



CHEMICAL MANUFACTURERS ASSOCIATION

*Copy To:
Colin Park
1873*

April 11, 1997

Mr. Neil Hawkins
The Dow Chemical Company
2020 Dow Center
Midland, MI 48674

Dear Neil:

The following items are enclosed for your information and action:

- 1) a copy of the Vinyl Chloride Health Committee commitment form that was sent to Jonathon Ramlow in November 1996;
- 2) a table containing the recent activities of the Vinyl Chloride Health Committee;
- 3) a report on the Vinyl Chloride Health Committee for 1995-1996;
- 4) the November 26 Record of Meeting; and
- 5) the February 18, 1997 Record of Conference Call.

I would appreciate your completing the 1997 commitment form as soon as possible. Please call me at 703/741-5637, if you need additional information.

Sincerely,

Hasmukh Shah

Has Shah, Ph.D.
Manager
Vinyl Chloride Health Committee

R&S 154525



**CHEMICAL MANUFACTURERS ASSOCIATION
Commitment Form**

- ☐ My company commits, Dow Chemical, commits \$21,000 for services as described in the attached proposed budget commitments for 1997. The Vinyl Chloride Panel is conducted under the policies and procedures outlined in the CHEMSTAR Panel Guidelines, briefly noted on the reverse of this form.
- ☐ While appreciating the opportunity, my company declines to participate.

CMA has estimated that 15% of the June 1, 1996 - May 31, 1997 fiscal year "dues and similar income" is allocable to lobbying and political expenditures to which Section 162 (e)(1) of the Internal Revenue Code of 1986, as amended, applies. Consequently, this portion of your commitment is not deductible as an ordinary and necessary business expense for federal income tax purposes. Further, contributions to CMA are not tax deductible as charitable contributions.

Panel Representative

Management Contact (Optional)

Name (Signed)

Name (Signed)

Name (Typed)

Name (Typed)

Title

Title

Company

Company

Address

Address

Address

Address

Telephone

Telephone

Fax

Fax

*Please return signed form to
Has Shah, Ph.D., Manager
Vinyl Chloride Panel
1300 Wilson Blvd.
Arlington, VA 22209
Tel: (703) 741-5637
Fax: (703) 741-6091*

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VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

04/11/97

MEMORANDUM OF UNDERSTANDING (MOU) WITH THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR) The MOU has been signed. A revised study plan was sent to ATSDR because of the delay in the initiation of the study. IMPORTANCE The MOU was developed to meet the research needs of ATSDR and the Environmental Protection Agency in lieu of a TSCA Section 4 testing requirement.	ACTION ITEMS DEADLINES Initial progress reports are due at ATSDR April 25 with subsequent reports due every 6 months thereafter until studies are completed and final reports submitted.
REPRODUCTIVE & DEVELOPMENTAL TOXICITY STUDIES AT HUNTINGDON LIFE SCIENCES (HLS) The contract with Huntingdon has been signed. Analytical work on the test material is complete and the animal exposure has begun. Preliminary results of the analytical work were delivered to CMA for inspection. Jim Knaak reviewed the material and approved it. Jim Knaak, David Penney, and Wendy Sherman will visit Huntingdon in mid-April to monitor progress of studies. IMPORTANCE This research is in lieu of a potential TSCA Section 4 testing requirement.	ACTION ITEMS Continue monitoring progress of study. DEADLINES Progress reports are due to CMA at intervals specified in the agreement.
MOLECULAR CARCINOGENESIS SATELLITE STUDIES AT HLS/ UNIVERSITY OF NORTH CAROLINA-JAMES SWENBERG Ray Schroeder (HLS) and James Swenberg (UNC) revised the protocols for the satellite studies. Fewer animals will be needed to conduct the studies and studies will not be subject to GLP standards. This significantly reduces the cost of the satellite studies. IMPORTANCE This series of studies on the formation and repair of DNA adducts induced by vinyl chloride should provide a better understanding of the mechanisms of vinyl chloride carcinogenesis.	ACTION ITEMS Execute agreement with HLS for in-life portion of satellite study. Prepare a gift letter for \$50K to University of North Carolina for the post-exposure treatment of animals and the adducts analyses. DEADLINES

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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SYNTHESIS OF 13C2 VINYL CHLORIDE / CAMBRIDGE ISOTOPE LABORATORIES The product was delivered to Huntingdon. According to Gary Hoffman (HLS) the analytical specifications of the material are acceptable. IMPORTANCE By utilizing 13C2-vinyl chloride, the formation and repair of vinyl chloride-induced DNA adducts can be studied relative to those adducts formed endogenously. This aspect of the satellite studies could provide important information for risk assessment dealing with low exposures, such as might be associated with accidental releases that reach the fenceline.	ACTION ITEMS DEADLINES
INTERNATIONAL LIFE SCIENCES INSTITUTE (ILSI) The VCHC contributed \$10,000 to ILSI for a project on the use of non-tumor data in cancer risk assessment. Gino Scarano of ILSI provided a progress report on the project. Gino Scarano will notify CMA of the date of the meeting of the sponsors when it has been set. IMPORTANCE The current scientific and regulatory climate is such that the use of endpoints other than tumors to quantitatively estimate cancer risk is on the horizon. This project was initiated to address the question of whether and how genotoxicity and other data could be used as part of a cancer risk assessment.	ACTION ITEMS Monitor ILSI activities on this project. DEADLINES
EPA INTEGRATED RISK INFORMATION SYSTEM PILOT PROJECT EPA has selected vinyl chloride for its IRIS pilot project. According to Mike Gargas, Harvey Clewell is the EPA contractor examining vinyl chloride. IMPORTANCE IRIS is an EPA database which contains consensus scientific positions on potential human health effects from environmental contaminants. The database has expanded	ACTION ITEMS Monitor EPA activities on this project. DEADLINES

CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Proposed Budget Commitments 1997

<u>Company</u>	<u>Capacity (millions of lbs.)</u>	<u>% of Total Capacity</u>	<u>1997 Commitment and Invoice Dates</u>	<u>1997 Proposed Additional Commitment*</u>
Dow Chemical	2,960	21.1	44,000 1/97 44,440 7/97	21,100

* For consultant services and a workshop for EPA/IRIS and ACGIH/TLV activities (external peer review services of Dick Reitz, and Mike Gargas of CHEMRisk and Mike Dourson of Toxicology Excellence for Risk Assessment) and 1997 administrative and legal services.

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and its use has increased over the last decade. It is the primary source of risk assessment and management information for many other agencies at the federal, state and local levels.	
BRAIN CANCER STUDY / UNIV OF LOUISVILLE The Study is proceeding on schedule. IMPORTANCE The 20-year prospective assessment of B.F. Goodrich's Louisville cohort provides a unique opportunity to determine whether there is any association between brain cancer and vinyl chloride exposure.	ACTION ITEMS The Committee and University of Louisville representatives will meet on April 18th to explore alternative methods for analyzing data so the final study is seen as credible by both clinical and traditional epidemiological communities. DEADLINES Study progress reports are due at CMA on dates indicated in the agreement.
VINYL CHLORIDE COHORT STUDY UPDATE / APPLIED EPIDEMIOLOGY INC. Ken Mundt received the remaining death certificate information from ENSR. He asked for assistance from Committee members to track employment and vital status on some of the cohort members. IMPORTANCE	ACTION ITEMS DEADLINES Study progress reports are due at CMA on dates indicated in the study agreement.
ATSDR TOXICOLOGICAL PROFILE FOR VINYL CHLORIDE Committee provided comments on the health and environmental portions of the profile to ATSDR. Data on production volume, facilities and use in the profile, is inaccurate. Caffey Norman is drafting a letter to ATSDR correct the data and suggest an alternative to the presentation of the storage data in Chapter 4 of the Tox Profile. IMPORTANCE	ACTION ITEMS Follow up with ATSDR on Committee comments. DEADLINES

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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ATSDR MEDICAL MANAGEMENT GUIDELINES FOR VINYL CHLORIDE Committee provided comments on the guidelines. IMPORTANCE	ACTION ITEMS Follow-up with Jennifer Hiese (617/674-7358) on when the guidelines will be finalized. DEADLINES
EPA / PETITION TO RAISE THE "REPORTABLE QUANTITY" (RQ) OF VINYL CHLORIDE The Vinyl Institute will take the lead on determining whether a petition to raise the RQ is feasible. The VCHC will provide technical expertise if the VI decides that it is feasible. Caffey Norman will provide background on the criteria for determining the RQ. IMPORTANCE	ACTION ITEMS DEADLINES
EPA / AIR TOXICS PROGRAM EPA identified vinyl chloride and 36 other chemicals as "high priorities" for regulation under its Air Toxics Program. The Agency plans to develop a comprehensive integrated strategy for establishing an "air toxics management model." Caffey Norman provided background on EPA's activities with the Air Toxics Program, and CMA has asked to be a stakeholder. IMPORTANCE	ACTION ITEMS DEADLINES
ASSOCIATION OF PLASTICS MANUFACTURERS IN EUROPE (APME) / REGISTRY OF CASES OF ANGIOSARCOMA APME has developed a protocol for the maintenance of a register of cases of angiosarcoma related to PVC production. IMPORTANCE	ACTION ITEMS CMA will monitor the development of the registry. DEADLINES
AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS (ACGIH) / INITIATIVE TO LOWER THE THRESHOLD LIMIT VALUE (TLV) FOR VINYL CHLORIDE The concern from ACGIH is based on an article by Simonato, et al. in the Scand J. Work	ACTION ITEMS The Committee will examine the Simonato paper and make contact with William Waddell to propose presenting information to ACGIH.

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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& E.H. ACGIH met on October 5, 6, 7, 1996 in Philadelphia. Peter de la Cruz of Keller & Heckman (Vinyl Institute) responded to Dr. William Waddell of the Univ. of Louisville (ACGIH) for Frank Borelli. IMPORTANCE	DEADLINES
CALEPA / DEVELOPMENTAL AND REPRODUCTIVE TOXICANT (DART) IDENTIFICATION COMMITTEE PRIORITY LIST Vinyl chloride is a potential candidate for listing under Proposition 65. The VCHC submitted comments to CalEPA. IMPORTANCE	ACTION ITEMS The Committee will monitor this issue. DEADLINES