SPAC-19

CHEMICAL MANUFACTURERS ASSOCIATION

Record of Meeting

of the

Special Program Advisory Committee (SPAC)

Place: Terrace Conference Room

Date: October 21, 1982
Time: 8:45 A.M.

Attendance

Members Present

Calvin Benning	Essex Chemical Corporation
John J. Clary	Celanese Corporation
John P. McCarthy	Koppers Company, Inc.
Barbara Price	Phillips Petroleum Company
R. J. Reichert	E. I. du Pont de Nemours and Company
Jerry M. Smith	Rohm and Haas Company
Gary Ter Haar	Ethyl Corporation
C. J. Terhaar	Eastman Kodak Company

Members Absent

Edward W. Callahan	Allied Corporation
Warren S. Ferguson	Allied Corporation
George J. Hanks, Jr.	Union Carbide Corporation
Gary A. Sunshine	ICI Americas, Inc.

Invited Guests

Norman W. Gaines	Union Carbide Corporation
James P. Mieure	Monsanto Company

CMA Staff

Debra Boltas
*Geraldine V. Cox
Robert J. Fensterheim
Elizabeth J. Moran
Joseph T. Seawell
Jacqueline A. Simmons
Langley A. Spurlock
Carol R. Stack
John C. Van Horn
*David F. Zoll

* part time

1.0 Approval of the September 14, 1982 Record of Meeting

The September 14, 1982, Record of Meeting was approved with the following changes: Section 5.0 on Ethylene Oxide, add:

The voluntary testing study plan submitted to EPA was discussed.

SPAC recommended that the protocol under development for the heritable translocation studies include multiple dose levels.

2.0 SPAC Reorganization

The revision of the September 14, 1982, Record of Meeting led to discussion of the course of action when SPAC makes an observation, comment, or recommendation. The Committee agreed that when SPAC makes a suggestion to a panel, it should be brought to the attention of the panel through the Program Administrator. SPAC will, in most cases, ask the Program Administrator to update them at a later meeting.

SPAC recommended that there be at least one member from the Chemical Regulations Advisory Committee, the Occupational Safety and Health Committee, the Environmental Management Committee, and the Regulatory Impact Special Committee. These four members plus a person with panel experience and a person with legal background would form the core of SPAC. Three more members could be added at staff or SPAC discretion. These suggestions on membership will be incorporated into the reorganization proposal, distributed to the members, and the proposal will be voted on at the December meeting.

3.0 Generic Issues

Dr. Moran outlined three areas of concern regarding users. User participation in panels and company/CMA responsibilities toward users were the principal issues. Mr. Zoll discussed the legal implications of decisions about user involvement and notification.

After much discussion, Ms. Price suggested that this issue be referred to CRAC. CRAC could then communicate with EPA on the problems associated with focusing on chemicals rather than on their uses.

It was suggested that the charter of all programs indicate whether the panel is made up of manufacturers, users, or a combination of both.

A second generic issue discussed was the problems associated with testing of mixtures. SPAC recommended that this issue be referred to CRAC. It was pointed out that this is not a new issue--it has been addressed by FDA in its constituency policy.

4.0 Proposed Program on Alkanolamines

The proposed charter for the alkanolamines program was presented to SPAC. The charter was reviewed, discussed, and accepted unanimously. SPAC recommended to the Executive Committee that it approve the Alkanolamines Charter.

5.0 Review of Phthalate Esters Program

Dr. James Mieure presented a status report on the activities of the Phthalate Esters Program. In the testing program negotiated with EPA, the first phase of the Health Effects Program is nearing completion and final reports will be sent to EPA by the end of the year. Dr. Mieure indicated that EPA has been reasonable in accepting explanations of delays and necessary changes in protocols. Ms. Price suggested that the Panel get a copy of EPA's mutagenicity decision tree. SPAC would like an update on the Phthalate Esters Program as soon as the Panel receives a response from EPA to the final submission of Phase I. Ms. Price suggested that in any negotiations with EPA the Panel make EPA state the basis of their concern.

6.0 Review of Epoxy Resins Program

Mr. Fensterheim presented the Epoxy Resins Program report. The principal activities of the Panel relate to the Interagency Testing Committee's (ITC) recommendation on testing needed for the category "glycidol and its derivatives."

Several SPAC members questioned whether the Panel has been devoting adequate resoures to addressing the ITC recommendation. Mr. Fensterheim noted that the Panel recently began to focus attention on the ITC recommendation and had just completed a survey to collect information on chemicals in the category. EPA has identified over 100 chemicals that belong to the category. CMA's Epoxy Resins Panel intends to address only the epoxy diluents which compose a subset of the category. Many of the chemicals identified by EPA are no longer manufactured and the Panel hopes to narrow EPA's focus to a more limited number of chemicals. The Panel has begun to discuss whether a voluntary testing program would be feasible. Developing such a program is complicated by the fact that companies on the Panel do not have uniform interests in all of the chemicals.

SPAC requested that Mr. Fensterheim provide an update of the Panel's activities at the December SPAC meeting. In addition, SPAC requested that the chairman of the Panel present a detailed review of the program's activities at the first SPAC meeting in 1983.

7.0 Review of Chlorobenzenes Program Panel

Dr. Stack remarked that the Chlorobenzenes Program illustrates how a CMA Panel and its task groups work with another trade association and outside parties to achieve a common goal. The Program was chartered to sponsor research on the "lower" chlorobenzenes, i.e., monochlorbenzene (MCB), orthodichlorobenzene (ODCB), and paradichlorobenzene (PDCB). The Panel conducted a literature review and identified teratology and reproduction as two areas in which research was needed.

The Interagency Testing Committee (ITC) recommended chlorobenzenes to EPA in 1978 for testing under TSCA Section 4(a). In response to this regulatory initiative, the chlorobenzenes producers formed the Chlorobenzenes Producers Association (CPA) under SOCMA to meet the advocacy needs of the industry. The CPA retained Cleary, Gottleib, Steen and Hamilton as legal counsel.

In October 1980, EPA published a proposed rule for testing chlorobenzenes in a Federal Register notice. The category included all commercial chlorobenzenes (mono- and di-), trichlorobenzenes (TCB), tetrachlorobenzenes, and pentachlorobenzene plus non-commercial isomers. Areas to be covered included testing for subchronic effects, teratogenicity, oncogenicity, and reproductive effects.

Intense negotiations between the EPA and CPA began after the appearance of the Federal Register notice. CMA's role in the negotiations was to provide technical support to the CPA. A Regulatory Task Group was established for this purpose. CRAC also addressed general legal and policy issues in the proposed test rule.

Coordination between the various parties involved was essential and CMA took the initiative to keep the lines of communication open. The end result was a negotiated voluntary testing program which will provide EPA with the information the Agency needs to properly evaluate the important members of the class. Unnecessary testing was eliminated and total cost to the industry will be several magnitudes below that required to carry out the program originally proposed by EPA.

Although negotiations for the program were carried out by the CPA, the testing is being conducted under the auspicies of CMA. The Panel has recently completed a series of teratology studies which were included in the proposed program. CMA released the studies to EPA and other federal agencies.

8.0 Review of Zinc Dialkyl Dithiophosphates Program

The ZDDP Program Panel was chartered in the Fall of 1980 primarily to meet the research needs of the manufacturers of

this class of oil additives. Recent concern within EPA over the possible health hazards associated with exposure to ZDDP may lead the Panel into an advocacy position. The Panel consists of all seven U.S. manufacturers of ZDDP and one user. Dr. Stack reviewed the completed, ongoing, and projected research programs sponsored by the Panel. The first phase of the program was completed and the report released earlier this year. Phase II is ongoing with an expected completion date of March 1983. Mutagenicity/carcinogenicity (Phase III) testing of several ZDDPs is about to begin.

DBoltas

Debra Boltas
Coordinator
Special Programs

Subject to Review
November 9, 1982