

**For Discussion  
Action By Subscribing Companies**

**API Executive Committee  
June 19, 2003**

**China Benzene/Shanghai Health Study**

**Issue:** Absent significant slippage in the project timetable; the participating companies should determine and communicate their decision, if they plan not to go forward with the project, before the group convenes at its Annual Meeting in California at the end of August.

**Background:** At its March 18, 2003 meeting, the Executive Committee discussed funding and management of the Shanghai Health Study. The March Executive Committee briefing paper is at Attachment E-1 for reference. At that time, questions were raised about the Benzene Health Research Consortium project's scope and the importance of assuring that the Consortium is adequately managing costs.

**Discussion:**

**Project/Scope.** Member company participation and funding of this study was conditional on developing the highest-quality science with full consideration of ethical issues involved in a study of exposed human subjects. To that end, the Consortium formed the independent Scientific Review Panel (SRP) and Ethics Review Panel (ERP) of distinguished scientific experts from a variety of fields to guide the study (membership lists attached). Improvements were recommended by the panels, reviewed by company scientific experts, and approved by the consortium members' Oversight Committee. These improvements increased cost beyond the original estimate of \$19.8MM to \$22.8MM but did not alter the scope of the project. These changes were incorporated at the outset of the project and included:

- Increased number of control subjects in the epidemiology portion of the study; and
- Consistency of exposure assessment methods between all segments of the study.

Accordingly, the only increases in budget were to enhance the quality of study results.

The SRP and ERP annually review the study with the Principal Investigators, and may propose changes. The consortium members Oversight Committee must, however, review and approve any recommended changes with a budgetary impact. Any changes the Consortium might find that could be recommended to maintain the scientific or ethical integrity of the study would be given strong consideration by the Oversight Committee of the participating companies.

**Consortium Management of Funds.** API, as contract administrator, manages the study on a day-to-day basis as part of API's self-supporting operations; the Consortium Technical Committee oversees financial tracking relative to project milestones. Both study progress and spending have slowed due to unforeseen events, such as restrictions imposed following 9/11, which delayed entry of Chinese scientists into the US for training at the University of Colorado. Most recently, SARS has delayed the enrollment of cases. At this time, however, the study is on the \$22.8 MM budget track and spending to date is consistent with work effort and work progress. The Oversight Committee and API staff continue to closely monitor spending to insure the study continues within its budget. Given the SARS impacts, some slippage in the near term timetable may occur.

**Near Term Activities.** An annual meeting of the project participants, including the Chinese officials involved, is scheduled for the end of August in California. If the companies in the consortium conclude they are to end the project, they may wish to communicate such before the August conference convenes.

The current level of funding would be sufficient to do the epidemiological (epi) study portion of the overall project, but the Chinese may well lose interest, since they are very committed to the other two projects. The epi study alone would not yield the desired benefits of the overall project for the companies.

An update will be provided on efforts to gain additional participation/funding from companies that will benefit from the study results. Recently, feedback has been received that both Dow and Sunoco have declined to participate.

**Recommendation:** If the participating companies elect to continue the project, direct API and the participants to communicate at every opportunity the importance and necessity of minimizing costs, while continuing to search for additional funding. If the study is not to be fully funded, API will await word from the participating companies as to their preferences for action. If intent is to terminate, it may be best to communicate such to the Chinese officials and the members of the SRP and ERP prior to the California annual meeting of the project.