

VINYL CHLORIDE HEALTH COMMITTEE ACTIVITIES

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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. Caffey Norman is drafting a letter to ATSDR to inform them of the satellite studies at Huntingdon. 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 Progress reports are due at ATSDR on dates indicated in the revised study plan.
HUNTINGDON LIFE SCIENCES (HLS)/ REPRODUCTIVE & DEVELOPMENTAL TOXICITY STUDY The contract with Huntingdon has been signed. Analytical work on the test material is nearly complete and trialing of the animal exposure chambers has begun. Preliminary results of the analytical work was delivered to CMA for inspection. Jim Knaak reviewed the material and approved it. Jim Knaak will visit Huntingdon in late January to examine the experimental set-up. IMPORTANCE As mentioned, this research is in lieu of a TSCA Section 4 testing requirement.	ACTION ITEMS DEADLINES Test animals will be ordered on December 23, 1996. The In-Life phase of the study will begin shortly afterwards. Progress reports are due at CMA on dates indicated in the revised study plan.
UNIVERSITY OF NORTH CAROLINA-JAMES SWENBERG / MOLECULAR CARCINOGENESIS SATELLITE STUDIES AT HLS Ray Schroeder (HLS) and James Swenberg have revised the protocols for the satellite studies. Fewer animals will be needed to conduct the studies and the protocol 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 vastly improved understanding of the mechanisms of vinyl chloride carcinogenesis.	ACTION ITEMS Ray Schroeder will send a calendar of study milestones to James Swenberg's for his approval. Use Ray Schroeder's final protocol to write the scope of work for the contract. DEADLINES
CAMBRIDGE ISOTOPE LABORATORIES / SYNTHESIS OF ¹³C₂ VINYL CHLORIDE 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	ACTION ITEMS DEADLINES

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can be studied relative to those adducts formed endogenously. This aspects of the satellite studies should impact critically on any risk assessment dealing with low exposures, such as might be associated with accidental releases that reach the fence line.	
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 should be used as part of a cancer risk assessment.	ACTION ITEMS DEADLINES
EPA IRIS PILOT PROJECT Vanessa Vu of EPA stated that the Agency is not interested in hearing from the Committee before the external peer review phase of the IRIS Pilot Project database update. The Committee agreed to wait until that phase to decide the next steps. The Committee also decided not to fund CHEMRisk's proposal. 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 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 Determine a date for the external peer review phase. DEADLINES
UNIV OF LOUISVILLE / BRAIN CANCER STUDY Carlo Tamburro addressed reviewer comments by writing a response and incorporating it into a revised protocol as an addendum. He is collaborating with C. Ralph Buncher of the University of Cincinnati on the next phase and will call Ken Mundt soon to begin working with him as well. IMPORTANCE The 20-year prospective assessment of B.F. Goodrich's Louisville cohort provides a unique opportunity to determine whether an initial observation of a possible association between brain cancer and vinyl chloride or the subsequent observations of no such association exist.	ACTION ITEMS Arrange a conference call with Jonathon Ramlow, Carlo Tamburro and Jim Barter. to discuss progress. DEADLINES Study progress reports are due at CMA on dates indicated in the study protocol.

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APPLIED EPIDEMIOLOGY INC. / VINYL CHLORIDE COHORT STUDY UPDATE 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 protocol.
ENSR AGREEMENT Linn Westberg mailed a \$14,000 check to CMA. This agreement is closed. IMPORTANCE	ACTION ITEMS DEADLINES
ATSDR TOXICOLOGICAL PROFILE FOR VINYL CHLORIDE Data on production volume, facilities and use is inaccurate. Caffey Norman is drafting a letter to ATSDR to request that they use nameplate capacity figures for Chapter 4 of the Tox Profile. IMPORTANCE	ACTION ITEMS DEADLINES
ATSDR MINIMAL RISK LEVEL (MRL) - Jim Knaack will attend and report on a "computational workshop" on the MRLs. IMPORTANCE	ACTION ITEMS DEADLINES
ATSDR MEDICAL MANAGEMENT GUIDELINES FOR VINYL CHLORIDE IMPORTANCE	ACTION ITEMS - Follow-up with Jennifer Hiese on the status of the report of the meeting to discuss comments on the <i>Guidelines</i> (617/674-7358) DEADLINES
EPA / PETITION TO RAISE THE "REPORTABLE QUANTITY" 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
CLARIFICATION OF MEDICAL SURVEILLANCE PROVISION IN OSHA'S VINYL CHLORIDE STANDARD 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. IMPORTANCE	ACTION ITEMS DEADLINES

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ASSOCIATION OF PLASTICS MANUFACTURERS IN EUROPE (APME) / REGISTRY OF CASES OF ANGIOSARCOMA The VCHC will not take action on this issue. IMPORTANCE	ACTION ITEMS 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 & E.H. - ACGIH met on October 5, 6, 7 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. - ACGIH will wait and reexamine the Simonato paper in light of Panel scientific interests and VI concerns. IMPORTANCE	ACTION ITEMS The Committee will examine the Simonato paper and make contact with William Waddell to propose presenting information ACGIH. DEADLINES
CALEPA / DEVELOPMENTAL AND REPRODUCTIVE TOXICANT (DART) IDENTIFICATION COMMITTEE PRIORITY LIST - CalEPA took no action on VC. The Committee will monitor this issue. IMPORTANCE	ACTION ITEMS DEADLINES
EPA REQUEST FOR ORGANIZATION FOR ECONOMIC COOPERATION AND DEVELOPMENT (OECD) SCREENING INFORMATION DATA SETS (SIDS) PROGRAM CANDIDATES - EPA has recommended that companies consider sponsoring vinyl chloride under the OECD SIDS Program. Charles Auer stated that he would like possible candidates in time for the OECD Joint Meeting and the Existing Chemicals Steering Group Meetings scheduled for Nov. 5-8, 1996. - Charlie Auer will talk at HSIA about this issue. Several Committee members will be present and will report at the next meeting or conference call. IMPORTANCE	ACTION ITEMS DEADLINES
CLERICAL - The next conference call is scheduled for January 16 at 2:00 p.m. IMPORTANCE	ACTION ITEMS DEADLINES
1997 BUDGET - Commitment forms have been sent. IMPORTANCE	ACTION ITEMS DEADLINES

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