MANUFACTURING CHEMISTS ASSOCIATION

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APR 24 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

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

Industrial BIO-TEST Laboratories, Inc.
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NORTHBROOK, ILLINOIS 60062

TABLE II

Summary of Tumors in Vinyl Chloride Exposed Mice
IBT Number 663-03222-MCA

Group, Animal No., Sex	Histopathologic Findings			Date of Death
	Lung	Liver	Skin	
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
77 Female	AA (s) Metastatic Skin Tumor?	HS (s)	EC (Para-Aural) MC (Abdomen) EC(Pelvic region)	4-9-74

TABLE III

Industrial **BIO-TEST** *Laboratories, Inc.*
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NORTHBROOK, ILLINOIS 60062

Summary 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 → Lun
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