



CHEMICAL MANUFACTURERS ASSOCIATION

November 23, 1981

V. Kirkland

Dear Vinyl Chloride Program Panel Member,

A meeting of the Vinyl Chloride Panel is scheduled for December 16, 1981 at 9:00A.M. in CMA headquarters, Board Conference Room B. This is an important meeting that I urge you to attend.

For the past several months, CMA staff have attempted to negotiate a contract with Environmental Health Associates (EHA) to conduct an update of a vinyl chloride epidemiology study. To date we have been unsuccessful in writing a contract that will satisfy EHA's requirements and, from CMA's viewpoint, protect the needs and financial interest of those companies supporting the study.

This past summer we thought an agreement was reached and CMA executed the contract. EHA responded with an amendment to the contract that we did not find acceptable and the situation is stalemated once again. At this point, CMA needs input from Panel members regarding the extent to which EHA's terms are acceptable, or unacceptable, to the sponsoring companies.

The contract and amendment are enclosed for your review. A memorandum written by Mr. Pat Joyce, CMA legal counsel, on the status of the negotiations is also included.

I look forward to meeting with you on December 16. Would you please indicate your attendance on the attached form and return it to me as soon as possible.

Sincerely yours,

Carol R. Stack

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

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Enclosures

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CMA INTEROFFICE MEMO

TO: Carol Stack
Program Administrator Vinyl Chloride

FROM: Patrick C. Joyce *Pat Joyce*
Staff Attorney

DATE: November 10, 1981

RE: Vinyl Chloride Contract with Environmental Health Associates

Based on our conversation of October 30, 1981, with Dick Davis of EHA and his lawyer, it is my recommendation that we communicate with the chairman of the Vinyl Chloride Panel on the status of our contract negotiations.

In August 1981, we believed there was agreement in principle with EHA on the terms of the contract to perform the update on the vinyl chloride study. On October 15, 1981, EHA proposed new and significant changes in the terms of the contract. The conversation Dr. Stack and I had with EHA on October 30, 1981, was intended to resolve my difficulties with those proposed changes. It was unsuccessful.

EHA insists that EHA be permitted to terminate the epidemiological study at some unknown time in the future if in the exclusive judgment of EHA the study should not be completed.

EHA has also taken the position that it cannot make a realistic estimate of the cost to complete this study. Therefore, EHA objects to our efforts to establish a maximum dollar amount for the completion of the study. EHA will not agree to a maximum cost even if CMA agrees to permit cost overruns beyond an estimated price.

EHA insists that CMA reimburse the contractor for the costs, as soon as they are incurred. Such a reimbursement arrangement is inconsistent with the conventional practice of reserving a significant percentage of the total contract price until the final report is presented and accepted by the program panel.

Obviously, EHA desires to have the type contract whereby CMA would be obligated to pay for all the costs, labor, and expenses incurred by EHA in the performance of this contract. However, under such circumstances there would be no means by which CMA could properly budget for this long term contract or exercise any meaningful control over cost overruns..

Carol Stack
November 10, 1981
Page Two

Accordingly, the standard practice at CMA is to award only fixed price contracts. Much leeway can be provided in fixed price contracts to provide for acceptable cost overruns without providing "blank checks" for the contractors.

It is my understanding that the vinyl chloride program panel is favorably impressed with the qualifications of EHA. It is also my understanding that the vinyl chloride panel found the estimate from EHA with some cost overruns acceptable. Since EHA has now withdrawn its estimate, I believe it advisable that the panel reconsider the value of EHA's services.

CMA can legally award a contract on a cost plus expense basis for EHA; however, the panel should be fully aware that many months from now CMA would have little control over EHA's cost overruns. Therefore, there are good policy reasons for not acceding to EHA's demands.

Other alternatives to a cost plus contract are available if EHA is sincerely interested in performing this study. As you know, EHA has requested a series of contracts so that the payments could be staggered. The difficulty with this approach is that it, like EHA's current proposal, could result in the expenditure of over \$100,000 without any substantive workproduct being completed other than an improved data base. EHA would not be obligated to render any professional opinions.

If I can be of further service to the Panel or Dr. Torkelson, please advise.

AMENDMENT TO AGREEMENT

ENVIRONMENTAL HEALTH ASSOCIATES, INC. (hereinafter "the Contractor") and CHEMICAL MANUFACTURERS ASSOCIATION, INC. (hereinafter "CMA"), hereby amend their Agreement for the Update of the Epidemiological Study of Vinyl Chloride Workers (CMA Reference No. VC 9.0 Epi-EHA) by amending and restating Paragraphs 24 and 25 thereof to read as follows:

24. The Contractor's Estimated Cost for this project is \$205,207 which consists of \$11,495 for Tasks 1 through 5 of Phase I (which have been completed at the initiation of this Agreement); \$63,567 for Tasks 6 through 8 of Phase I; and \$130,145 for Tasks 1 through 6 of Phase II. The aforementioned Estimated Costs are itemized by tasks in Exhibit A and a Ceiling Cost is indicated for each task.

The Scope of Work set forth in Contractor's proposal will be performed within the total Ceiling Cost of \$263,230. However, if the Contractor determines that its projected actual costs for the entire project, calculated at the labor rates set forth in the proposal, will exceed the total Ceiling Costs for the project by more than 30%, CMA agrees to review the Contractor's itemized projected cost overruns. CMA shall not unreasonably and without good cause refuse to compensate the Contractor for that portion of those previously unforeseen expenses which are more than 30% in excess of the ceiling costs.

In the unlikely event of a dispute over cost overruns, the Contractor shall not delay completion of the Scope of Work pending resolution of the negotiations, provided that CMA agrees to reimburse Contractor for any costs incurred in continuing performance of this Agreement pending such resolution.

In the event that (i) the Contractor is unable to complete the Scope of Work because of circumstances beyond its control (including, without limitation, a material lack of available data or a material delay or failure to perform on the part of CMA or a study plant) or (ii) CMA determines for any reason that it will not compensate the Contractor for that portion of its costs which are more than 30% in excess of the Ceiling Costs; then the Contractor may terminate the Agreement in the manner provided in Paragraph 28.

For performance of this Agreement by the Contractor, CMA shall make payments to the Contractor as follows:

- | | | |
|-------------------------|----|--|
| <u>Initial Payment</u> | a) | Upon execution of this Agreement by both parties \$55,000. |
| <u>Interim Payments</u> | b) | Upon receipt of each quarterly report described in Paragraph 16, quarterly payments in the amount stated in Attachment A (Payment Schedule) (adjusted as provided below) until such time as the total amount paid by CMA (including the initial payment) shall reach the lessor of (i) 85% of the Contractor's total costs, or (ii) \$223,000. |
| <u>Final Payment</u> | c) | Upon receipt of the Final Report by CMA as defined in Paragraph 26 accompanied by a detailed accounting of materials and services purchased, and time expended for the total project, a sum in the amount of \$15,207, subject to adjustments as provided herein. |

Interim payments called for by the Payment Schedule shall be adjusted upward by an amount equal to the difference (if any) between (i) 85% of the Contractor's total costs through the quarter to which the interim payment relates and (ii) the total of all payments previously made by CMA and the scheduled interim payment for such quarter.

If the actual costs at the completion of the project are less than the Estimated Costs of \$205,207, the Contractor shall deduct the difference between the actual costs and \$205,207, and credit CMA for that difference in the final invoice.

25. Within 60 days of the completion date defined in the Work, the Contractor will provide to CMA one unbound original and 25 copies of its draft final report. This draft final report will describe all work performed, record essential data and discuss results and conclusions in a manner customary in similar reports.

The Contractor's scientific conclusions and professional judgments arising out of performance of the Work shall be the responsibility of the Contractor and shall not be subject to CMA control. However, CMA shall have the right to review such judgments and conclusions prior to preparation of the final report for the purpose of proposing clarifications, and making format and editing comments, but not for the purpose of substituting CMA's opinion for that of the Contractor.

DATED: October 15, 1981.

ENVIRONMENTAL HEALTH ASSOCIATES, INC.

By Richard L. Davis
Vice President and Treasurer

CHEMICAL MANUFACTURERS ASSOCIATION, INC.

By _____
Vice President and Treasurer

Agreement

between

CHEMICAL MANUFACTURERS ASSOCIATION

and

Environmental Health Associates, Inc.

CMA Reference Number: VC 9.0-Epi-EHA

1. The parties to this Agreement are Environmental Health Associates, Inc. (hereinafter the Contractor) and the Chemical Manufacturers Association, Inc. (hereinafter CMA).
2. CMA will be represented during this Agreement by Carol R. Stack, Ph.D. the Program Administrator. All communications with CMA shall be directed to the Program Administrator. Changes in this Agreement must be authorized in writing by the Program Administrator and any increase in cost must be authorized in writing by CMA's Treasurer.
3. The Contractor will employ Dr. Donald Whorton to personally direct and supervise the performance of this Agreement. If any change in key personnel occurs, the Contractor must promptly notify CMA, in which event the Agreement is subject to renegotiation or termination at CMA's option.
4. The Contractor agrees to perform in the manner described in the Scope of Work "A Proposal for the Update of the Epidemiological Study of Vinyl Chloride Workers" March 1981, which is attached and expressly made part of this Agreement.
5. This Agreement and the attached Scope of Work represent a contract between the parties. There are no promises, terms, conditions, or obligations other than those contained herein; and this Agreement shall supersede all previous communications, representations or agreements, either verbal or written, between the parties hereto.
6. If it is deemed necessary to make changes in the approved Scope of Work after this Agreement is made effective, such changes and reasons for the changes are to be documented by the Contractor in the final report. Oral authorization by CMA for changes in the Scope of Work is permitted but a memorandum of the change must be sent by the Contractor within five working days.

7. The Contractor shall maintain the highest standard of professional conduct and apply its best efforts in the performance of this Agreement in conformity with generally accepted standards for the type of Work specified.
8. The Contractor shall be an independent contractor throughout the term of this Agreement. The Contractor will employ the staff, control the personnel, provide the facilities, and have exclusive control over its employees and the expenditure of funds provided by CMA in this Agreement.
9. The Contractor shall agree to protect, defend, indemnify, and hold CMA harmless from any and all judgements, orders, decrees, awards, costs, expenses, attorney's fees, settlements and claims on account of damage to property or personal injury, including death, which may be sustained by the Contractor, its employees, CMA, CMA's employees or third parties (except for damage or injury caused by the negligence of CMA) where such damage or injury occurs in connection with the performance of this Agreement.
10. The Contractor, by executing this Agreement, shall certify that it has comprehensive liability insurance covering the performance of this Agreement.
11. CMA and the Contractor agree to full disclosure of scientific information developed through this Agreement. However, the Contractor shall not release such information ~~before publication by CMA~~ without prior CMA knowledge and review. This provision is not intended to inhibit private scientific exchange and consultation with the personnel or organizations participating in support of the project.
12. If patentable discoveries should ensue, these shall be declared in the public domain without any retention of proprietary interest by any party to this Agreement.
13. The Contractor shall use its best efforts to comply with all Government regulations in existence or promulgated during the term of the Agreement which are relevant to the performance of this Agreement. If compliance will result in additional unforeseeable expense to the Contractor, the Agreement may be renegotiated or terminated at either party's option.
14. The Contractor shall enter into a reasonable confidential business information agreement with any participant in this Work who requests such an agreement.

15. In the event that the Contractor's facilities become the subject of a Governmental inspection where confidential records or data pertaining to this Agreement are requested, the Contractor shall immediately notify CMA. The Contractor shall inform the Government of the confidential nature of the material. CMA shall have the right to participate in the Contractor's response to the inspection notice. The Contractor shall provide CMA copies of any data provided to the Government relevant to this Agreement or scientific research conducted for CMA.

(a) The Contractor shall notify CMA of any private or Governmental request for information on matters relating to either an ongoing or completed Agreement with CMA.

(b) In the event the Contractor receives any legal instrument requiring production of data, work papers, computer printouts or other material related to corporate data obtained by the Contractor in the course of this Agreement, the Contractor shall promptly notify CMA. In such an event the following provisions apply.

(1) The Contractor shall give CMA the opportunity to quash, modify or otherwise respond to any compulsory process.

(2) The Contractor shall cooperate fully with any effort by CMA to narrow the scope of any such compulsory process, to obtain a protective order limiting use of disclosure of the information sought therein, or in any other way to obtain continued protection of the confidentiality of CMA members' data.

(3) The Contractor shall be entitled to be represented by counsel of its choice. CMA will share reasonable expenses in connection with any joint actions taken by CMA (or by others acting for CMA) with the Contractor in response to any such compulsory process.

16. The Contractor will furnish written quarterly progress reports and invoices to CMA. Progress reports will include procedures and findings during the reporting period and will include a status report giving the timetable for completion of the Work. The timetable shall indicate any delays in the completion of the technical tasks which may affect the timely completion of the Work.

17. In the event of significant adverse findings during the course of the study, the Contractor agrees to notify promptly the designated representative of CMA by

telephone with a follow-up letter within five working days.

18. It shall be the responsibility of CMA and the participating companies to provide data, material, and expertise which are required of them in the Work. Any delay arising out of the failure of CMA or its participating companies to complete their respective tasks shall be the sole responsibility of CMA and its participating companies, provided that the Contractor shall have, in writing and in a timely fashion, identified such responsibilities and the effect of such delays in its periodic progress reports.
19. If the Contractor should be prevented from performing the Work on account of flood, riot, legal prohibition, strikes, Acts of God, epidemics, explosions, acts of war or other catastrophes beyond the control of the Contractor, premature termination of the Agreement may be permitted by CMA upon five working days' notice to either party. The Contractor shall take all necessary steps to remedy any delays resulting from such catastrophic occurrences and notify CMA promptly of such events. Records shall be stored in facilities secure from fire or theft.
20. The Contractor agrees, if requested by CMA, to appear as a witness before or prepare a written statement for a court, regulatory agency or other organization regarding any matters connected with this Agreement. The Contractor's fees for such testimony shall be negotiated in the event of such a request by CMA; the Contractor's fees, however, shall not exceed the fees the Contractor usually charges for professional consultations.
21. The Contractor agrees to use reasonable care in handling any property of CMA entrusted to the Contractor's care or purchased by the contractor with CMA funds. The final report and any supporting documentation originating with the Contractor will be retained by the Contractor. Upon completion of the Work, the Contractor shall store these notebooks, data, photographs, etc., in a safe, secure manner. CMA shall have free access to such material. The Contractor shall not dispose of any materials relating to the study without the prior written approval of CMA. Such materials will be retained in confidence unless otherwise authorized by CMA in writing for a period of 5 years.
22. Personnel designated by CMA will have reasonable access to the Contractor's personnel, facilities, records, samples, and data relevant to the Work. CMA may designate one or more consultants who may observe or audit the conduct of Work. The Contractor shall cooperate fully

with such observations and audits. CMA shall compensate EHA for professional services expended beyond 48 hours if an audit is conducted after submission of the Final Report.

23. The Contractor shall obtain CMA's written approval before subcontracting or assigning any portion of the Work. No such approval shall relieve the Contractor from any of its obligations pursuant to this Agreement. The Contractor agrees to bind each of the approved subcontractors to the provisions of this Agreement.
24. The Contractor's Estimated Cost for this project is \$205,207 which consists of \$11,495 for Task 1 through 5 of Phase I (which have been completed at the initiation of this Agreement); \$63,567 for Tasks 6 through 8 of Phase I; and \$130,145 for Tasks 1 through 6 of Phase II. The aforementioned Estimated Costs are itemized by tasks in Exhibit A and a Ceiling Cost is indicated for each task.

The Scope of Work set forth in Contractor's proposal will be performed within the total Ceiling Cost of \$263,230. However, if the Contractor determines that its projected actual costs for the entire project, calculated at the labor rates set forth in the proposal, will exceed the total Ceiling Costs for the project by more than 30%, CMA agrees to review the Contractor's itemized projected cost overruns. CMA shall not unreasonably and without good cause refuse to compensate the Contractor for that portion of those previously unforeseen expenses which are more than 30% in excess of the ceiling costs.

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For performance of this Agreement by the Contractor, CMA shall make payments to the Contractor as follows:

- | | |
|-------------------------|---|
| <u>Initial Payment</u> | a) Upon execution of this Agreement by both parties \$55,000. |
| <u>Interim Payments</u> | b) Upon receipt of each quarterly report described in paragraph 18, quarterly payments in the amount stated in Attachment A (Payment Schedule) until such time as the total amount paid by CMA shall reach \$190,000 including the initial payment. |

Final Payment

- c) Upon receipt of the Final Report by CMA as defined in paragraph 26 accompanied by a detailed accounting of materials and services purchased, and time expended for the total project, a sum in the amount of \$15,207, subject to adjustments as provided herein.

In the event that costs exceed the Estimated Cost, CMA will make payment of the excess up to the total ceiling costs upon submission and approval of the Final Report. If the actual costs at the completion of the project are less than the Estimated Costs of \$205,207, the Contractor shall deduct the difference between the actual costs and \$205,207, and credit CMA for that difference in the final invoice.

25. Within 60 days of the completion date defined in the Work, the Contractor will provide to CMA one unbound original and 25 copies of its draft final report. This draft final report will describe all work performed, record essential data and discuss results and conclusions to the satisfaction of CMA.

The Contractor's scientific conclusions and professional judgments arising out of performance of the Work shall be the responsibility of the Contractor and shall not be subject to CMA control. However, CMA shall have the right to review such judgments and conclusions prior to their submission for the purpose of clarifications, and format and editing comments, but not for the purpose of substituting CMA's opinion for that of the Contractor.

26. The final report will be due at CMA within four weeks of the Contractor's receipt of CMA comments on the draft final report. The Contractor shall provide CMA with one unbound original and 40 copies of the Final Report.

27. The Contractor shall not, without the prior written approval of CMA, use the name of CMA in connection with any advertising, promotional literature, or other public disclosures. In scientific articles published with CMA's consent, the Contractor shall give credit to CMA and company personnel as appropriate.

28. CMA may terminate the Agreement with 30 days written notice to the Contractor. In such event, the Contractor will present to CMA a detailed accounting of costs to date of termination, including reasonable and necessary expenses incurred in terminating the project in an appropriate manner as well as providing for the proper storage of the raw data for a period of time agreed to at termination. In the course of such termination, the

Contractor shall make every effort to submit to CMA all data and information relevant to the Work accumulated to the date of termination.

29. All correspondence, reports, and manuscripts sent to CMA concerning this Agreement will contain the CMA Reference Number VC 9.0-Epi-EHA and shall be in English.
30. The Agreement becomes effective when Execution is complete.

ACCEPTED FOR:

ACCEPTED FOR:

Chemical Manufacturers Association,
Inc.

Signed _____

Mary C. Herrman

Name Typed _____

Gary C. Herrman
Vice President and Treasurer

Title _____

Date 10/8/81

Date _____

EXHIBIT A

	<u>Estimated Cost</u>	<u>Ceiling Cost</u>
<u>Phase I</u>		
Tasks 1 - 5	\$11,495	\$11,495
Task 6	40,347	52,450
Task 7	10,308	13,400
Task 8	<u>12,912</u>	<u>16,785</u>
Total Phase I	\$75,062	\$94,130
<u>Phase II</u>		
Task 1	\$ 8,406	\$ 10,900
Task 2	31,078	40,400
Task 3	18,985	24,700
Task 4	16,174	21,000
Task 5	13,649	17,700
Task 6	<u>41,853</u>	<u>54,400</u>
Total Phase II	\$130,145	\$169,100
Total Project	\$205,207	\$263,230

<u>PAYMENT SCHEDULE</u>		<u>ESTIMATED COST SCHEDULE</u>
Initial	\$ 55,000	\$11,495
End 1st Qrt.	20,000	33,697
End 2nd Qrt.	20,000	29,870
End 3rd Qrt.	20,000	5,043
End 4th Qrt.	25,000	16,597
End 5th Qrt.	25,000	60,887
End 6th Qrt.	25,000	33,667
Final	<u>15,207</u>	<u>13,951</u>
Total	\$205,207	\$205,207

November 20, 1981

MR. V. L. KIRKLAND

Vance:

RE: CMA EPIDEMIOLOGY UPDATE OF VCM

On a recent visit to California in reference to another Shell problem, I was informed by Dr. Don Whorton of Environmental Health Associates (EHA) that a contract with CMA on the subject project had not been reached. It had been my feeling through previous conversations with you that this agreement had been reached and that the study was probably underway. This was especially important since Dorothy McCraw (Senior Specialist - Epidemiology) has been selected to act as a peer reviewer for the project and was anticipating a schedule of meetings.

It was further revealed to me that Dr. Whorton and EHA felt that CMA had been negligent on the contract formulation. According to Dr. Whorton CMA would call EHA and propose certain items in the contract which EHA would agree to verbally. Later when the contact would arrive, these verba agreements were not found in the body of the contract.

EHA certainly appears willing to sit down across the table and finalize discussions so the contract can be officially signed and to "get the show on the road."

C. E. Ross, D.O. /jlt

C. E. Ross, D.O., F.A.C.Pr.M.
Associate Corporate Medical
Director, Epidemiology

cc - R. E. Joyner, M.D.
Ms. D. A. McCraw

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November 20, 1981

MR. V. L. KIRKLAND

Vance:

RE: CMA EPIDEMIOLOGY UPDATE OF VCM

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C. E. Ross, D.O. 1/8

C. E. Ross, D.O., F.A.C.Pr.M.
Associate Corporate Medical
Director, Epidemiology

cc - R. E. Joyner, M.D.
Ms. D. A. McCraw

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KELLER AND HECKMAN (SPI LAWYER)
06-K-004 JAN-APRIL, 1980