

1240B

Proposed China Consortium Committee Structure
For Presentation at
August 31, 2000 Consortium Development Meeting

The following is intended as a draft description of the major duties, roles and makeup of committees that could function as the administrative, scientific, and ethics oversight components of the China Benzene Research Consortium. This draft is intended for discussion only, and does not represent the final, or recommended committee structure or responsibilities.

Please see the attached flow chart for a schematic of the reporting relationships of the committees described below.

COMMITTEES

Business Oversight Committee

Membership: One member from each sponsor company. The Chairman of the Technical Oversight Committee is *ex officio* member of this committee, non-voting unless also designated as full member of this committee.

Input: The Business Oversight Committee receives input from the Technical Oversight Committee regarding the technical progress of the research and recommendations for research related expenditures, and from the Ethics Review Board regarding recommendations for bioethics related issues.

Responsibilities: The Business Oversight Committee shall be the ultimate administrative authority for the consortium and shall make all final decisions regarding budget, reporting and interaction with the Chinese authorities. The Business Oversight Committee shall have final approval over the membership of the Ethics Review Board and over the membership of the Scientific Review Board subsequent to the recommendation of the Technical Oversight Committee.

The Business Oversight Committee shall report Annually to the member companies on the financial status of the consortium. All expenditures of the consortium shall be approved or delegated by the Business Oversight Committee.

The Business Oversight Committee shall be responsible for TSCA 8(e) reporting on behalf of the consortium. This role in no way limits the ability of individual members of the consortium from filing individual 8(e) submissions if they deem it appropriate.

Technical Oversight Committee

Membership: The membership of the Technical Oversight Committee shall include one member from each contributing member of the consortium. (Outside entities such as governmental agencies or NGOs could have a place on this committee subject to approval of the Business Oversight Committee.)

Input: The Technical Oversight Committee shall receive semiannual reports from the principal investigators regarding the progress of research. This committee shall also receive reports from any Quality Assurance activities undertaken during the course of the research. This committee would receive recommendations from both the Ethics Review Board and the Scientific Review Board regarding the conduct of research and, in the case of the latter board, the acceptability of proposed manuscripts and abstracts.

Responsibilities: The Technical Oversight Committee shall act as the technical consultant to the Business Oversight Committee of the consortium. This committee would review all manuscripts for publication and abstracts of presentations stemming from the consortium research and advise the Business Oversight Committee on the validity and interpretation of the results received from the principal investigators. This committee shall be responsible for recommending protocol alterations, abstracts of presentations and manuscripts for publication to the Scientific Review Board for approval.

Scientific Review Board:

Membership: Internationally recognized experts in scientific/medical fields that are recommended by the Technical Oversight Committee and approved by the Business Oversight Committee. There are also potential seats on the Committee for other stakeholders as approved by the Business Oversight Committee. The chair of the Ethics Review Board shall also be a member *ex officio* of the Scientific Review Board.

Input: The Scientific Review Board shall receive progress reports from the principal investigators on at least a semi-annual basis. The Scientific Review Board shall meet annually to receive a report from the Principal investigators on the progress of the research relative to the proposed protocols. Otherwise, the Scientific Review Board shall meet in person or by conference call as deemed necessary to carry out their duties. The Scientific Review Board shall consult with the Ethics Review Board regarding the ethical conduct of research under this program.

Responsibilities: It shall be the responsibility of the Scientific Review Board to approve the initial research protocol and all significant protocol changes thereafter. The Scientific Review Board based upon the decision of the chair of that group shall determine what protocol changes are considered significant. These approvals shall be transmitted via the Technical Oversight Committee to the Business Oversight Committee for final acceptance. The Scientific Review Board shall approve all manuscripts for publications and all abstracts for presentation by whatever medium that include data generated as part of this research project.

Ethics Review Board:

Membership: Determined by the Business Oversight Committee. This Board should include at least one recognized bioethicist from the United States, The European Union and the Peoples Republic of China. This board should also include one or more representatives of the community under study. The Chair of the Scientific Review Board shall be an *ex officio* member of the Ethics Review Board.

Input: The Ethics Oversight Board will receive input from the Technical Oversight Committee and the principal investigators regarding proposed research and from the NGO Liaison Committee regarding actions to address bioethics issues raised by this research.

Responsibilities: The Ethics Review Board shall be responsible for recommending all actions by the consortium that are intended to ensure that all research performed by the Consortium shall conform to ethical standards as identified by the Ethics Review Board and approved by the Business oversight Committee. The Ethics Committee shall maintain close communication with the Scientific Oversight Committee to ensure that the implementation of all research protocols is consistent with ethical standards as defined above. To this end the Ethics Review Board shall meet Annually to review the progress of research and to assure itself that the research is being conducted in a manner consistent with the approved ethical guidelines.

NGO Liaison Committee:

Membership: At a minimum the membership of the Non-Governmental Liaison Committee (NGO Liaison Committee) shall consist of a member of the Business and Technical Oversight Committees, a member of the Ethics Review Board and a member of each outside agency with which the Consortium is affiliated.

Responsibilities: The NGO Liaison Committee shall exist for the purpose of addressing bioethical issues raised by the research program of the Consortium that can met by collaboration with entities other than governmental regulatory bodies or industry associations. The NGO Liaison Committee shall recommend programs and a budget to the Business Oversight Committee to address these issues.

Input: The NGO Liaison Committee shall consult with the Ethics Review Board regarding programs to address bioethics issues.