RECORD OF MEETING
OF THE
SPECIAL PROGRAMS ADVISORY COMMITTEE

DATE: October 20, 1981
TIME: 8:30 AM
PLACE: Terrace Conference Room

ATTENDANCE

MEMBERS PRESENT	
Calvin Benning	Essex Chemical Corporation
H. Donald Feeney	Borg-Warner Chemicals, Inc.
George Levinskas	Monsanto Company
Robert Neal	Chemical Industry Institute of Toxicology
S. Noble Robinson	Mallinckrodt, Inc.
Curtis Smith	Shell Chemical Company
Jerry M. Smith	Rohm & Haas Company
Gary A. Sunshine	ICI Americas, Inc.
Gary Ter Haar	Ethyl Corporation
Carl Umland	Exxon Chemical Americas
*Sturzenegger, Otto - Chairman	
Hasmukh Shah	CMA Staff

MEMBERS ABSENT	
William C. Becker	BFGoodrich
Conrad Kent	Stauffer Chemical Company
Joan E. Young	Petrolite Corporation

PRESENT BY INVITATION	
Charles Brush	Koppers
John P. Murphy	Stauffer Chemical Company
John F. Quast	Dow Chemical USA
Terry G. Pullin	Ethyl Corporation

Staff Present	
Patrick C. Joyce	CMA Staff
Joseph T. Seawell	CMA Staff
Carol R. Stack	CMA Staff
Elizabeth J. Moran	CMA Staff
Robert J. Fensterheim	CMA Staff
Debra J. Boltas	CMA Staff

1.0 Executive Session

Members of the Special Programs Advisory Committee (SPAC) met with members of the Special Programs staff for one hour to review the programs which would be presented and any other controversial issues which arose since the last meeting. Issues raised during this meeting are reported on elsewhere in these minutes.

*add

2.0 The August 28, 1981, Record of Meeting was approved with the following addition:

Page 5, Section 8.0, listing of purposes of SPAC, "to make sure panel positions don't conflict with CMA positions and policies."

3.0 Allyl Chloride Program.

Dr. Quast presented the SPAC report for the Allyl Chloride Program Panel. SPAC was concerned that several studies, not yet completed, dated back to 1977. This type of lateness leaves panel sponsored research open to questions of credibility. Dr. Quast noted that the second 90 day inhalation study was completed and results were being reviewed. There are several inconsistencies with the prior study and these are being examined. The report should be ready for distribution to the Panel by the end of November.

SPAC discussed the need to communicate the findings of the Panel's research to the decision makers within the various regulatory agencies in order to have an impact on regulatory activity. For example, allyl chloride is on a list of 37 compounds being considered for regulation as a hazardous air pollutant. SPAC recommended that a report be prepared which lays the foundation for why there is no need for addditional testing nor a change in the allyl chloride TLV. SPAC recommended that the Panel consider adding an advocacy amendment to their charter. SPAC members felt that the allyl chloride industry may further benefit by having people with regulatory and business experience on the Panel. They They suggested that CMA staff and CMA's Environmental Management Committee's Health Effects Task Group assist the Panel in preparing their report to the Agencies. The Panel should also alert their management contacts that this activity would be ongoing in order to get them involved in the review process.

The results of the teratology and pharmacokinetics studies will be presented at the Society of Toxicology meeting in March.

4.0 Butylated Hydroxytoluene

Charles Brush of Koppers presented the report for Dr. Lederer and the Panel. SPAC asked if there was any purpose in trying to convince the French government not to remove BHT from use as a direct food additive. Mr. Brush replied that Dr. Lederer has spoken to members of the French ministry and explained the meaning of the proposed interim regulation. He felt that the European Economic Community (EEC) and other European governments correctly understood the situation. The use of BHT as a direct additive in France is too small to merit further effort.

5.0 Ethylene Dichloride

John Murphy presented the Ethylene Dichloride SPAC report. Mr. Murphy reviewed the history of the EDC Panel which was formed in 1974. The Panel has undertaken several research projects.

By mid-1980, the Panel had completed all its studies and decided to disband. That decision was reconsidered when the Panel learned that EPA was formulating a proposed Section 8(a) rule. Since that time, the Panel has become concerned about possible other regulatory action under Section 6 of TSCA and Sec. 112 of the Clean Air Act.

Several Panel members were individually contacted by a contractor who is collecting information and preparing a report on EDC for EPA. The report will be used in evaluating necessary regulatory action to control EDC as a hazardous air pollutant.

SPAC recommended that the EDC Panel interact directly with CRAC's Reporting Task Group. Mr. Murphy will follow up on this with Dean Leib, Reporting Task Group Chairman.

SPAC suggested that the Panel consider using either CMA or outside counsel in its advocacy and advised getting more business people on the Panel.

6.0 Zinc Dialkyl Dithiophosphates (ZDDP)

Mr. Terry Pullin presented the ZDDP program to SPAC. In his opening remarks, Mr. Pullin spoke about the series of events that led to the formation of the Panel in October, 1980. At that time there was concern over study results that indicated testicular effects in immature rabbits following dermal application of ZDDPs.

Phase I of the Panel's research program expanded the protocol to include another species (rat) and both mature and immature animals were put on test. Some animals in each test group were allowed a 30-day recovery, testicular zinc levels were measured, and histopathological examination of the testes was performed. ZDDP was applied to the backs of the animals over a 21 day period.

A draft final report of this study is presently under review by the Toxicology Research Task Group (TRTG). The study confirmed earlier results and indicated that mature and immature rabbits react similarly to ZDDP application. Signs of recovery were noted in some animals after the 30-day recovery period. No testicular effects were seen in the rat.

The TRTG made plans for continuing the research effort as outlined in Phase II and III of the written presentation.

Company managements, however, have asked for a reassessment of the program before any further research is done. In particular, managements are questioning use of the rabbit as an animal model for testicular effects and the value of continued testing in this species. The research program was the major topic of discussion at a management meeting held on September 24, 1981. The TRTG responded to management's concerns and is reworking their research proposal.

Mr. Pullin reviewed with SPAC some of the problem areas associated with the Panel's activities. The first problem concerned selection of a representative ZDDP for testing. There is considerable variety and propriety surrounding each manufacturer's product. This problem was solved when Exxon offered to synthesize the di-2-ethylhexyl compound. However, each company's willingness to accept the results of the study as being applicable to their own product is still a question that the companies are necessarily faced with.

Another problem concerns the fact that one of the participating companies has considerably more data on these compounds in house than other members of the Panel. To date, this company has been willing to share pertinent data with the Panel but it is not certain if company management will allow this practice to continue.

Company managements have expressed a strong desire for the ZDDP program to continue following resolution of the present problem areas. Expansion of the Panel's activities to include other classes of oil additives also received management approval.

7.0 Update of Ethylene Dibromide

Mr. Seawell updated SPAC on the activities of the Ethylene Dibromide Panel following the Panel's decision to disband.

Upon acceptance of the Panel's recommendations, as transmitted by Dr. TerHaar during SPAC's August 25, 1981 meeting, the Panel was terminated. At this same time, there was under consideration by the California Occupational Safety and Health Standards Board an emergency regulation for EDB. This new regulation would lower the Permissible Exposure Limit (PEL) significantly below the present federal limit of 20 ppm.

On September 24, 1981, the CAL/OSHA Advisory Committee conducted an open review of the Draft Permanent Standard for EDB, the Emergency Temporary Standard on EDB having gone into effect on September 23, 1981.

During the Advisory Committee Meeting on September 24, 1981, CAL/OSHA stated its intent of sticking to its ceiling of 130 ppb (15 minute ceiling) and preposed a 15 ppb so-called

"action level." Those work areas consistently falling below the action level, such as in retail grocery storage areas, would be exempt from posting signs and the requirement to meet monitoring and training procedures. Currently, CAL/OSHA plans to include in its Permanent Standard the working "action level" concept.

Since the Emergency Temporary Standard for EDB was put into effect on September 23, 1981 by CAL/OSHA, suppliers of treated fruit have ceased to ship to California. The papaya industry in Hawaii has been particularly hard hit and is described as "being in a shambles."

Spinoffs from the publicity given the CAL/OSHA situation could seriously affect the entire cross section of EDB markets.

Federal OSHA officials informed CMA that they consider that the work environment in industry is well controlled and is "stable." Federal OSHA intends to issue fruit handling protocols, but only after its 100 industrial hygienists have gathered exposure data in Florida, Texas, and California. Federal OSHA is not satisfied with the 20 ppm standard and expects to lower it markedly.

On October 19, 1981, the Ethylene Dibromide Program Panel held its initial meeting under a new charter that will be structured around an advocacy position. The main objective of the October 19 meeting was the development of plans for the preparation of a position paper to be prepared for presentation during the November 12, 1981, CAL/OSHA hearing on its Draft Permanent Standard.

8.0 General Business

During the course of program presentations, SPAC made several suggestions which can be applied to all programs. Issues and suggestions include:

8.1 Panel Reports to SPAC. Panel representative should give only the essence of the reports verbally. They should concentrate on things that are bothering the Panel and things the Panel is thinking about.

8.2 Contractor/Participant Role. There is the possibility for confusion of priorities when a Panel member is also the contractor for a Panel-sponsored study. CMA staff should advise panels to exercise caution in such situations.

8.3 Late Contractor Reports. CMA should review its standard agreement and provide greater penalties for late reports.

8.4 Business Decisions. Several panels are running into difficulty when business decisions arise which company managements feel a need to get involved in. SPAC encourages program panels to put more people on their panels who have business orientations.

9.0 Special Programs Guidelines

Dr. Shah will begin revision of the Special Program Guidelines. He will attempt to simplify them and to make them less bureaucratic-appearing to prospective program sponsors. The draft of these revisions will be sent to SPAC for their review and comments before the next meeting.

10.0 Future meetings

10.1 Now that all programs have been through their initial review SPAC members will decide on the format for next year's meetings. Dr. Shah will set the schedule for these meetings.

10.2 The next SPAC meeting will be on January 19, 1982 in the Terrace Conference Room.

D. J. Boltas for
H. C. Shah

Subject to approval