

165,000

MCA

MANUFACTURING CHEMISTS ASSOCIATION

1872 A CENTURY OF SERVICE 1972

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D. C. 20009 (202) 483-8128

GEORGE E. BEST
TECHNICAL DIRECTOR

March 13, 1972

To the Designated Representatives of
Companies Contacted regarding Research on
the Carcinogenic Potential of Vinyl Chloride

RECEIVED

MAR 16 1972

R. N. WHEELER

This copy for R. N. Wheeler, Jr.

Dear Sirs:

Thirty companies have replied to my letter of January 28, 13 having indicated they will contribute to support of research outlined in the draft Description dated January 27, and 17 having declined. No reply has yet been received from the other 14 companies to which the communication was sent.

From the commitment ceilings indicated, the funding so far subscribed falls far short of the \$350,000 called for in the proposal. Accordingly, the Ad Hoc Planning Group on Vinyl Chloride Research will be meeting on March 22 to consider its modification. Some comments received question the inclusion of testing with acetylene-derived vinyl chloride and express a preference for reserving a full-scale epidemiological study for later consideration. All are hereby invited to submit comments or suggestions as guidance for the Planning Group, and those on hand by March 22 will be reviewed at the upcoming meeting.

Attached is a list of the companies that have made a commitment to participate, those that have declined, and those from which no reply has so far been received. Will the representatives of those in the latter group please do their best to respond prior to March 22 so that the Planning Group may have a better perspective of the probable base of support.

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March 13, 1972
Page Two

No further communication on this development will be directed to those whose companies have declined, unless specifically requested.

With appreciation for your cooperation,

Sincerely yours,

George E. Burr

GEB:tp

Attachment

cc: Dr. K. D. Johnson

Information Copy
K. S. Lane, M.D.

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Proposed Research Program
on the
Carcinogenic Potential of Vinyl Chloride

Status as of March 10, 1972

350 320

Support Committed

Support Declined

No Response

Air Products ✓ 1.7500
Allied Chemical
Borden Chemical 1.05
Conoco (Continental Oil) 1.80
Dow ✓ 3.55 4.57
Firestone Plastics 1.01
B. F. Goodrich 3.24 6.37
Olin ✓ 6.0
PPG ✓ 31.0
Standard Oil (N. J.) ?
Stauffer ✓ 10.0
Union Carbide ✓ 15.0
UNIROVAL ✓ 5.0

Commitment Pending

Shell Chemical 124

Ashland Oil ?
C I L
Diamond Shamrock - 1.49
Du Pont ?
General Tire & Rubber - 2.0
Great Lakes Chemical ?
Gulf Oil Canada ?
Gulf Oil Chemicals ?
Phillips Petroleum ?
P. & G. ?
Kohn and Haas ?
Standard Oil (Calif.) ?
Standard Oil (Ind.) ?
Sun Oil ?
Virginia Chemicals ?
Vulcan Materials ?

Solvay American* ?

Ethyl - 2.0
FMC ?
Goodyear Tire & Rubber -
Hooker Chemical - 0
ICI America ?
Kerr-McGee ?
Marbon Div/Borg-Warner ?
Monsanto - 7.0
Pantasote - 4.0
Tenneco Chemicals - 1.25
American Chemicals - 1.05
Atlantic Tubing & Rubber*
Great American Chemical*
Keysor-Century - 2.0

*Non-members of MCA

MCA 3/10/72

57
1.0% 2.00
10
2.8
4.9
10
6.3
6.6
31.6
1.6
1.9
24.5

20
3
✓ 7
4
17
10
13
2
2
68



MANUFACTURING CHEMISTS ASSOCIATION

1825 CONNECTICUT AVENUE, N.W. WASHINGTON, D. C. 20009 (202) 483-8128

GEORGE E. BEST
TECHNICAL DIRECTOR

March 30, 1972

To the Designated Representatives of
Companies indicating Support of Research
on the Carcinogenic Potential of Vinyl Chloride

RECEIVED
APR 03 1972
R. N. WHEELER

This copy for Mr. R. N. Wheeler, Jr.

Information copies to: K. S. Lane, M.D.
A. B. Steele

Dear Sirs:

Since my March 13th letter was sent to you, additional replies have increased to 17 the number of companies committing financial support, plus one indicating probable support but not definite commitment. These companies are as follows:

Air Products & Chemicals	Monsanto
Allied Chemical	Olin
Borden	PPG Industries*
Conoco	Shell*
Dow	Standard Oil (N.J.)*
Ethyl*	Stauffer
Firestone Plastics*	Tenneco*
B. F. Goodrich*	Union Carbide
ICI America*	UNIROYAL

Companies marked with an asterisk have not yet furnished vinyl chloride monomer plus polyvinyl chloride production capacity (publicly disclosed figures) on which to base a pro-ration of project costs.

Meanwhile, as indicated in my letter of the 13th, the Ad Hoc Planning Group met on March 22 as planned, and the revised program they now recommend is detailed on the attached sheet. Except for restricting the testing of acetylene-derived monomer to a single exposure level, this represents only minor changes in the

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March 30, 1972
Page Two

animal studies. It does, however, eliminate the epidemiology study, the idea being to defer it for separate consideration depending on the outcome of the animal studies.

It will be necessary to obtain a revised quotation from Industrial Bio-Test Laboratories, Inc., for the animal studies. The Planning Group estimates laboratory costs at about \$150,000; allowing \$5,000 to defray the cost of the monomer supply and \$10,000 as contingency would round out the total to about \$165,000, over a three-year period.

Several companies urged that a review meeting be called of representatives of all the prospective sponsors, including management as well as technical representatives if desired, before presenting any revised program for formal approval and specific financial commitment. In response to that desire, a meeting for this purpose is scheduled for Thursday, April 20, at the MCA offices beginning at 10 AM, and a reply sheet to indicate attendance is enclosed. It will be helpful, of course, if those attending are able to make tentative commitments on the company's behalf, in order to expedite final resolution of the program.

A letter is also being sent to the other companies previously contacted in this connection, on the chance that some might reconsider participation.

Sincerely yours,

George E. Burr

GEB:gr

Enclosures

cc: Dr. M. D. Johnson
Ad Hoc Planning Group

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Revised Program

proposed by the

Ad Hoc Planning Group for Vinyl Chloride Research

March 22, 1972

Animal Study

Inhalation Exposure Levels: (Tentative, subject to specification
before start of testing)

<u>Set A</u>	<u>or</u>	<u>Set B</u>
Control		Control
10,000 ppm VCM-A		5,000 ppm VCM-A
10,000 ppm VCM-E		5,000 ppm VCM-E
3,000 ppm VCM-E		1,000 ppm VCM-E
1,000 ppm VCM-E		500 ppm VCM-E

Test Animals:

Rats, Wistar strain weanlings, equally divided between sexes
Mice, strain not hypersusceptible to tumors, weanlings,
equally divided between sexes
200 animals of each species per test (2,000 total)

Exposure Schedule:

Rats, 7 hours/day, 5 days/week, for 24 months
Mice, 7 hours/day, 5 days/week, for 12 months

Epidemiology Study - None (Deferred for subsequent consideration)

*

VCM-A = Vinyl chloride monomer, acetylene-derived
VCM-E = Vinyl chloride monomer, ethylene-derived

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UNION CARBIDE CORPORATION

CHEMICALS AND PLASTICS

P. O. BOX 8004, SOUTH CHARLESTON, W. VA. 25303

SOUTH CHARLESTON PLANT

February 9, 1972

Dr. Kenneth D. Johnson
Manufacturing Chemists Association
1825 Connecticut Avenue, N. W.
Washington, D. C. 20009

Re: Revised Industrial Biotech Proposal

Dear Doctor Johnson:

Consideration of the revised Industrial Biotech Proposal would appear to be the first task of the Steering Committee after the program is funded. The letter requesting funding pledges has been sent to resin and monomer producers with returns requested by February 18, 1972. If the program is fully subscribed and approved by MCA in March, then the Steering Committee can make modifications to secure additional data and to stay within the proposed budget. If, however, the industry is provided with an increased budget and increased subscriptions before the first proposal is digested, the least that can happen is further delay.

If I were on the Steering Committee for the program, my reactions to the revisions would be as follows:

1. Both T-III groups should be increased to 200 rats and 200 mice.
2. Histology on all groups may be necessary and should be funded. However, Groups I & II would not be studied unless warranted by results from the control and Group III studies.
3. The control group needs to be only 200 rats and 200 mice; thus all groups have the same population.
4. Commitment of contingency funds early in the program is not desirable.

Very truly yours,

R. N. Wheeler, Jr.
R. N. Wheeler, Jr.

RNWJr/ra

cc: Dr. Kenneth S. Lane, NYO-4

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UNION CARBIDE CORPORATION

CHEMICALS AND PLASTICS

P. O. BOX 8004, SOUTH CHARLESTON, W. VA. 25303

SOUTH CHARLESTON PLANT

February 14, 1972

Mr. George E. Best
Technical Director
Manufacturing Chemists Association
1825 Connecticut Avenue, N. W.
Washington, D. C. 20009

Subject: Proposed Research Program on the
Carcinogenic Potential of
Vinyl Chloride

Dear Mr. Best:

Union Carbide will act favorably on the subject program. However, return of the approved form will be delayed beyond the requested return date of February 18.

Very truly yours,



R. N. Wheeler, Jr.

RNWJr/ra

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Manufacturing Chemists Association

MINUTES OF MEETING

Ad Hoc Planning Group for Vinyl Chloride Research

Washington Hilton Hotel

Washington, D. C.

March 22, 1972

MEMBERS PRESENT:

R. N. Wheeler, Jr., Chairman	Union Carbide Corporation
N. V. Hendricks	Standard Oil Company (N. J.)
K. S. Lane, M.D.	Union Carbide Corporation
M. N. Johnson, M.D.	Monsanto Company
R. L. Maycock	Shell Chemical Company
(for N. G. White)	
W. E. McCormick	B. F. Goodrich Chemical Co.
T. R. Torkelson	The Dow Chemical Company
K. D. Johnson, Secretary	MCA Staff

GUEST PRESENT:

Z. G. Bell	PPG Industries
------------	----------------

MEMBERS ABSENT:

M. V. Anthony	Stauffer Chemical Company
B. M. G. Zwicker	B. F. Goodrich Chemical Co.

1.0 Minutes of the Meeting of December 14, 1971

There being no corrections offered to the subject minutes, they were approved as distributed.

2.0 Report of Current Status of Responses to Requests for Support of Research Program

Copies of the summary reproduced in the Appendix to these minutes were distributed to those in attendance. The total (qualified) commitment of funds is now \$165,000.

3.0 Proposed Program Revisions

Dr. Torkelson reported that, on the basis of informal discussions with Industrial Bio-Test, he believed that the

modification of the initially proposed program, as shown below, could be completed for approximately \$150,000:

Exposure Levels -

Highest Level -

200 rats + 200 mice -- ethylene derived VCM

200 rats + 200 mice -- acetylene derived VCM

Intermediate Level -

200 rats + 200 mice -- ethylene derived VCM only

Lowest Level -

200 rats + 200 mice -- ethylene derived VCM only

Control -

200 rats + 200 mice.

953000

EXTEND MOUSE EXPOSURE TO 18 HRS FROM 12 HRS.

Exposure Schedule -

7 hours per day (or maximum attainable in one shift operation)

5 days per week.

The Planning Group agreed to recommend this program to the industry and to defer a decision on exposure levels until input had been obtained on current results from European on-going studies.

4.0 Proposed Project Budget

The Planning Group recommended a minimum budget as follows:

Industrial Bio-Test Services	\$150,000	153,000
Vinyl Chloride Monomer Supply	5,000	5,000
Contingency Funds	10,000	7,000
	\$165,000	165,000

The Secretary was asked to seek written confirmation from Industrial Bio-Test of the cost estimate given by them to Dr. Torkelson for the performance of the reduced scope test program.

Support for this budget level is potentially available in returns already received. Should added support develop, it was recommended that the Board authorization and member support be so stated that some of the widened support might be used to increase available contingency funds, rather than be limited to reducing individual contributions toward a fixed budget.

5.0 Consultation with Current Research

The Secretary reported that Dr. Knoepfel of Solvay American was now in Europe and would be back in the U. S. the first of next week. Upon his return he would be prepared to discuss the current status of European vinyl chloride monomer research. If initial telephone contacts indicate the usefulness of so doing, Dr. K. S. Lane, Mr. N. V. Hendricks, and Dr. K. D. Johnson were asked to arrange for a conference with Dr. Knoepfel at the earliest opportunity.

The value of having Dr. Dinman, who is now in Switzerland on sabbatical leave, visit the European research institutions was discussed at some length. It was agreed that a decision be deferred on this point, but that the project budget be set up to permit the proposed project to finance such a trip from contingency funds if this should prove advantageous.

No decision was reached on the value of an effort to solicit input to, and support for, the project from Japanese manufacturers of vinyl chloride monomers and/or polyvinyl chloride.

6.0 Communications with the Industry

MCA was asked to address a new mailing to companies that have already offered support for the program. Such a letter should detail:

1. Names of companies that have offered support, however qualified.
2. Production capacity data available to MCA, the source of that data, and the pro rata share of that company, calculated on the base of the total production capacity of the companies listed in (1).
3. The dollar value of the support requested of the company.
4. A description of the proposed new research program protocol.
5. An authorization form that will permit the MCA, with the concurrence of the sponsors advisory group, discretionary authority to expend any added funds available

from subsequent contributions of new sponsors, should such funds be necessary to defray costs in excess of present budget estimates for services within the scope of the proposed study.

6. A schedule for the first meeting of the sponsors advisory group by the middle of April.

7. The proposed membership of the ad hoc task group to serve as project coordinators. These are:

Dr. Z. G. Bell	PPG Industries
Dr. Walter Harris	Uniroyal
W. E. McCormick	B. F. Goodrich Chemical Co.
Dr. G. Rousch <i>W. R. RINEHART</i>	Ethyl Corporation
Dr. T. R. Torkelson	The Dow Chemical Company
R. N. Wheeler, Jr.	Union Carbide Corporation

MCA was asked to send a separate communication to vinyl chloride monomer and/or polyvinyl chloride companies that had not yet volunteered support for the project, describing the new scope and its reduced cost and stressing the importance of this project to the industry. It is to be made clear that their support may be used to broaden the scope and depth of the work, increasing its value to all concerned. Their support is not sought merely to lessen the burden on those who have already committed themselves.

7.0 Future Meetings

The Planning Group adjourned sine die, subject to call of the chair in the event that such a meeting would be required before the function of that Group is assumed by a Board-designated Ad Hoc Task Group to coordinate a funded program.

Respectfully submitted,


K. D. Johnson
Secretary

Minutes Subject to Approval
April 18, 1972
KDJ:mkb

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Proposed Research Program
on the
Carcinogenic Potential of Vinyl Chloride

Status as of March 22, 1972

Support Committed
or Probable

Air Products
Allied Chemical
Borden
Conoco
Dow
Ethyl
Firestone
Goodrich
ICI America
Monsanto
Olin
PPG
Shell
Standard Oil (N. J.)
Stauffer
Union Carbide
UNIROYAL

Support Declined
or Improbable

Ashland
C I L
Diamond Shamrock
Du Pont
FMC
General Tire & Rubber
Goodyear Tire & Rubber
Great Lakes Chemical
Gulf-Canada
Gulf Oil
Phillips Petroleum
P & G
Rohm and Haas
Standard Oil (Calif.)
Standard Oil (Ind.)
Sun Oil
Virginia Chemicals
Vulcan Materials

No Response

Hooker
Kerr-McGee
Marbon
Pantasote
Tenneco

American Chemical*
Atlantic Tubing & Rubber
Great American Chemical
Keysor-Century*

Solvay American*

*Non-members of MCA

MCA 3/22/72

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Proposed Research Program
on the
Carcinogenic Potential of Vinyl Chloride

Comments Received as of March 22, 1972

Borden (By phone)

Alarmed about any possibility of less than equal consideration of acetylene-derived monomer.

Agree to deferring full-scale epidemiologic study for later consideration.

Dow - See attached.

Ethyl - See attached.

Goodrich

"It may be necessary to reduce the scope of the proposed protocol and budget, in order to get adequate funding.... We would also hope that interaction with others in Europe and Japan would be helpful in finalizing a reduction in scope of the MCA project for the U. S. portion of the work."

Shell

Recommends management level review prior to seeking approval of MCA. "It would appear that significant questions relating to the need, objectives, and effect of such a program need answering."

*

Attachments

MCA 3/22/72

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Dow

- a) The analytical data of ethylene and acetylene derived vinyl chloride should be reviewed to determine if the difference is significant enough to warrant animal studies on each material. If not, the total costs of the animal exposure study could be reduced by approximately \$90,000, by testing only the ethylene derived material.
- b) Although we will support the \$20,000 feasibility epidemiological investigation, we will not at this time commit to the main epidemiological program costing \$100,000. However, upon completion of the feasibility investigation and a review of the protocol, we will again consider supporting our share of the main epidemiological program.
- c) Since the projected duration of the initial undertaking (animal studies) is three years, we suggest that our share of the funding be paid: Initially - 33 1/3% of share; one year later - 33 1/3% of share; and end of second year - remainder of share. We suggest paying our share of the epidemiological feasibility investigation upon initiation of the study.

Ethyl

1. We have a continuing interest in participation in an industry supported study on the carcinogenic potential of vinyl chloride.

2. We believe the study should be limited to ethylene derived monomer. Acetylene derived monomer represents a very small amount of the total and even this amount is apparently declining.

3. We do not wish to incur any obligation in support of an epidemiology study at this time — nor do we think the industry should commit itself to such a study until the results of the animal studies justify it. Thus, the epidemiology phase should be completely separate.

4. We believe the Planning Group should consider a review of the final protocols with governmental parties who might be interested. The MCA sponsoring group need not be bound from the input of such a review, but at least the benefits of their thoughts on experimental adequacy would be available.

5. Once a revised protocol is developed by the Planning Group, an opportunity should be provided for all interested (sponsoring) companies to submit questions and comments prior to making a final commitment. A group meeting might serve this purpose.

Hart - 0303

Revised Program

proposed by the

Ad Hoc Planning Group for Vinyl Chloride Research

March 22, 1972

Animal Study

Inhalation Exposure Levels: (Tentative, subject to specification before start of testing)

<u>Set A</u>	<u>or</u>	<u>Set B</u>
Control		Control
10,000 ppm VCM-A		5,000 ppm VCM-A
10,000 ppm VCM-B		5,000 ppm VCM-B
3,000 ppm VCM-B		1,000 ppm VCM-B
1,000 ppm VCM-B		500 ppm VCM-B

Test Animals:

Rats, Wistar strain weanlings, equally divided between sexes
Mice, strain not hypersusceptible to tumors, weanlings,
equally divided between sexes
200 animals of each species per test (2,000 total)

Exposure Schedule:

Rats, 7 hours/day, 5 days/week, for 24 months
Mice, 7 hours/day, 5 days/week, for 12 months

Epidemiology Study - None (Deferred for subsequent consideration)

VCM-A = Vinyl chloride monomer, acetylene-derived
VCM-B = Vinyl chloride monomer, ethylene-derived

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UNION CARBIDE CORPORATION

270 PARK AVENUE, NEW YORK, N. Y. 10017

RECEIVED

APR 03 1972

[R. N. WHEELER

March 30, 1972

Mr. W. E. McCormick
The B. F. Goodrich Co.
500 S. Main Street
Akron, Ohio 44318

Dr. T. R. Torkelson
Toxicology Specialist
Chemical Biology Research
1803 Building
The Dow Chemical Co.
Midland, Michigan 48640

M. N. Johnson, M. D.
Monsanto Co.
800 Lindbergh Blvd.
St. Louis, Missouri 63166

Gentlemen:

At Dr. Torkelson's suggestion I discussed the proposed protocol for the vinyl chloride inhalation study with Mr. Carrol Weil at Mellon Institute. From the brief description I gave him, he had two recommendations: the first was to specify that the strain of rats also be selected for a low incidence of spontaneous tumors, as we have already done for the mice, and the other was to expose the mice for 18 months instead of 12 months. If it is not possible to use an 18 month exposure span for the mice, then he feels they should be exposed 12 months and retained until the end of the 18 month period.

I have also sent a copy of the protocol to Mr. Weil and asked for any other comments after he has read it in detail.

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Mr. W. E. McCormick
Dr. T. R. Torkelson
M. N. Johnson, M. D.

-2-

March 30, 1972

I notice International Research & Development Corporation also recommended extending the mouse exposures to 18 months in their proposal. I had neglected this point when I first read the proposals.

Very truly yours,

H. S. Lane, M. D. /ek.

Assistant Medical Director

K. S. Lane, M. D.

lk

cc: Mr. N. V. Hendricks
Dr. K. D. Johnson
Mr. Carrol Weil
✓ Mr. R. N. Wheeler, Jr.

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