



CHEMICAL MANUFACTURERS ASSOCIATION

April 13, 1981

TO: Vinyl Chloride Program Panel

Dear Panel Members:

Enclosed is the final revision of the Vinyl Chloride Annual Report to the Special Programs Advisory Group (SPAG). This report is scheduled for presentation to SPAG on April 21, 1981.

Sincerely,

A handwritten signature in cursive script that reads 'Carol R. Stack'.

Carol R. Stack, Ph.D.
Administrator
Vinyl Chloride Program

CRS:cr
Enclosure

Vinyl Chloride - SPAG Review

1.0 Charters

a. Panel Charter

The Program Panel will be concerned with vinyl chloride monomer and polyvinyl chloride resin. The Panel will develop a program that examines the possible health effects of vinyl chloride through toxicological research and human (epidemiological) studies. The testing program will include appropriate monitoring to ensure adherence to sound scientific practice and compliance with prevailing regulations. The Program Panel will review and evaluate the results of all studies.

Consistent with CMA practices and policies, the Program Panel will represent the interests of the Chemical Manufacturers Association (CMA) before Federal agencies in all matters relating to safety and health issues arising out of the production, reaction, release, packaging, storage, handling or use of vinyl chloride.

The Program Panel will also be responsible for certain administrative matters, including the election of officers, deciding the basis for sharing the cost of the program among the participating companies, designation of appropriate task and/or working groups, and liaison with interested non-participating parties.

The Program Panel will function as a special committee under CMA's bylaws, and as such will be subject to the Special Programs Guidelines.

b. Research Coordinators Charter

The Vinyl Chloride Research Coordinators, operating within the Charter of the Vinyl Chloride Program Panel, will provide interpretation of available data on the toxicology of vinyl chloride. The coordinators will advise the Panel on appropriate studies, both in the areas of toxicological research and human studies, required to expand the data base. The Group will provide the necessary protocol design or protocol review and will conduct or make provision for appropriate monitoring and auditing of all research programs.

2.0 Uses

Manufacture of polyvinyl chloride and copolymers; organic synthesis; adhesives for plastics.

3.0 Background and Objectives

a. Introduction

CMA has had a long-standing interest in vinyl chloride monomer. In the early 1960s, the then Manufacturing Chemists Association arranged for a study at the University of Michigan on acroosteolysis (softening of finger tip bones) in VCM/PVC workers. The findings were published by the American Medical Association in the January 1971 issue of "Archives of Environmental Health".

In 1971, at the recommendation of MCA's Occupational Health Committee, U.S. VCM/PVC producers were approached with the proposal that they might wish to support a research program to answer questions on vinyl chloride carcinogenesis raised by Dr. Viola's studies at the Regina Elena Institute for Cancer Research in Italy. A conference of interested member companies was held in November 1971; twenty producers were represented. An ad hoc planning group for vinyl chloride research (precursor to the present Vinyl Chloride Research Coordinators) was formed at the conference to provide review of research proposals and funding requirements. By early 1972, it was established that seventeen companies would support a vinyl chloride research program. The group of sponsoring companies, known then as the "Technical Task Group on Vinyl Chloride" was the first Vinyl Chloride Program Panel. The objective of the Task Group (Panel) was to expand the toxicology data base, thereby lending support to certain health and safety issues surrounding exposure to vinyl chloride monomer in the workplace.

b. Research Programs

i. IBT Study

A research contract was negotiated with Industrial Bio-Test Laboratories in February 1973 to conduct a chronic vinyl chloride inhalation study in rats, mice and hamsters. IBT submitted interim reports to CMA during the course of the two-year study but issued no final report. Subsequent audits by both CMA and third parties found irreparable deficiencies in the study. CMA entered into negotiations for settlement with IBT last year and an agreement was reached. Companies participating in the research program will be refunded on the same pro-rated basis as they contributed to the program.

ii. Dow Studies

In 1974, the Program Panel agreed to fund a teratology study in mice, rats and rabbits to be conducted at Dow Chemical Research Laboratories. Results were published in a March 1977 issue of "Toxicology and Applied Pharmacology". The data indicated that vinyl chloride did

not cause significant embryonal or fetal toxicity and was not teratogenic in any of the species at the concentrations tested (up to 2500 ppm).

A contract was executed with Dow in November 1976 to conduct a pharmacokinetic/metabolism study of vinyl chloride in rats. This research was an extension of similar studies being performed at Dow. A summary of the research was submitted to CMA in May 1977.

iii. University of Louisville Research Program
(Phase VII)

In 1975, the emphasis on research shifted from toxicological investigations to one more directly related to the early diagnosis and clinical management of vinyl chloride injuries resulting from past industrial exposure. Accordingly, the Panel approved support of a grant to the University of Louisville for the development of "Research Techniques and Methods for Detection and Prevention of Carcinogenesis in Industrial Workers". Support of the research continued and two further agreements were signed with the University in 1978 and 1979. Final reports for the first and second years were received; the third is anticipated shortly. Continued funding of this program by the Panel is not likely.

iiii. Epidemiology Studies

A contract was awarded to Tabershaw Cooper Associates, Inc. (TCA) in June 1973 to conduct an epidemiology study of vinyl chloride workers. A final report issued by Equitable Environmental Health Associates (successor to TCA) included 10,173 individuals. Brain tumor incidence was found to be in excess but did not appear to be related to either the duration or intensity of exposure to vinyl chloride. Weak associations between vinyl chloride exposure and malignancies at other sites were noted. EEH suggested that the cohort be studied again five years hence, since observation time would be extended and more deaths available for analysis.

4. Membership

See attachments A, B and C.

5. Research Programs

a. Completed studies (See attachment D).

b. Future studies

The Program Panel has considered a proposal from Environmental Health Associates, Inc. (EHA) to update the 1978 EEH epidemiology study (see above). In this study,

work histories of the 10,173 member cohort will be updated through December 1979. Twenty companies are supporting this program (re: Vinyl Chloride Program Panel - Phase VIII). A budget has been established and a contract agreement with EHA will be drawn up shortly. Of particular interest in this study is whether or not the brain tumor incidence remains in excess. Also, are the associations seen in the earlier study strengthened or weakened?

6. Advocacy

Although there has been limited activity, advocacy has not been emphasized by the Panel. This is partially the result of the extremely close liaison of the members of the Panel with the Vinyl Chloride Health and Safety Committee of the Society of the Plastics Industries, Inc. This arrangement has appeared to work well and at the present time increased advocacy is not anticipated.

Several regulatory issues remain, however:

1. EPA is currently considering lowering the air standard for vinyl chloride. The Environmental Defense Fund is involved in these negotiations.
2. The FDA has delayed action on a request for approval of PVC liquor bottles.
3. OSHA appears interested in PVC dust and in vinyl chloride itself. However, no notice has been published and no time table has been established.

7. Key Issues

A small number of key issues remain, but it should be emphasized that because of the high visibility of vinyl chloride, these issues can change rapidly and dramatically.

1. Whether single exposures to vinyl chloride are capable of causing cancer is an important question. The study sponsored by CPSC, at Edgewood Arsenal, purports to have shown a positive effect from single exposure. Study conditions and the type of response were questionable, but adverse publicity may result when the report is published.
2. Vinyl chloride has been shown to cause other cancers in animals besides angiosarcoma. Human data is inconsistent; with some studies positive and others not.
3. Scientific quality of the proposed epidemiological study is critical. It is essential that the study be acceptable by current scientific standards.

Furthermore, it is essential that the study population include all those eligible from the Tabershaw Cooper study, so as to maintain the cohort. This may require liaison with companies who have lost interest in vinyl chloride as a product, but still have former employees that were in the original cohort.

4. The EPA air standard may be an issue, depending upon the pressure placed on that Agency by the Environmental Defense Fund.
5. Transportation accidents are a possibility. This may present an emotionally charged situation for activists.

8. Liaison

Liaison has been and continues to be an important activity. The relationship to the SPI has been very effective, primarily because of the significant overlap in committee membership.

Liaison with European countries was extremely active and still continues at a lower activity. Several European based companies are represented on the Panel and many Panel members have European affiliates. The four European companies sponsoring Dr. Maltoni's studies have been most helpful. Working primarily through ICI (Dr. David Duffield and later Dr. John Stafford) we have succeeded in transmitting information rapidly between our groups.

9. Controversial Issues

None.

10. Financial Status

(See attachments E, F and G).

11. Critical Dates

June 1981 - start of vinyl chloride epidemiology study update (Environmental Health Associates, Inc.).

Spring 1983 - epidemiology study completed.

May 15, 1981 - final report on University of Louisville study expected.

12. Future Needs

None.

13. Summary.

The Panel has undertaken several animal studies to expand the toxicological data base on vinyl chloride monomer. These phases of the program were completed and it is not anticipated that the Panel will sponsor further research in this area. The University of Louisville Program is winding down and continued funding of this research is unlikely. At the moment, the Panel's attention is focused on human studies and the use of epidemiological research to clarify the relationship between the etiology of certain diseases and vinyl chloride exposure.

The Panel's pursuit of an advocacy program has been limited. Members of the Program Panel have maintained a close liaison with the VC Health and Safety Committee of the Society of the Plastics Industries, Inc. (SPI), the lead organization in the vinyl chloride advocacy area. Several regulatory issues do remain and the Panel will continue to maintain interest through its association with SPI.

ATTACHMENT A

VINYL CHLORIDE PROGRAM PANEL PHASE VIII

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ATTACHMENT B

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ATTACHMENT C

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ATTACHMENT D

VINYL CHLORIDE

<u>Report Title and Contract Number</u>	<u>Contractor</u>	<u>Contract Execution Date</u>	<u>Present Level of Funding</u>	<u>Comments</u>
Epidemiological Study of VC Workers (VC 1.4)	Tahershaw-Cooper. Assoc.	April 25, 75	\$42,500	Released Feb. 23, 78
Chronic Vapor Inhalation Study with Vinyl Chloride (VC 2.1)	Industrial BIO-TEST Labs., Inc.	Feb. 8, 73	188,450	Terminated
VC Pathology Report (VC 2.4)	Experimental Pathology Labs	Feb. 2, 78	3,687	Released May 30, 80
Pathology Report on the Brains from Mice, Hamsters, and Rats Exposed to VC in IBT Study (VC 8.0A)	Experimental Pathology Labs	April 15, 80	16,460	Released May 30, 80
Validation of Strip Charts at IBT (VC 8.0B)	Bob West Assoc.	April 8, 80	4,000	Released May 30, 80
Summary of the Studies Conducted on the Pharmacokinetics/Metabolism of VC in Rats (VC 3.1)	The Dow Chemical Company	Nov. 2, 76	115,000	Released Sept. 2, 77
Effects of Maternally Inhaled Vinyl Chloride on Embryonal & Fetal Development in Mice, Rats and Rabbits (VC 3.2)	The Dow Chemical Company	Aug. 19, 74	224,090	Released Sept. 5, 80
Research Techniques and Methods for Detection and Prevention of Carcinogenesis in Industrial Workers (Yr. 1) (VC 6.4)	University of Louisville	Dec. 12, 76	191,771	Released May 22, 80
Research Techniques and Methods for Detection and Prevention of Carcinogenesis in Industrial Health Workers (Yr. 2) (VC 6.5)	University of Louisville	Feb. 27, 78	252,820	Released May 22, 80
Research Techniques and Methods for Detection and Prevention of Carcinogenesis in Industrial Workers (VC 6.7)	University of Louisville	March 23, 79	287,784	In Progress

CMA 100669

ATTACHMENT E

Vinyl Chloride Financial Statement - Phase VIII

Period Ending 30 March 1981

Date Phase Began: 1 June 1980

<u>Service/Program</u>	<u>Budget Authorized</u>	<u>Amount Committed</u>	<u>Disbursements</u>	<u>Unpaid Balance</u>	<u>Available for Commitment</u>
<u>RESEARCH</u>					
5-Year Epidemiology Update	\$ open	\$ open	\$ - 0 -		
<u>ADMINISTRATION</u>	\$ open	\$ open			
Direct Charges (3/30/81)			\$ 11,817		
Travel			1,326		
Miscellaneous			159		
<u>Subtotal Administration</u>	<u>\$ open</u>	<u>\$ open</u>	<u>\$ 13,302</u>		
TOTAL Phase VIII	\$ open	\$ open	\$ 13,302		

ATTACHMENT F

VINYL CHLORIDE FINANCIAL STATEMENT

Period Ending 30 March 1981

Phase VII - 17 Companies

Amount Pledged: \$325,055
 Amount Received: 333,488^a
 Budget Authorized: 325,055

<u>Service/Program</u>	<u>Budget Authorized</u>	<u>Amount Committed</u>	<u>Disbursements</u>	<u>Unpaid Balance</u>	<u>Available for Commitment</u>
<u>RESEARCH</u>					
VC 7.0 DP/PREV-UL	\$ 287,784	\$ 287,784	\$ 202,925	\$ 84,859	\$ - 0 -
<u>ADMINISTRATION</u>					
Direct Charges (3/30/81)			\$ 22,080		
Travel			0		
Miscellaneous			493		
Subtotal Administration	\$ 37,271	\$ 37,271	\$ 22,573	\$ 14,698	\$ - 0 -
TOTAL Phase VII	\$ 325,055	\$ 325,055	\$ 225,498	\$ 99,557	\$ - 0 -

^aIncludes carryover from Phase VI of \$37,271

ATTACHMENT G

VINYL CHLORIDE FINANCIAL STATEMENT

Period Ending 30 March 1981

Phase II - 31 Companies

Date Phase Began: February 8, 1972
 Amount Pledged: \$ 240,201
 Amount Received: 240,281
 IBT Refund: 110,000^b
 Budget Authorized: 349,949

Service/Program	Budget Authorized	Amount Committed	Disbursements	Unpaid Balance	Available for Commitment
RESEARCH					
VC 2.0-IBT	\$ 149,000	\$ 149,000	\$ 130,375	\$ 18,625	
Restart Agreement	15,000	15,000	10,000	5,000	
Holding 4 Chambers/14 Weeks	7,840	7,840	7,840	- 0 -	
Holding Animals/2 Years	1,610	1,610	1,610	- 0 -	
Overrun	22,000	22,000	22,000	- 0 -	
Consulting-Dr. W. M. Bussey I	2,500	2,500	3,680	(1,180)	
Subtotal Initial IBT Study	\$ 195,950	\$ 195,950	\$ 173,513	\$ 22,437	
Unpaid Balance Redistributed ^a	(22,437)	(22,437)		(22,437)	
Adjusted Subtotal	\$ 173,513	\$ 173,513	\$ 173,513	\$ - 0 -	
VC B.0A-AUB/IBT/EPL-Bussey	\$ 16,460	\$ 16,460	\$ 16,460	\$ - 0 -	
VC B.0B-AUB/IBT-West	4,000	4,000	4,000	- 0 -	
Subtotal Research	\$ 193,973	\$ 193,973	\$ 193,973	\$ - 0 -	
ADMINISTRATION					
Direct Charges (3/30/81)	\$ 45,976	\$ 45,976	\$ 32,930		
Travel			6,157		
Miscellaneous			734		
Subtotal Administration	\$ 45,976	\$ 45,976	\$ 39,821	\$ 6,155	
TOTAL PHASE II	\$ 239,949	\$ 239,949	\$ 233,794	\$ 6,155	

^a \$ 22,437 was redistributed to subsequent audits by Drs. Bussey & West and to Administration

^b To be refunded, based on pro-rate share, to participating companies.

ADDENDUM TO ATTACHMENTS
E, F, & G.

VINYL CHLORIDE BALANCE SHEET
PERIOD ENDING 30 MARCH 1981

Prepared By: []
Reviewed By: []

PHASE #	BEGIN DATE	CLOSE DATE	TOTAL REC'D INCLUDING CARRYOVER	AUTHORIZED BUDGET	ADMINISTRATION	RESEARCH	PHASE COMMITMENTS CONTINGENCY OR OTHER	REFUND	TOTAL PHASE COMMITMENT	TOTAL DISBURSED	UNPAID BALANCE ON COMMITMENTS	CARRYOVER TO PHASE #	AVAILABLE FOR COMMITMENT PHASE #	AMOUNT
I	2/8/72	2/22/79	144537	144395	9901	134495	-0-	93	143089	143089	-0-	IX 1448	-0-	-0-
II	2/8/72	OPEN	240281 + 110000 ⁽¹⁾	239944	45976	193973	-0-	110000	238973	238973	6155	X 12008	-0-	-0-
III	6/5/74	12/19/75	251240	251240	13960	237280	-0-	692	236588	236588		XI 3928	-0-	-0-
IV	8/11/76	12/20/77	196048	201245	4187	191958	-0-		196048	196048		XII 3928	-0-	-0-
V	8/11/76	7/12/77	124318	122808	9600	113208	-0-	290	120398	120398		XIII 3928	-0-	-0-
VI	12/30/77	8/1/79	301349	297418	11258	286160	-0-		269978	269978		XIV 3928	-0-	-0-
VII	1/12/79	OPEN	333488	325055	37271	287784	-0-		825055	725490	99567		-0-	-0-
VIII	6/1/80	OPEN	OPEN	OPEN	13302	-0-	ADMIN		13302	13302			ADMIN	OPEN
TOTAL - ALL PHASES			1701261	1587070	138445	1399533	-0-	111525	1699503	1434898	105712	55455	-0-	-0-
TOTAL W/OUT CARRYOVER			1645806						1645806					
(1) REFUND FROM IBT: TO BE REIMBURSED, BASED ON TWO PERCENT SHARE TO PARTICIPATING ORGANIZATIONS														
PHASE # RESEARCH ORGANIZATION														
I	TABERSHAW/COOPER ASSOCIATES, INC.													
II	EQUITABLE ENVIRONMENTAL HEALTH, INC.													
III	INDUSTRIAL BIO-TEST LABORATORIES, INC. / BOB HEST ASSOCIATES, INC. / EXPERIMENTAL PATHOLOGY LABORATORIES, INC.													
IV	DOW CHEMICAL U.S.A.													
V	UNIVERSITY OF LOUISVILLE (1 st YEAR)													
VI	DOW CHEMICAL U.S.A.													
VII	UNIVERSITY OF LOUISVILLE (2 nd YEAR)													
VIII	UNIVERSITY OF LOUISVILLE													
	5-YEAR EPIDEMIOLOGY UPDATE													