

Detailed Explanation of 1994-1995 Proposed Activities

1) Epidemiology Study Update

Contractor Cost:

CMA conducted an epidemiology study of vinyl chloride workers from 1942-1972. The study was updated to cover the period of 1942-1982. The Vinyl Chloride Health Committee proposed to further update the study to 1992. The Committee requested proposals from potential contractors. After reviewing the proposals received, the Committee has narrowed its selection to Applied Epidemiology, Inc. (estimated cost - \$350,000) and Applied Health Sciences, Inc. (estimated cost - \$275,000). The Vinyl Chloride Health Committee is leaning toward Applied Epidemiology, Inc. based on an overall evaluation of the proposals.

ENSR Data Transfer Cost:

All raw data for the previous vinyl chloride epidemiology study are with ENSR Corporation. These data are extensive (100 banker's boxes) and will have to be reviewed, screened, and copied by ENSR prior to the release of the information to the selected contractor.

Dow Chemical's Monitoring Cost:

This cost will compensate Dow Chemical for its efforts in designing the study; evaluating the proposals; resolving technical issues with contractors; conducting site-visits; monitoring progress of the study; reviewing interim and draft reports; and, liaising with CMA and the Vinyl Chloride Health Committee.

2) Outside Counsel for TSCA Section 4 Proposed Rule

On September 30, 1994, EPA published a "Notice of Opportunity to Initiate Negotiations for TSCA Section 4 Enforceable Consent Agreements; Solicitation of Testing Proposals for ATSDR Chemicals" (Fed. Reg. 59, 49934-49938, 1994). For vinyl chloride, the notice proposes testing for reproductive, developmental, and neurotoxic effects by the inhalation route. The estimated cost of these testing is \$850,000 (developmental = \$150,000; reproductive = \$450,000; and neurotoxicity = \$250,000). In its Federal Register notice, EPA did not provide a rationale for the testing requirements and has exceeded the ATSDR requirements. The Committee recommends retaining a counsel to effectively negotiate a testing program with EPA that requires only those studies necessary to meet the ATSDR data needs.

Please note that no provision is made in the 1994-1995 proposed budget for any testing cost because of uncertainty as to what studies ultimately will be included in the Enforceable Consent Agreement or the TSCA Section 4 final rule. If an Enforceable Consent Agreement is executed with EPA, an additional testing budget may have to be developed in 1995.

5) Administration:

The following services are integral parts of the CMA administration:

a) General Services

- 1) meeting preparation, attendance, and action item follow-ups
- 2) coordination of Panel activities with outside counsel
- 3) financial management services including monthly financial statements
- 4) legal services (anti-trust protection; review of Records of Meetings; review of contractual agreements; guidance in cases of contractual non-compliance and/or earlier termination; guidance in protecting against restriction of trade practices; facilitating resolution of Panel/Task Force issues
- 5) communication services (press/news releases; responses to media/public inquiries; spokesperson for industry)
- 6) mail room services (copying; first class postage; local messengers)
- 7) management support in resolving Panel issues, if necessary

b) Advocacy Management

- 1) maintain awareness of pertinent regulations relating to the Panel's activities
- 2) communicate with government agencies on scientific and regulatory matters on behalf of the Panel
- 3) coordinate information flow to and from agencies, companies, other trade associations, and academic institutions
- 4) coordinate the development of advocacy positions with the CMA Office of General Counsel and other appropriate CMA standing committees and outside consultants

c) Research Management

- 1) assist in developing testing programs
- 2) develop budgets, assure commitments, and process invoices to participating companies

- 3) work with Panel to prepare protocols, identify labs, and send Request for Bids
- 4) assist Panel in selecting contract laboratory for testing based on bids received or prior experience
- 5) conduct site visits, if necessary
- 6) prepare and negotiate contracts
- 7) manage activities of contractor and outside auditor/monitor for the research program
- 8) legal oversight by CMA
- 9) manage finances of contracts, set up budget areas, verify and pay invoices
- 10) facilitate information exchange between contract laboratories, monitor/auditors, and Panel members and government agencies
- 11) facilitate Panel consensus on technical issues and communicate the consensus position with contractors
- 12) prepare periodic status reports for submission to Panel and regulatory agencies
- 13) provide regulatory compliance (TSCA, FIFRA) services at Panel's request
- 14) arrange for and participate in Panel meetings and in meetings with contractors and agencies
- 15) assist in developing the next phase of activities