



CHEMICAL MANUFACTURERS ASSOCIATION

Vinyl Chloride Health Committee

FAX

March 31, 1998

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FROM: Wendy K. Sherman CMA (703) 741-5639 (703) 741-6091

MESSAGE

The attached material will be discussed on today's conference call at 2:00 pm. The Access Conference Call Service will contact you for the call. If you have any questions, please call me at 703/741-5639. Thank you.

SENDER: Cynthia Barrett
PHONE: 703/741-5642
PAGE(S) 6 (including cover)



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March 30, 1998

**VINYL CHLORIDE HEALTH COMMITTEE
1998 ACTIVITIES TIME LINE**

PROJECT	DATE	ACTIVITY
<u>Update of Mortality Among Vinyl Chloride Workers</u> / Applied Epidemiology, Inc.	<i>April 15, 1998</i>	Complete overall and cause-specific SMR analyses on updated cohort.
	<i>June 1, 1998</i>	Complete sub-cohort and advanced statistical analyses.
	<i>August 1, 1998</i>	Prepare first complete draft of final study report and outline for journal manuscript, submit to Expert Advisory Panel and CMA for review and comment.
	<i>October 1, 1998</i>	Submit final report and manuscript to CMA for approval.
<u>Vinyl Chloride Combined Inhalation Two-Generation Reproductive and Developmental Toxicity Study in CD Rats/</u> Huntingdon Life Sciences	<i>April 1998</i>	Draft reproductive report due to CMA for review by mid-April.
	<i>April 1998</i>	Status report on reproductive study due to CMA, to forward to ATSDR.
	<i>May 1998</i>	CMA comments on draft reproductive report due to Huntingdon by mid-May.
	<i>June 1998</i>	Final Reproductive Study due to CMA for ATSDR July due date.
<u>Use of Non-Tumor Data in Cancer Risk Assessment/</u> International Life Sciences Institute	<i>June 1998 (tentative)</i>	Draft vinyl chloride case study to CMA for review.
<u>Brain Cancer Study/</u> University of Louisville		[W. Sherman to call for timeline.]

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VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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MEMORANDUM OF UNDERSTANDING (MOU) WITH THE AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY (ATSDR)

The final developmental study was sent to ATSDR in January 1998. ATSDR acknowledged receipt of the report; acceptance of the report is subject to Agency review and the Committee's satisfactory response to ATSDR's comments.

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.

REPRODUCTIVE & DEVELOPMENTAL TOXICITY STUDIES AT HUNTINGDON LIFE SCIENCES (HLS)

A preliminary macroscopic and microscopic pathology report and terminal organ weight data on the reproductive study have been submitted for Committee review.

IMPORTANCE

This research is in lieu of a potential TSCA Section 4 testing requirement.

MOLECULAR CARCINOGENESIS SATELLITE STUDIES AT HLS/ UNIVERSITY OF NORTH CAROLINA-JAMES SWENBERG

Dr. Swenberg made a presentation to the Committee at their February 1998 VCHC meeting in North Carolina. At that time Dr. Swenberg clarified his request for financial support from the Committee.

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

A progress report on the status of the reproductive study, and then a final report are due to ATSDR.

DEADLINES

A progress reports on the reproductive study is due to ATSDR in April 1997. The final reproductive study report is due to ATSDR in July 1998.

ACTION ITEMS

A progress report on the reproductive study is due to CMA by mid-April 1998.

DEADLINES

A progress report on the reproductive study to CMA by mid-April 1998. The draft reproductive report is due to CMA by mid-April; CMA comments due to Huntingdon by mid-May; and final report to CMA by June 1998.

ACTION ITEMS

Respond to '98 and '99 budget request from J. Swenberg.

DEADLINES

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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. Case studies are being performed for three chemicals: benzene, vinyl chloride and butadiene. Case study reports are due to ILSI from the work groups by April 1998. A copy of the draft vinyl chloride report is tentatively scheduled to be forwarded to the Committee for their review by June 1998.

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

Continue to monitor ILSI activities on this project.

DEADLINES

EPA INTEGRATED RISK INFORMATION SYSTEM PILOT PROJECT

EPA has selected vinyl chloride as one of eleven plus chemicals for its IRIS pilot project. The goal of the pilot is to improve the efficiency in gathering and reviewing data and the quality of the information available through IRIS. The revised document has been through the external peer review process, and has been commented on by EPA's Consensus Work Group. After undergoing another revision, the report is expected to be resubmitted to the Consensus Work Group by mid-April. Acceptance of the report by the Consensus Work Group is the last step prior to finalizing the revised IRIS report.

IMPORTANCE

IRIS is an EPA database which contains consensus scientific positions on potential human health effects from environmental contaminants. The database has expanded 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.

ACTION ITEMS

Monitor EPA activities on this project through Amy Mills (202/260-0569), the project manager and William Pepelko (202/564-3309), the chemical manager for the vinyl chloride risk assessment.

DEADLINES

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BRAIN CANCER STUDY / UNIV OF LOUISVILLE At the February VCHC meeting in North Carolina, the Committee accepted the most recent version of the revised protocol submitted by Dr. Carlo Tamburro. 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 W. Sherman will forward the Committee's acceptance of the revised protocol to Dr. Tamburro. W. Sherman will forward a copy of the revised protocol to the protocol peer review consultants, Gary Marsh and Harvey Checkoway. DEADLINES Study progress reports are due at CMA on dates indicated in the agreement.
VINYL CHLORIDE COHORT STUDY UPDATE / APPLIED EPIDEMIOLOGY INC. In March 1998, K. Mundt submitted a revised time line for completion of the VCM cohort update. Delays in receiving requested death certificates from several states necessitated a revised delivery schedule. IMPORTANCE	ACTION ITEMS Continue to monitor this activity. DEADLINES Draft study reports and manuscripts are due at CMA following the revised schedule.
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. A letter was sent in April 1997 to ATSDR correcting the data and suggesting an alternative to the presentation of the storage data in Chapter 4 of the Toxicological Profile. A recent Federal Register Notice announced the release of the latest version of the Vinyl Chloride Toxicology Profile. IMPORTANCE	ACTION ITEMS Review the revised toxicology profile to see if Committee's comments were addressed. DEADLINES
ATSDR MEDICAL MANAGEMENT GUIDELINES FOR VINYL CHLORIDE Committee provided comments on the guidelines. As of March 1998, there was no established timeline for finalizing the Guidelines. IMPORTANCE	ACTION ITEMS Follow-up with Jennifer Hiese (781/674-7358) on when the guidelines will be finalized. DEADLINES

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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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." The Committee submitted comments on EPA's inclusion of vinyl chloride as a "high priority" chemical. 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 DEADLINES
AMERICAN CONFERENCE OF GOVERNMENTAL INDUSTRIAL HYGIENISTS (ACGIH) / INITIATIVE TO LOWER THE THRESHOLD LIMIT VALUE (TLV) FOR VINYL CHLORIDE ACGIH has proposed a change in the 1998 Threshold Limit Value for vinyl chloride. IMPORTANCE	ACTION ITEMS Determine if the Committee will submit comments on ACGIH's proposed change to the vinyl chloride TLV and/or the supporting documentation. 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