

CHEMICAL MANUFACTURERS ASSOCIATION
Vinyl Chloride Health Committee
Record of Meeting

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DATE: Tuesday, November 26, 1996
TIME: 9:00 a.m. to 3:00 p.m.
PLACE: CMA Offices
Arlington, VA

List of Attendees:

Jim Barter (p/t)	PPG Industries, Inc.
Mark Gruenwald	Borden Chemicals & Plastics, Inc.
Jim Knaak	Occidental Chemical Corp.
Dave Penney	CONDEA Vista Chemical Company
David Pun	Formosa Plastics Corp.
Jonathan Ramlow	The Dow Chemical Company
Jay Strange	Georgia Gulf Corporation
Caffey Norman	Patton Boggs, LLP
Cynthia Barrett	CMA
Robert Venezia	CMA

1.0 Approval of November 8, 1996 Record of Conference Call

Changes were made to Item #2.0 in the Record. Robert Venezia will make the changes and send the revised Record to the Committee.

2.0 Update on the Developmental, Reproductive and Mechanistic Research Studies

2.1 Memorandum of Understanding with the Agency for Toxic Substances and Disease Registry (ATSDR)

Dr. Venezia noted that ATSDR had been sent a revised study plan and had been notified on October 25 initiation of the study.

2.2 Developmental and Reproductive Toxicity Study

Jim Knaak gave an update of study activities at Huntingdon. Dr. Knaak was interested in the results of the preliminary analytical work on the test material and exposure chambers. Based upon Dr. Knaak's appraisal of Huntingdon's analytical data, the Committee agreed that verification of the chamber concentrations using a gas chromatograph-infrared comparison method will be performed once a week during the first month of the study and twice a month thereafter. However, Dr. Knaak will continue to monitor the results of the analytical work to determine if adjustments in the proposed verification schedule will be necessary.

The Committee also discussed a replacement for Bill Breslin as a technical consultant assigned to the studies. The Committee agreed that Dr. Knaak would replace Dr. Breslin. Dave Penney agreed to serve as a consultant to the Committee for the studies. The Committee approved funds for Drs. Knaak's and Penney's travel expenses to visit Huntingdon laboratories at critical points during the study.

Dr. Knaak also reported that study animals will be ordered during the week of December 23, 1996 and that the chambering should begin during the second week in January. Dr. Venezia will request a calendar of critical study dates from Ray Schroeder of Huntingdon Life Sciences.

2.3 Satellite Study

Dr. Venezia reported that Jim Swenberg and Mr. Schroeder are collaborating to develop a final protocol for the satellite studies. Dr. Swenberg determined that the number of animals needed for the studies could be reduced without undermining validity and that the studies need not be held strictly to GLP standards. Therefore, the total cost of the studies is significantly lower than had been expected. Mr. Norman noted that ATSDR would need to be notified if this is an add-on to the protocol submitted with the MOU.

2.4 $^{13}\text{C}_2$ Vinyl Chloride Synthesis

Dr. Venezia reported that Huntingdon received the $^{13}\text{C}_2$ -VC.

3.0 Update on the International Life Sciences Institute Genotoxicity Project

The Committee reviewed the status report on the Project provided by Gino Scarano of ILSI. Dr. Venezia explained that the Committee and EPA are among several sponsors of the Project. Dr. Venezia will propose a meeting between ILSI and the sponsors of the project to ask more in-depth questions about the nature of the project and its intended uses.

4.0 Update on EPA's IRIS Pilot Project

The Committee agreed to wait until the external review phase of the IRIS Pilot Project before commenting to EPA on the IRIS entry for vinyl chloride.

5.0 Update on the University of Louisville Brain Cancer Study

Jonathan Ramlow provided background on the study protocol and Carlo Tamburro's progress. Jim Barter identified pagination errors in the final study protocol. Dr. Venezia will correct the errors with Dr. Tamburro. Dr. Venezia also will arrange a conference call among Drs. Tamburro, Barter and Ramlow to discuss progress on the study.

6.0 Update on the Vinyl Chloride Cohort Study with Applied Epidemiology Inc.

Ken Mundt was conferenced into the meeting to provide an update. Dr. Mundt reported that he requires additional data collection assistance from Occidental Chemical Corp. and Formosa Plastics Corp. Dr. Mundt will contact those Committee members directly with details of the information he still needs.

Dr. Mundt reported that he had not yet heard from Carlo Tamburro. Dr. Venezia will send to Ken Mundt the final protocol from Dr. Tamburro's study.

7.0 Discussion of National Institutes of Health Activities with Vinyl Chloride

Dr. Venezia verified that NIH is not working on vinyl chloride issues.

8.0 Update on the Agreement with ENSR

Dr. Venezia reported that this issue has been resolved to the Panel's satisfaction.

9.0 Update on ATSDR Activities

9.1 Status of Comments on the Toxicological Profile for Vinyl Chloride

The Committee will send corrections to the section on manufacture, use and disposal to Dr. Venezia. Dr. Venezia and Mr. Norman will draft a letter to ATSDR recommending that ATSDR incorporate these corrections and use published statistics on the name plate capacities or TRI data.

9.2 Status of Activity on the Minimal Risk Level for Vinyl Chloride

Dr. Knaak reported that HSIA intends to hold a computational workshop on the MRLs in conjunction with ATSDR. Dr. Knaak will report on the workshop at a later Committee meeting.

10.0 Status of a Petition to Raise the EPA Reportable Quantity (RQ) for Vinyl Chloride

Mr. Norman described a 1987 EPA proposal to raise the RQ for vinyl chloride to 10 pounds. Mr. Norman will provide more background on the methodology currently used by EPA in establishing RQs for carcinogens. Dr. Venezia will contact Frank Borelli of the Vinyl Institute to determine its intended course of action on this issue.

11.0 Discussion of OSHA Clarification of Medical Surveillance Provision of Vinyl Chloride Standard

The Committee discussed the possible relevance of this standard to the ATSDR Medical Management Guidelines.

12.0 Discussion of EPA's Air Toxic Program

Mr. Norman described the air toxics strategy paper released by EPA and HSIA's response to the strategy. Mr. Norman will provide the Committee with an update on EPA's activities and additional background on this issue. Mr. Norman will write a letter to EPA requesting that the Committee be included on its list of interested stakeholders.

13.0 Discussion of the Association of Plastics Manufacturers in Europe Registry of Angiosarcoma Cases

Dr. Venezia will determine if this registry is the world registry formerly maintained in England. Dr. Venezia also will provide a list of world manufacturers of vinyl chloride. Committee members decided that no further action will be taken.

14.0 Discussion of the ACGIH Initiative to Lower the Threshold Limit Value for Vinyl Chloride

Potential problems resulting from the Vinyl Institute's request to ACGIH not to review the TLV for vinyl chloride were discussed. Dr. Venezia will prepare a letter to William Waddell of ACGIH offering to present to his Committee information relevant to the TLV for vinyl chloride.

15.0 Discussion of CalEPA's Developmental and Reproductive Identification Committee Priority Listing of Vinyl Chloride

Dr. Venezia will contact a member of CalEPA's Developmental and Reproductive Toxicant Identification Committee to ensure that CalEPA received the Committee's comments.

16.0 Discussion of EPA's Request for Company Sponsorship of Vinyl Chloride in the Organization for Economic Cooperation and Development's Screening Information Datasets Program.

Dr. Barter and Mr. Norman reported on the discussion at a previous HAP Task Force meeting of having Charles Auer of the EPA address the Task Force and the Committee as to the benefits of sponsoring a SIDS dossier for ethylene dichloride or vinyl chloride. Mr. Norman was asked to invite Dr. Auer to address this issue at the January 8 Task Force meeting. Committee members and staff were invited to attend.

Dr. Venezia will obtain the existing SIARS and HEDSETS on vinyl chloride and ethylene dichloride and distribute them to the Committee.

17.0 Discussion of the Draft Study Report of the Cost Impact of Canadian New Substances Notification Regulations

Dr. Venezia will discuss this issue with the CMA International Affairs Department to determine if they have addressed this issue. Mr. Norman will determine if any response was submitted on the methylene chloride chapter.

18.0 Discussion of the 1997 Budget

The budget for 1997 was approved unanimously.

19.0 Schedule Next Conference Call or Meeting

The next conference call will be on Thursday, January 16, 1997 at 2:00 p.m.

Subject to Approval

for *Has Shah*
Robert A. Venezia, Dr.P.H.
Manager
Vinyl Chloride Health Committee