CHEMICAL MANUFACTURERS ASSOCIATION

Record of Meeting

of the

Special Programs Advisory Committee

PLACE: CMA Terrace Conference Room
DATE: June 9, 1981
TIME: 8:00 A.M.

ATTENDANCE

MEMBERS PRESENT

Calvin J. Benning	Essex Chemical Corporation
H. Donald Feeney	Borg-Warner Chemical Corporation
Conrad Kent	Stauffer Chemical Company
George J. Levinskas	Monsanto Company
Curtis W. Smith	Shell Chemical Company
Jerry M. Smith	Rohm and Haas Company
Gary Sunshine	ICI Americas
Gary Ter Haar	Ethyl Corporation
Carl Umland	Exxon Chemical Americas
Joan E. Young	Petrolite-Tretolite Division
John J. Zimmerman	ARCO Chemical Company
Geraldine V. Cox	CMA Staff
Hasmukh C. Shah	CMA Staff

MEMBERS ABSENT

William C. Becker	BF Goodrich Company
Myrl E. Miller	IMC Chemical Group
Thomas W. Mooney	Proctor & Gamble Company
Robert Neal	CIIT
Noble Robinson	Mallinckrodt, Inc.
Otto Sturzenegger	CIAB-GEIGY Corporation

PRESENT BY INVITATION

James R. Keith	Dow Chemical Company
James D. Spainhour	Borg-Warner Chemicals, Inc
Debra J. Boltas	CMA Staff
Robert Fensterheim	CMA Staff
Patrick C. Joyce	CMA Staff
Joseph T. Seawell	CMA Staff
Carol R. Stack	CMA Staff

1.0 Dr. Curtis Smith called the meeting to order at 8:10 A.M. on behalf of Dr. Otto Sturzenegger who could not

attend. The April 21, 1981 Record of Meeting was approved with the following changes:

1.1 Page 2, Section 2.0, Paragraph 3, Line 8 should read, "meeting with Dr. Hernandez, the new deputy administrator of;"

1.2 Page 7, Section 8.0, Last Line: change "and" to "any".

2.0 Acrylonitrile Program

Dr. Spainhour reviewed information presented under Tab 1 of the SPAC Workbook.

The Panel's research program was completed during 1980. Currently, the acrylonitrile manufacturers are pursuing advocacy activities under SOCMA. Future research will be contingent on results evolving from studies being sponsored privately by Monsanto.

SPAC members asked how the $134,000 cost overrun by Dow is going to be resolved. Thorough discussion of this question led to SPAC's RECOMMENDATION that the matter be placed in the hands of CMA's Legal Department. If there are no legal liabilities for CMA, the matter will be turned over to Dr. Spainhour for a most orderly resolution. SPAC asked for a final report on the matter when it is resolved.

3.0 Chlorobenzenes Program

Mr. Jim Keith, Chairman of the Chlorobenzenes Program Panel, reviewed activities of the group for SPAC.

The Program Panel was formed in 1974 to serve as a forum for the assessment of research needs and to develop a program to expand the toxicological data base on chlorobenzenes. All of the major U.S. chlorobenzenes producers are members of the Panel.

In order to effectively carry out its objectives, the Panel formed a Toxicology Research Task Group (TRTG) to design and review protocols, monitor the research, and provide technical assistance to the Panel. The Panel's activities include: 1) deciding the basis of cost-sharing; 2) deciding the order of test sequence; and 3) liaison with other interested parties.

Initially, the Panel conducted a world-wide literature search that subsequently was used to identify gaps in the data base and assess the need for future research. The Panel is presently co-sponsoring a series of teratology studies on monochlorobenzene, orthodichloro-

benzene and paradichlorobenzene at the Dow Chemical Research Laboratories.

In October 1977, the Interagency Testing Committee placed monochlorobenzene(MCB) and the three dichlorobenezene isomers on a candidate list for mandatory testing under TSCA, Section 4(a). EPA's interest in chlorobenzenes later broadened to include all six commercial and five non-commercial isomers. EPA concluded that the chlorobenzenes presented a significant health risk on the basis that: 1) benzene and hexachlorobenzene are carcinogens; therefore, all chlorinated benzenes are suspect; and 2) according to the NIOSH National Occupational Hazard Survey (NOHS) almost four million people are potentially exposed.

In response to the EPA initiatives, the chlorobenzenes producers formed the Chlorobenzenes Producers Association (CPA) under SOCMA. Company membership in the CPA is identical to the CMA Program Panel with the exception of Olin and Rhone-Poulenc, who are not members of the CMA group. The CPA functions under a broad-based advocacy charter.

CPA contracted with an independent consultant to assess the number of people potentially exposed to chlorobenzenes. The study, which was submitted to EPA, estimated 55,000 people exposed vs. NIOSH's four million.

EPA issued a formal test rule proposal in July 1980. Six commercial chlorobenzenes were selected for a proposed test program that would cost the industry approximately $20-40 million to complete. In October, the CPA submitted written comments in which it was stated that EPA did not recognize the economic impact of their proposal and had grossly overestimated exposure. Furthermore, the CPA felt that chlorobenzenes did not present an unreasonable health risk.

EPA's calendar calls for a final Section 4(a) Test Rule in October 1981, however, a dialogue has been opened with the Agency that may lead to an agreement for a voluntary industry testing program in lieu of a formal test rule. If an agreement is reached, it is expected that the testing program would be carried out under the CMA umbrella.

Mr. Keith distributed a chart that showed the commercial isomers and the status of testing in each area. EPA also felt testing should include behavioral teratogenicity and neurotoxicity for which protocols have not yet been defined. Mutagenicity and metabolism were deferred from active consideration at present. As

a result of the earlier comment and meetings, EPA has agreed to drop the "category" appproach to testing of chlorobenzenes and not require testing for the five non-commercial isomers, tetrachlorobenzene, and pentachlorobenzene. Mr. Keith added that it was important to include company business managers in talks with EPA as well as toxicologists.

In conclusion, Mr. Keith expressed appreciation to Dr. Stack and Dr. Zeb Bell, former Chairman of the Program Panel, for their efforts in the development of the CMA program and coordination of activities with the CPA.

4.0 Rubber Additives Program

Mr. Paul Graham, Chairman of the Program Panel, was unable to attend the meeting due to a sudden illness in his family. Dr. Stack presented the program to SPAC for Mr. Graham.

The Program Panel has been in operation for a little over a year. In late 1979, CMA received a request from the Monsanto Company to establish a program that would expand the toxicological data base on rubber additives.

There are approximately 60-70 rubber chemicals that are used as accelerators, retarders, and antioxidants in the curing of green rubber. The Work Task Group of Rubber Manufacturers Auxiliaries (WTR) has assigned numbers and acronyms to members of the class for easy reference.

The WTR is a European-based international association of rubber manufacturers. The Association holds meetings biannually and several members of the Program Panel serve on the WTR Toxicology Subcommittee. This committee is responsible for developing research programs that are sponsored by the Association. The Program Panel has kept a close watch on WTR developments in order to identify research needs that are specific for U.S. products and are not of interest to the international group. The WTR's last meeting was in May of this year and it was reported that nitrosamines in the workplace are still viewed as a problem in Europe, particularly in West Germany.

Workplace concentrations of nitrosamines in the U.S. rubber industry have been of concern over the past several years. In 1977, NIOSH began a survey of nitrosamines in the air of large rubber manufacturing facilities. NIOSH analyzed for nitrosomorpholine, nitrosodiphenylamine, nitrosopyrrolidine and nitrosodimethylamine and found concentrations ranging from approximately 5 ug/m^3 up to 250 ug/m^3 (nitrosomorpholine). The large rubber manufacturers

have since increased ventilation and modified the chemical process so as to reduce airborne nitrosamines to levels below 1 ug/m^3 (1 ppb).

NIOSH appears satisfied with the performance of the larger companies but is still concerned about smaller operations. There are no indications that NIOSH will recommend a workplace standard for exposure to nitrosamines, as there is a lack of data to properly evaluate what levels constitute a hazard in the workplace.

The nitrosamine problem has also been of interest to the Rubber Manufacturers Association (RMA), a Washington-based association of rubber processors. The Program Panel also maintains a liaison with this group through duplication in company membership. The RMA recently completed a simulated study of the rubber manufacturing process in which ambient concentrations of nitrosamines were related to the composition of the rubber additive(s). Results of the study will be published in the AIHA journal.

The Program Panel's research program consists of a series of in vitro mutagenicity tests on a sulfenamide accelerator (MBS). The commercial product is known to be contaminated with nitrosomorpholine; levels vary according to the manufacturer. Previous in vitro testing on Goodrich's product produced some positive results and there was a question if the mutagenic potential was related to the presence of nitrosomorpholine.

To test this hypothesis, the Panel supplied two commercial samples and a recrystallized, pure MBS to the contract laboratory for testing. A sample of pure nitrosomorpholine was also provided. A draft final report on the study is due this month. The results will be evaluated by the Toxicology Research Task Group (TRTG) and it is possible that the TRTG will recommend further testing on MBS.

The Program Panel has also maintained an interest in the NCI/NTP Carcinogenesis Bioassay Program. NCI is about to begin a 2 year oncogenicity study of mercaptobenzothiazole (MBT) and Xiuram (a zinc carbamate) is coming off test shortly. The Program Panel will meet with NCI on June 16 to discuss these programs and any future plans for testing of rubber chemicals. The meeting should also aid the Panel in deciding on future co-sponsored research under CMA.

Dr. Stack responded to questions from SPAC members concerning the financial statement, pursuit of advocacy and the Panel's possible interest in epidemiology studies. The Panel has not considered sponsoring

epidemiology studies; however, several such studies have been conducted on rubber workers. Workers in the rubber industry are exposed to a variety of chemicals and it would be difficult to define a cohort exposed only to rubber additives.

Although the Panel's activities have been rather low key with respect to advocacy, the membership has been mindful of federal regulations and there has been some information exchange with Federal agencies. The Panel's charter focuses on research but does contain a provision for advocacy.

5.0 Vinylidene Chloride Program

Dr. Z. G. Bell's oral report incorporated by reference the more detailed report on VDC presented under Tab 4 of the SPAC Workbook.

Dr. Bell summarized the Panel's organization and that of the four task groups, the charters for both the Panel and task groups, the Panel's sponsors, the chemical and physical properties of this chemical, the uses of VDC, the generic classes of its reaction products, and background information on the origin of the Panel. He also summarized all of the toxicological investigations conducted to date, and the major points in his annual report to SPAC.

The Panel's foresight in planning its overall research program is noteworthy. The research sponsored by the Panel permits scientific interpretation to assess all health data and to place new data in proper perspective. Pharmacokinetics and metabolism research show a species sensitivity of mouse> rat> man. Further, the total data bank indicates oncogenicity is not observed without recurrent tissue damage and without a cytotoxic dose, a tumorigenic response in man would be an improbable event.

Four task groups under the panel are: Analytical, Medical, Toxicology, and Work Practices.

Two instances illustrate the high caliber work performed by these task groups (work that contributes to improved overall worker safety, optimum placement of workers, and improved worker protection from exposure to VDC monomer) are as follows:

- The Medical Task Group, after analyzing and interpreting data evolving from toxicologic and pharmacodynamic studies, advised on appropriate medical surveillance of employees exposed to VDC. This task group has been especially concerned with

criteria and test parameters to be used during initial consideration of placement of a worker in an area where exposure to VDC is possible.

- The Work Practices Task Group completed thorough analyses of working areas and operations involving VDC. It developed comprehensive guidelines on procedures to protect employees from VDC monomer. This task group is primarily concerned with work practices procedures applicable to the manufacture, storage, and handling of VDC monomer and its reaction and polymerization.

Two important key issues with which the Panel will be concerned are:

- the preparation of a response to a Health Risk Assessment Criteria Document on VDC under preparation by the EPA Criteria and Health Assessment Group, and,

- follow and take appropriate action on future proposals to label VDC as a cancer hazard.

At the November 15, 1979 meeting of the Program Panel, the members present voted to have the original project proposal expanded to include an advocacy activity. An amendment to the proposal is presently under review. Action and proposed action by the California Occupational Safety and Health Administration's Air Resources Board (CAL/OSHA/ARB) emphasizes the need for a new Panel charter that makes ample provision for advocacy. CAL/OSHA/ARB introduced a list of hazardous chemicals. Chlorinated solvents are on this list. CAL/OSHA/ARB is working on the new "Bubble Rule", however, it does not propose to permit "bubbling" of chemicals on the hazardous chemicals list.

SPAC voted affirmatively on a motion to include advocacy in a revised charter for the VDC Program Panel.

6.0 New Business

6.1 Dr. Cox explained that SPAG was given a status of a Special Committee at the last Executive Committee and so from now on it will be referred to as Special Programs Advisory Committee (SPAC).

6.2 SPAC will make its annual report to the Executive Committee in October. Dr. Shah will coordinate with Dr. Sturzenegger on this.

6.3 Bill Buckley, Director of State Legislative and Regulatory Affairs for CMA was introduced to the

Panel and he commented on the California bubble concept.

6.4 Debbie Boltas was asked to compile a list of the total amount invoiced and total amount paid for all CMA special programs, noting those invoices which have been outstanding for more than 60 days.

6.5 A revised SPAC roster was distributed.

Hasmukh C. Shah, Ph.D.
Director
Biomedical and Environmental
Special Programs

Subject to approval