

For Action

API Executive Committee

Issue: The Benzene Health Research Consortium is seeking guidance on options to address a shortfall in funding the industry-sponsored Shanghai Health Study (SHS). A five-year project designed to investigate the potential health effects of benzene, the study has secured \$16.5 million of the \$22.8 million required to carry it to fruition. Although preparations for the research have begun, this funding gap - - if not closed - - will either compromise the study or lead to its demise.

Background: Continued concern about the potential health effects of benzene is reflected by two recent studies that suggest a link between benzene exposure and certain cancers not previously associated with the chemical. The Consortium is thus sponsoring a five-year study in Shanghai, China, which could significantly decrease the uncertainty surrounding the issue. A joint investigation primarily managed by the University of Colorado and Fudan University, the SHS includes protocols developed with the assistance of a 12-member international scientific review panel and Chinese, European and American bio-ethics specialists. It also has strong support and active participation from Chinese universities, hospitals and regulatory agencies. The USEPA has agreed to actively participate in the project.

The quality of Shanghai's occupational benzene exposure records offers an unprecedented opportunity, and perhaps the last of its kind, to study the relationship between benzene exposure and the risk of certain blood diseases. The SHS will enhance industry's product stewardship, while providing the scientific, regulatory and business communities with better information on benzene.

Project Status: Three inter-related studies are underway: (1) a Case-Control Epidemiology study; (2) a Disease Progression Study; and (3) a Molecular Epidemiology Study. Laboratory construction, technical training and exposure assessments are nearing completion and individual case acceptance will begin in spring, 2003. Legal and public affairs expertise has been retained to facilitate Consortium activities.

Funding Status: Current funding for the program is projected to run out during the first quarter of 2004. Five companies (BP, ChevronTexaco, ConocoPhillips, ExxonMobil and Shell Chemical Company) have contributed \$16.5 million. The initial cost estimate for the study was \$19.8 million; the study was initiated with a funding shortfall requiring recruitment of additional funding sponsors to fully fund the study. Subsequent protocol enhancements recommended by independent scientific and ethics review panels led to the final budget of \$22.8 million as necessary to complete the five-year study.

The Consortium has made presentations to IPIECA, CONCAWE, ARPEL, ACC, and NPRA; held focused discussions with Marathon Ashland, Dow Chemical Company, and Sunoco, and approached Citgo, Dupont, BASF, Lyondell-Equistar, TotalFinaElf, Statoil, AGIP-ENI, ARPEL and Petronas. To date, none of these entities has agreed to join the Consortium and contribute funds.

Implications of funding shortfall: The Consortium Technical Committee has studied the impacts of a funding shortfall and determined that, at best, only one of the three studies could be completed with current funds. The reality, however, is that an unclosed gap would result in loss of Chinese collaboration, in which case none of the studies could be completed. In addition to the lost scientific and product stewardship opportunities, this situation could have public relations and legal ramifications.

At this point, recruitment of additional members has been unsuccessful and Consortium members are not optimistic that any will commit. Given that the study would benefit the entire industry, the Consortium is requesting that API leadership consider whether API can provide support to eliminate the current shortfall. Possible options include API (1) providing direct funding for the study; (2) underwrite the remaining shortfall while recruitment efforts continue with the expectation of being repaid in full or in part by the Consortium; or (3) provide no additional funding for the study.

For Action: The Executive Committee is requested to advise the Consortium what assistance API can provide to eliminate the shortfall and allow the SHS to be completed.