS (s)		3-22-74
1574 Female	AA (s)	HS (s)		3-22-74
1531 Female		HS (s)	EC & MC (Femoral region)	3-23-74
1588 Female		HS (s)		3-25-74
1593 Female	AA (s)	HS (s)		3-30-74
1505 Female	AA (s)	HS (s)		4-3-74
1565 Female	AA (s)	HS (s)		4-3-74
1409 Male	AA (s)	HS (s)		4-5-74
1543 Female	AA (s)	HS (s)		4-5-74
1544 Female	AA (s)	HS		4-5-74
1546 Female	AA (s)	HS (s)	MC (Axillary region)	4-5-74
1535 Female	AA (s)	HS (s)		4-7-74
1432 Male	AA (s)			4-8-74
1477 Female	AA (s) Metastatic Skin Tumor?	HS (s)	EC (Para-Aural) MC (Abdomen) EC (Pelvic region)	4-9-74

What about T-IV

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TABLE III*Industrial BIO-TEST Laboratories, Inc.*1810 FRONTAGE ROAD
NORTHBROOK, ILLINOIS 60062Summary of Mortality & Tumor Data Among Vinyl Chloride Mice
IBT Number 663-03222 (MCA)

Group	No. Mortalities with Neoplasms	Location of Tumors			
		Lung	Liver	Skin	Metastasis → Lung
T-I	4 (1 Male, 3 Females)	2(50%)	2(50%)	2(50%)	2
T-II	6 (1 Male, 5 Females)	3(50%)	4(66.7%)	2(33%)	1
T-III	19 (4 Males, 15 Females)	17(89.5%)	17(89.5 %)	3(15.8%)	

Key to Symbols

- * Alveologenic Adenoma of Lung (AA)
- ** Hemangiosarcoma of Liver (HS)
- *** Epidermoid Carcinoma of Skin (EC)
- + Mammary Carcinoma of Skin (MC)
- ⊕ Lymphosarcoma of Thymus
- (s) Multiple tumors of indicated type

Don't test went 6 mo at 400 ppm (?) with no tumors



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W. A. R.

APR 18 1974

FOR RELEASE

For Immediate Release

CONTACT:

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WASHINGTON, D. C., April 16 -- The Manufacturing Chemists Association (MCA) announced today preliminary indications that vinyl chloride exposure has produced angiosarcoma -- a liver cancer -- in mice at several exposure levels.

Industrial Bio-Test Laboratories, Inc., who are conducting the MCA-administered vinyl chloride animal exposure study, informed MCA that their work -- although very preliminary at this point -- tends to confirm the findings of Professor Cesare Maltoni, an Italian scientist who found that vinyl chloride exposure in rats caused cancer.

MCA immediately notified the Occupational Safety and Health Administration, the National Institute for Occupational Safety and Health and the Environmental Protection Agency of the preliminary test results.

In the MCA-administered study, rats, hamsters and mice are being exposed seven hours a day, five days a week, to 2500 parts per million (ppm), 200 ppm and 50 ppm. After seven months of exposure, angiosarcoma has been observed in mice at all levels, but not in rats or hamsters.

(more)

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Professor Maltoni reported at the OSHA hearings on vinyl chloride February 15 that he had observed the liver cancer in rats exposed four hours a day, five days a week, to 250 ppm for up to 12 months. However, he did not find the cancer in testing at the 50 ppm level.

The animal exposure study is continuing. Another MCA-administered study on the chemical, documenting the health experience of present and former employees who have worked with the material, the results of which also will be released, is expected to be completed in the near future. Further vinyl chloride testing is under consideration.

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MCA-3839

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