Vinyl Chloride Health Committee

Proposed 1994-1995 Budget

Budget	Activity (Explanation Attached)
$ 400,000	Epidemiology Study Update Contractor Cost - $ 350,000 ENSR Data Transfer Cost - $20,000 Dow Chemical's Monitoring Cost - $30,000
30,000	Outside Counsel for TSCA Section 4 Prop. Rule The estimated cost of the EPA recommended testing program is $850,000.
60,000	University of North Carolina Research Program Synthesis of ^{13}C-vinyl chloride - $10,000 Determination of Half-Life of Etheno-Adducts in Animals & Determination of P-450 in Human Tissues at Diff. Ages - $50,000
10,000	Vinyl Chloride Risk Assessment Consultant for Modification of the Heast Table (R. Reitz) Consultant to Demonstrate a Biological Threshold for Vinyl Chloride Induced Liver Angiosarcoma and Absence of Cause-Effect Relationship Between Vinyl Chloride and Brain Cancers (C. Tamburo) International Workshop to be Sponsored by the Vinyl Chloride Panel to Assess Available Scientific Information and Review Work in Progress or Planned to Assess Vinyl Chloride Risk
100,000	Administration Direct Time Oct.1994 - Dec.1995 - $90,000 (Based on Estimated Level of Effort of Four Days/Month) Travel and Miscellaneous - $10,000
25,000	Contingency
$ 625,000	TOTAL

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, liaisoning 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 t 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.

3) Univ rsity of North Carolina Research Program:

This research program is designed to evaluate toxicity of vinyl chloride exposure at high concentrations over a short period of time. The information developed through this program may help in establishing levels of vinyl chloride to trigger catastrophic release evacuation plans.

The program also would enable industry to develop early diagnostic tools to determine significant vinyl chloride exposures and their relevance to health risk assessment.

4) Vinyl Chloride Risk Assessment:

Modification of Heast Table

The current EPA Heast Table for carcinogenicity of vinyl chloride mentions that the consideration of metabolism pharmacokinetics will result in increased risk. According to the table, one unpublished physiologically-based pharmacokinetic model may predict a 100-fold increased risk. In the Committee's communication with EPA, we now understand that this is a speculation on the part of EPA. Documents like the Heast Table often become the basis for regulatory activities at federal, state and local levels. It is critical, therefore, to correct the Heast Table to prevent potential regulations based on misinformation. The Committee plans to work with EPA to correct the Heast Table.

Biological Threshold for Vinyl Chloride Induced Liver Angiosarcoma and Lack of Correlation Between Vinyl Chloride Exposure and Brain Cancer

Dr. Carlo Tamburo of the University of Louisville has proposed a threshold for vinyl chloride induced human liver angiosarcoma. Dr. Tamburo also suspects, based on information available to him, that there is no association between vinyl chloride exposure and incidence of brain tumors. The Committee plans to pursue these hypotheses with Dr. Tamburo. If these hypotheses are substantiated by valid and credible scientific data, the benefits to the industry will be significant.

International Workshop on Vinyl Chloride

The Committee considers an international workshop on vinyl chloride an integral part of vinyl chloride risk assessment. The workshop participants may include: regulatory agency personnel (EPA, OSHA, ATSDR); academia; other scientific research organizations; and, vinyl industry personnel.

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 t 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