

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

07/28/97

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 in April 1997 with subsequent reports due every 6 months thereafter until studies are completed and final reports are 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 exposure portion of the study 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 visited Huntingdon on April 10, 1997 to monitor the progress of the studies. Jim Knaak plans a follow-up visit to Huntindon in August. 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 ATSDR at intervals specified in the revised study plan of April 22, 1997.
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. <i>As of July 1997</i> \$50K to University of North Carolina for the post-exposure treatment of animals and the adducts analyses. <i>Prepare a gift letter for</i> DEADLINES <i>has been paid</i>

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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 <i>Case studies by fall</i> <i>still working toward fall</i>
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. Gino Scarano of ILSI provided a progress report on the project. A meeting of committee members and sponsors is expected sometime this fall. Gino Scarano will notify CMA of the date of the meeting. 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 through Gino Scarano. DEADLINES <i>Since April 21</i> <i>June 4th - con call w/ (eff. Hain) Cuts, his previous work might be used</i> <i>Swenberg, Clewell & T. Serio looked into info</i> <i>processing leaves</i> <i>done w/ critical study - data analysis not to put w/ Clewell in August</i>
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. A peer review of vinyl chloride is scheduled for the week of May 12th. The pilot study is scheduled to conclude this summer, with a decision on the success of the program expected by the fall of 1997. According to Mike Gargas, Harvey Clewell is the EPA contractor examining vinyl chloride.	ACTION ITEMS Monitor EPA activities on this project through Amy Mills (202/260-0569), the project manager and William Pepelko (202/260-5904), the chemical manager for the vinyl chloride risk assessment. DEADLINES <i>believe new info</i> <i>differentiated adduct form in liver cells</i> <i>2 liver cells</i> <i>quantification of adducts</i> <i>hemangio sarcom (non parenchymal liver cells)</i> <i>vs endogenous adduct formation</i>

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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.	
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 met 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. Dr. Carlo Tamburo will revise the protocol to incorporate the comments received at the meeting and will send a revised draft protocol to Has Shah at CMA by May 18, 1997. 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 <i>July 7th progress report</i>	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. <i>sent</i> 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. IMPORTANCE	ACTION ITEMS Follow up with ATSDR on Committee comments. DEADLINES
ATSDR MEDICAL MANAGEMENT GUIDELINES FOR VINYL CHLORIDE Committee provided comments on the guidelines. As of July 1997, there was no established	ACTION ITEMS Follow-up with Jennifer Hiese (617/674-7358) on when the guidelines will be finalized.