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SPAG-10

Chemical Manufacturers Association

Record of Meeting

Special Programs Advisory Group

DATE: January 26 & 27, 1981

PLACE: CMA Terrace
Conference Room

TIME: 26th: 1:30 to 5:00
27th: 8:30 to 10:45

ATTENDANCE

MEMBERS PRESENT

Otto Sturzenegger, Chairman
William C. Becker*
Calvin J. Benning
Frank A. Bower

Jackson B. Browning*
H. Donald Feeney

Conrad Kent
Richard J. Kociba
George J. Levinskas
Myrl E. Miller*
Curtis W. Smith
Gary Ter Haar
Carl W. Umland*

CIBA-GEIGY
The BFGoodrich Company
Essex Chemical Corporation
E. I. du Pont de Nemours
& Co.
Union Carbide Corporation
Borg-Warner Chemical
Corporation
Stauffer Chemical Company
Dow Chemical Company
Monsanto Company
IMC Chemical Group
Shell Chemical Company
Ethyl Corporation
Exxon Chemical Americas

EX-OFFICIO MEMBERS PRESENT

Robert A. Neal

Chemical Industry
Institute of Toxicology

MEMBERS ABSENT

Edward W. Callahan
Fred C. Dehn

Allied Chemical Company
PPG Industries, Inc.

PRESENT BY INVITATION

Zeb G. Bell, Jr.
David H. Chadwick
W. Mills Dyer, Jr.*
Donald L. Heywood**
A. B. Palmer

Terry G. Pullin*
William M. Reiter**

PPG Industries
Mobay Chemical Corp.
Tennessee Eastman Company
Union Carbide
E. I. du Pont de Nemours
& Co.
Ethyl Corporation
Allied Chemical Corp.


CMA 121917

James Spainhour
Carol R. Stack
Donald R. Strobach

Theodore R. Torkelson
Leo W. Ziemplak

Borg-Warner Chemicals, Inc
CMA Staff
E. I. du Pont de Nemours
& Co.
Dow Chemical U.S.A.
American Hoechst Corp.

CMA STAFF

Debra J. Boltas
Geraldine V. Cox*
Patrick C. Joyce
Randal P. Schumacher*
Joseph T. Seawell*
Hasmukh C. Shah
Carol R. Stack
John C. Van Horn

CMA Staff
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CMA Staff
CMA Staff
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CMA Staff

* = January 26 only
** = January 27 only

Dr. Otto Sturzenegger, Chairman of SPAG, called the meeting to order at 1:30 P.M.

1.0 The Record of Meeting of October 29, 1980 was approved as written.

2.0 Review of the Benzene Program

2.1 Dr. Curtis Smith, Chairman of the Benzene Program Panel, reviewed his Panel's Annual Report to SPAG.

2.2 Outside Consultants

Dr. Smith mentioned that outside consultants do much more than provide consultation in the Panel's reactions to regulations. Legal consultants accompany Panel representatives to hearings, court sessions and, if necessary, to the Supreme Court. There is currently a shortage of outside legal expertise in the area of OSHA regulations.

2.3 Epidemiology

Dr. Smith described the problems the Benzene Panel is having with Tabershaw Occupational Medicine Associates (TOMA). Personnel turn-over at TOMA has been excessive and as a result the study is far behind schedule. Mr. Carl Umland mentioned that as a result of the lessons learned in dealing with Dr. Tabershaw, CMA may be benefitted by having on its staff an epidemiologist with a good understanding of industry for any future studies. CMA should look at the contractor's staff, its other resources

and its reputation. Mr. Umland also suggested consulting with the AIHC Subcommittee on Epidemiology for recommendations on potential contractors. Whichever epidemiologist is used in future studies, Dr. Smith emphasized the need for a clear understanding, before signing the contract, of what and how much is expected from each side.

2.4 Outside Counsel

Interaction between API, AIHC and CMA has run smoothly because the outside counsels of the different groups have worked together.

2.5 CMA/API Joint Research Program

API and CMA have a joint research program to study subchronic and chronic toxicity of benzene. API is in charge of administering this program and has the responsibility of keeping CMA informed. The program was jointly developed by CMA and API.

2.6 General

The Panel has encountered some problems in dealing with OSHA because of the strong influence of labor unions. Dr. Smith stressed the need for peer review of scientific research to avoid situations where questionable studies are used by Government Agencies to support regulation.

3.0 Review of the Titanium Dioxide Program

Dr. Allan B. Palmer, Chairman of the Titanium Dioxide Panel, reviewed the report that was submitted to SPAG. The future of this Program will be contingent mainly on whether or not significant findings evolve from the long-term inhalation study now in progress at DuPont. There was no evidence implicating titanium dioxide in adverse health effects among workers investigated in the National Paint and Coatings Association's (NPCA) epidemiological study completed during 1979. NPCA's data gives little credence to recommendations by outside epidemiologists that mortality and morbidity studies were feasible in the absence of data on co-irritants. SPAG recommended that in the absence of any significant findings from the DuPont study, the Panel should consider disbanding.

4.0 Review of the Phthalate Esters Program

Mr. Harry L. Hunter, Jr., Chairman of the Phthalate Esters Program, reviewed his report to SPAG. Currently this program focuses on environmental and human health

effects of various phthalate esters. One of the goals of this Panel is to avoid a Section 4 Test Rule by developing a meaningful test program acceptable to both industry and EPA. The environmental program which the Panel has proposed seems satisfactory to EPA. Discussions are continuing with EPA on the health effects testing program.

4.1 Health Effects Testing Program

Phthalate esters is one of 16 classes of compounds recommended by the Interagency Testing Committee for the environmental effects test program. EPA would like to expand the requirements for testing to include the health effects test program. Members of the Panel have met with Steven Newburg-Rinn of EPA to discuss CMA's plan for testing chemicals for health effects. The Toxicology Research Task Group under the Panel has devised a screening procedure to select the phthalate esters for long-term testing. The first year cost of the program is expected to be about \$400,000.

Participants in the Human Health Effects program fall into three categories: (1) manufacturers of phthalate esters, (2) users of phthalate esters and (3) manufacturers of raw materials used in the manufacture of phthalate esters. The users are not very likely to get deeply involved in the development of the program.

4.2 Environmental Effects Program

This Program involves manufacturers of phthalate esters only. Fourteen phthalate esters will be tested for potential environmental effects. All manufacturers producing a specific phthalate ester will share the cost of the test program. The cost of the program is expected to be about \$450,000.

4.3 Interaction with EPA

The early stages of TSCA Section 4 discussions on the environmental effects test program with EPA appear to be successful. However, some misunderstanding has developed on the part of EPA on the human health effects test program. EPA personnel felt that the sole purpose of the CMA human health effects test program was to discredit the NCI study on DEHP. This misunderstanding was cleared up at a subsequent meeting with EPA. The phthalate esters panel has developed a screening program to identify which phthalate should be tested for carcinogenicity.

EPA, under Section 4(f) of TSCA, has determined that DEHP can produce health hazards, and so will propose a TSCA Section 6 action. Under Section 6 of TSCA, EPA can limit the production of a chemical, ban certain uses of the chemical, or it can completely ban the production of the chemical. The main concern of the Panel is that there is no suitable replacement for these phthalate esters in commerce.

The Panel will continue to develop a health effects testing program that is satisfactory to both CMA and EPA.

5.0 Report on Polychlorinated Biphenyls (PCBs)

Mr. Randal P. Schumacher informed SPAG of CMA's work on PCB's. On October 30, 1980, the D.C. Circuit Court overturned EPA's determination to exclude from its regulations concentrations of less than 50 parts per million (ppm) and EPA's definition of totally enclosed uses of PCB's. If these decisions are not reversed, PCB's would be banned regardless of their concentration and whether incidentally manufactured or inadvertently generated in products, wastestreams or processes. Since CMA membership has a significant interest in these issues it has agreed to assist EPA in gathering information pertaining to the generation of PCB's below 50 ppm. EPA is also obtaining data for use in defining the totally enclosed uses which should be exempted from regulations. CMA will volunteer information on this issue.

There will be an organizational meeting to explore the interests of member companies in participating in this Program on February 11, 1981. If company representatives at this meeting decide to form a group, SPAG will be requested to consider establishment of a special program on PCBs. It is anticipated that the budget for information gathering will be from \$65,000 to \$70,000. This will give industry the opportunity to reopen the question of exposure and EPA's approach to this type of issue.

6.0 Review of the Styrene Program

Dr. Leo W. Ziemlak, Chairman of the Styrene Program Panel, highlighted areas of his written report. A new Regulatory Task Group (RTG) has been formed under the Styrene Panel to deal with benzene emissions from ethyl benzene/styrene plants. Members of this Task Group were working under the Environmental Management Committee (EMC). The Regulatory Task Group is setting up a legal

budget to establish an administrative record on ethyl benzene/styrene. If the issue should go to litigation, SPI will probably assume the lead role.

Based on some sketchy details regarding an EPA contract for a \$30,000 styrene epidemiology study, the comment was made that panels should critique the protocols before the study begins, particularly if there is some question concerning the qualifications of the contractor.

An important issue to this Panel is EPA's decision to regulate industry without reviewing plans within the industry itself for technological modifications.

7.0 Review of New Program on New Source Performance Standards for the Non-Metallic Mineral Industry

Mr. William M. Reiter presented a proposal for a new program on non-metallic minerals. Work on this program is currently being conducted under the EMC. The three main goals of this program are to: (1) request the assistant administrator of EPA to re-evaluate the need to propose the standard; (2) establish an administrative record for future litigation, if necessary; and, (3) perform technical and economic evaluations of support material used by EPA in developing the standard. An ad hoc group under EMC started working on these objectives last year; however, as EMC could not support the Group financially, it decided to continue its efforts under Special Programs. The cost of this program is estimated at \$150,000 for outside counsel and consultation fees (excluding litigation). In a unanimous opinion SPAG VOTED that a strong effort be made vis a vis the Executive Committee and the Board to incorporate the non-metallic minerals program into EMC. If SPAG members need to take any action on this matter after the Executive Committee meeting but before their next meeting, they will do so by telephone survey.

8.0 Review of Format

SPAG reviewed the format used in the first four Special Program reports. Additions to the outline are as follows:

8.1 Panel Membership

In listing panel membership the panel chairman should also list the area of expertise for each person. This will allow SPAG members to get an overall feel for the makeup of each panel.

8.2 Critical Dates

A projected timetable of dates for the year following the date of report. This will include action plans with anticipated dates.

8.3 Future Needs

Includes special problems that the panel may be encountering.

8.4 Summary

The panel chairman will tie together the major points from his or her presentation and review the areas requiring specific recommendations by SPAG.

9.0 Future Dates

Meetings for the remainder of 1981 will be held on Tuesdays from 8:00 a.m. to 3:00 p.m. in CMA's Terrace Conference Room. Future dates are:

April 21, 1981;
June 9, 1981;
August 25, 1981; and
October 20, 1981.

A tentative meeting has also been scheduled for December 8.

Hasmukh Shah

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

Subject to approval
February 12, 1981