

Report to CMA - Special Project Advisory Group

January, 1981

by Benzene Special Program Panel

C. W. Smith, C. R. Stack

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CHARTER OF THE BENZENE PROGRAM PANEL

Consistent with CMA practices and policies, the Benzene Program Panel will represent the interests of the members of the Chemical Manufacturers Association (CMA) before federal and state agencies in all matters relating to safety and health issues arising out of the production, reaction, release, packaging, repackaging, storage, transportation, handling or use of benzene.

The Panel may support and direct research and studies to expand the data base on matters relating to benzene safety and health issues.

The Panel functions as a special committee under CMA's bylaws. As such it is fully subject to the "general principles applicable to the structure and operations of committees". The Panel is subject to CMA's advocacy policy and appropriate coordination and control by CMA's president, staff, and executive committee.

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CHARTER OF THE PROTOCOL SUBGROUP OF THE TOXICOLOGY
RESEARCH TASK GROUP OF THE BENZENE PROGRAM PANEL

Operating within the charters of the Benzene Program Panel and the Toxicology Research Task Group (TRTG) the protocol subgroup will recommend to TRTG the protocol design for the toxicology research specified by TRTG and monitor its progress.

CHARTER OF THE TOXICOLOGY RESEARCH TASK GROUP
OF THE BENZENE PROGRAM PANEL

The Toxicology Research Task Group (TRTG) operating within the charter of the Benzene Program Panel, will provide expert interpretation of available data on the toxicology of benzene and advise the Panel on appropriate research required to expand the toxicological base. TRTG will provide the necessary protocol design or protocol review and will conduct or make provisions for appropriate monitoring and auditing of funding toxicological research. Each company shall have one vote.

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CHARTER OF THE EPIDEMIOLOGY TASK GROUP OF THE BENZENE
PROGRAM PANEL

Within the Charter of the Benzene Program Panel (BPP) the Epidemiology Task Group (ETG) will represent the Panel in the resolution of technical questions concerning the study under contract with Tabershaw Occupational Medicine Associates, P.A. (TOMA) and will seek Benzene Program Panel responses to alternatives recommended by the TOMA. The ETG will provide stimulus to TOMA to expedite its obligations to complete this study appropriately and in a timely manner. The chairman of the Task Group, or his designee, will be the contact person for TOMA regarding the technical aspects of this epidemiology study. All contractual matters will be handled directly by CMA staff. The Task Group will cease to exist when TOMA has properly completed all obligations in its contract with the CMA for this study, or at the discretion of the members of the Panel.

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OCCURRENCE AND USES

Besides the small amount of benzene that occurs naturally in petroleum, commercial production processes in the U.S. include the catalytic reforming of light naphtha (54% of production), dealkylation of toluene (22%) and steam cracking of naphtha (19%). The remaining 5% is produced as a by-product of the cooking process in steel mills. About half the benzene in the U.S. goes into gasoline and the other half (1.4×10 gallons) goes into the manufacture of ethylbenzene (for styrene) cumene (for phenol), cyclohexane (for nylon), nitrobenzene (for aniline), dodecylbenzene (for detergents), aldy-, chloro-, and bromo- benzenes, and maleic anhydride. These uses account for about 98% of benzene in the chemical industry.

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OBJECTIVES AND ACTION PLANS

In November 1976, representatives from seventeen companies recommended the formation of a group that would conduct a program to:

- 1) assess the data being used by NIOSH and OSHA in proposing workplace standards for benzene;
- 2) develop its own recommendations;
- 3) gather additional data and/or conduct special studies to substantiate establishment of a standard.

The first objective mentioned above was met in industry's challenge to OSHA's proposed workplace standard. The Program Panel continues to be concerned with expansion of the benzene toxicological data base and the development of industry guidelines for workplace standards.

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CMA BENZENE PROGRAM PANEL

Paul D. Halley
AMOCO CHEMICALS CORP.
200 E. Randolph Dr.
Chicago, Illinois 60680

B. J. Knauff
ARCO CHEMICAL COMPANY
1500 Market St.
P.O. Box 7258
CS-2907B
Philadelphia, Pa. 19101

Stanley T. Wagner
ARCO CHEMICAL COMPANY
1500 Market St.
P.O. Box 7258
Philadelphia, Pa. 19101

Dr. Norman S. Salomons
ASHLAND CHEMICAL COMPANY
P.O. Box 2219
Columbus, Ohio 43216

Dr. A. E. Moffitt, Jr.
BETHLEHEM STEEL CORPORATION
B-238 Main Tower
Bethlehem, Pa. 18016

David L. McWherter
COSDEN OIL & CHEMICAL COMPANY
P.O. Box 1311
Big Spring, Texas 79720

Roger L. Daniel
DOW CHEMICAL U.S.A.
Building B-101
Freeport, Texas 77541

Carl W. Umland
EXXON CHEMICAL COMPANY
P.O. Box 3272
Houston, Texas 77001

Dr. S. N. Boyd, Jr.
E. I. du PONT de NEMOURS & COMPANY
Chemicals, Dyes, & Pigments Dept.
B-6210
1007 Market St.
Wilmington, De. 19898

John A. Burgess
GULF OIL CHEMICALS COMPANY
P.O. Box 3766
Room 3070
Houston, Texas 77001

J. P. McCarthy
Vice President and Manager
Administrative Services
KOPPERS COMPANY
1201 Koppers Bldg.
Pittsburgh, Pa. 15219

Dr. John D. Behun
MOBIL OIL CORP.
150 E. 42nd St.
New York, N.Y. 10017

Harry M. Keating
MONSANTO COMPANY
800 N. Lindbergh Blvd.
St. Louis, Mo. 63166

A. Merrill Schnitzer
PHILLIPS PETROLEUM COMPANY
Senece Building
Bartlesville, Ok. 74004

Ian W. E. Harris
POLYSAR LIMITED
P.O. Box 52
Port Huron, Michigan 48060

Dr. Curtis W. Smith, Chairman
SHELL CHEMICAL COMPANY
1 Shell Plaza
Room 1806
Houston, Texas 77001

Dr. C. W. Stallard
Director
Corporate Health Services
STANDARD OIL COMPANY (OHIO)
815 Cuyahoga Building
Cleveland, Ohio 44115

Howard A. Kirsch
TEXACO CHEMICAL
P.O. Box 430
Bellaire, Texas 77401

Dr. H. Michael D. Utidjian
UNION CARBIDE CORP.
22nd Floor
270 Park Ave.
New York, N.Y. 10017

John R. Weinert
USS CHEMICALS DIVISION OF
UNITED STATES STEEL CORP.
600 Grant St.
Room 2813
Pittsburgh, Pa. 15230

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CMA PROTOCOL SUBGROUP OF THE TOXICOLOGY RESEARCH TASK GROUP OF
THE BENZENE PROGRAM PANEL

Dr. Charles E. Holdsworth*
Toxicologist
AMERICAN PETROLEUM INSTITUTE
2101 L Street St. N.W.
Washington, D.C. 20037

Dr. R. A. Kuna
Toxicologist
EXXON CHEMICAL COMPANY
P.O. Box 235
East Millstone, N.J. 08873

Dr. Charles O. Ward
GULF SCIENCE & TECHNOLOGY
4400 Fifth Ave.
P.O. Box 3240
Pittsburgh, Pa. 15230

Dr. Peter H. Craig
MOBIL OIL CORPORATION
Toxicology Division
P.O. Box 1026
Princeton, N.J. 08540

Dr. F. Ben Thomas
SHELL CHEMICAL COMPANY
1 Shell Plaza
Room 1018
P.O. Box 4320
Houston, Texas 77210

Dr. Paul J. Garvin, Jr.
STANDARD OIL COMPANY (INDIANA)
200 E. Randolph Dr.
MC3801
Chicago, Illinois 60601

*Non voting; liaison with API

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YZ0024297

CMA BENZENE TOXICOLOGY RESEARCH TASK GROUP

Charles E. Holdsworth, Ph.D.
Toxicologist
AMERICAN PETROLEUM INSTITUTE
2101 L Street, N.W.
Washington, D.C. 20037

Dr. Seward Ridlon
ARCO CHEMICAL COMPANY
500 S. Ridgeway Ave.
Glenold n, Pa. 19036

Dr. Bernard A. Schwetz
DOW CHEMICAL U.S.A.
Building 1803
Midland, Michigan 48640

Dr. R. A. Kuna
Toxicologist
EXXON CHEMICAL COMPANY
P.O. Box 235
East Millstone, N.J. 08873

Dr. R. A. Scala
EXXON CHEMICAL COMPANY
P.O. Box 235
East Millstone, N.J. 08873

Dr. A. Michael Kaplan
Hask ll Laboratory
E. I. du PONT de NEMOURS & COMPANY
Elkton Road
Newark, De. 19711

Dr. Charles O. Ward
GULF SCIENCE & TECHNOLOGY
4400 Fifth Ave.
P.O. Box 3240
Pittsburgh, Pa. 15230

Peter E. Berteau, Ph.D.
Senior Toxicology Specialist
MONSANTO COMPANY
800 N. Lindbergh Blvd.
G2WD
St. Louis, Mo. 63166

Dr. F. Ben Thomas
SHELL CHEMICAL COMPANY
1 Shell Plaza
P.O. Box 4320
Room 1018
Houston, Texas 77210

Dr. M. B. Slomka, Chairman
SHELL OIL COMPANY
1 Shell Plaza
Houston, Texas 77001

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YZ0024298

CMA BENZENE PROGRAM PANEL EPIDEMIOLOGY TASK GROUP

Stanley T. Wagner
ARCO CHEMICAL COMPANY
1500 Market St.
P.O. Box 7258
Philadelphia, Pa. 19101

David L. McWherter
COSDEN OIL & CHEMICAL COMPANY
P.O. Box 1311
Big Spring, Texas 79720

Roger L. Daniel
DOW CHEMICAL COMPANY
Building 101
Ft Worth, Texas 77541

William E. Faverweather
E. I. du PONT de NEMOURS & CO.
Wilmington Trust 508
Wilmington, De. 19898

Gerry Raabe
MOBIL OIL CORPORATION
150 E. 42nd St.
New York N.Y. 10017

Clar nce Buckley
MONSANTO COMPANY
WG-Krummrich Plant
Sauget, Illinois 62201

Harry M. Keating
MONSANTO COMPANY
800 N. Lindbergh Blvd.
St. Louis, Mo. 63166

Judith A. Zack
MONSANTO COMPANY
800 N. Lindbergh Blvd.
C2SH
St. Louis, Mo. 63166

Paul D. Halley
STANDARD OIL COMPANY (INDIANA)
200 E. Randolph Dr.
Chicago, Illinois 60601

Dr. H. M. D. Utidjian
UNION CARBIDE CORP.
22nd Floor
270 Park Ave.
New York, N.Y. 10017

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AUDITING

CMA recommends that all Program Panels consider third-party auditing of research projects that may be of particular interest to federal regulatory agencies, such as studies designed to test for potential mutagenicity, carcinogenicity, or reproductive effects. The Benzene Program Panel arranged for Dr. Bob West of Bob West Associates to monitor and audit the recently completed male and female reproduction studies. This and other research projects were also closely monitored by members of the Task Groups and the CMA Program Administrator.

The Epidemiology Task Group made arrangements with Tabershaw Occupational Medicine Associates (TOMA) to conduct a data audit of information provided for the benzene epidemiology study. This audit will be conducted prior to analysis of the data base.

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ADVOCACY

OSHA, EPA, and the Consumer Product Safety Commission have been attempting to develop regulations for benzene for several years. These efforts have been resisted by CMA and other trade associations as being extreme and unsubstantiated by the existent scientific data base. As a result no regulation other than the formalization of the ANSI values of an 8 hour TWA of 10 ppm and a 15 minute ceiling of 25 ppm have been promulgated.

OSHA

In response to OSHA's efforts to develop new workplace standards, industry was successful in obtaining a stay-of-execution of an emergency temporary standard, and in voiding most features of a permanent standard by the Fifth Circuit Court in New Orleans. The Supreme Court upheld the decision of the Fifth Circuit Court when it was challenged by OSHA. The Supreme Court decision challenged OSHA's "no threshold" carcinogen policy which requires that carcinogens, such as benzene, be banned or regulated at the lowest feasible level. The Court placed the burden of proof on OSHA to establish that the present workplace standard presented a significant risk that would be reduced by the new standard.

Studies underway by CMA, API, NYU, CIIT, and Jefferson Medical College should provide much more information to aid in benzene risk assessment. In the future, CMA will try to work with OSHA to develop a reasonable benzene regulation dealing with exposure, monitoring, medical surveillance, and safe workplace practices.

EPA

Under injunction by NRDC, EPA has been attempting to develop a standard under Section 112 (for carcinogens) of the Clean Air Act to control emissions of benzene from stationary sources. EPA developed three reports; a study of environmental exposure, a study of health effects, and a risk assessment prepared by the Cancer Assessment Group that were reviewed by the EPA Science Advisory Board. CMA sponsored a study of environmental exposure by Foster D. Snell and industry provided comments which produced some changes in the EPA reports.

On August 21, 1980, EPA held a hearing on proposed rules for emission of benzene associated with the manufacture of maleic anhydride. CMA and API presented comments on health effects and CMA (under EMC committee) commented on environmental emissions. Exposures to ambient benzene in areas surrounding maleic anhydride plants are

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well below 10 ppb. The risk of developing adverse health effects at these exposure levels is negligible and EPA may abandon this approach to regulation of benzene. In addition, benzene emissions are controlled by other regulations pertaining to volatile organic chemicals.

CONSUMER PRODUCT SAFETY COMMISSION

On May 19, 1978, the CPSC proposed a rule banning any products where benzene was added intentionally, and limiting the benzene concentration in products in commerce to no more than 0.1%. CMA, API, and other trade associations presented comments to the effect that the benzene content of solvents has been decreased and that the proposed level of regulation was extreme. A market survey sponsored by CPSC indicated that benzene is no longer being intentionally added to consumer products and that only 10% of the products surveyed contained over 0.1% benzene; none of the products contained more than 0.25% benzene. CPSC further states that "Since the commission has relied on much of the same underlying data as that used by OSHA on benzene, the commission needs to carefully analyze the opinion in terms of CPSC regulations of benzene."

The CPSC has extended the deadline for this issuance of a benzene ban or withdrawal of the rule until January 1981. The CMA Benzene Program Panel will continue to monitor this activity.

RELATION TO OTHER TRADE ASSOCIATIONS

In addition to CMA, other trade associations that participated in advocacy action on benzene with OSHA include:

American Petroleum Institute (API)
American Iron and Steel Institute (AISI)
Rubber Manufacturers Association (RMA)

The CMA and API collaborated closely from the beginning with cross representation at their respective meetings. Retained outside attorneys were in close contact. Presentations at the OSHA hearing were made independently, but Mr. Ed Warren of Kirkland and Ellis, under contract with the API, presented the case for producers and users to the Fifth Circuit Court and the Supreme Court. This collaboration worked well and contributed to the success of the venture.

OUTSIDE CONSULTANTS

Early in the program the group recognized the need for advice and assistance by outside consultants; therefore, Dr. I. Tabershaw and his organization and Mr. Andrew McDonald,

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Esq., of Wilmer, Cutler, and Pickering were brought into meetings early in the process. As an expert in occupational medicine, Dr. Tabershaw's knowledge of benzene and of other health experts in the field was most helpful. Mr. McDonald's advice as to possible legal maneuvers was essential. By bringing them into discussions early, they developed a firm understanding of the intricacies involved and provided important guidance as well.

For the OSHA and EPA hearings, papers were presented from outstanding experts, mostly from universities. With growth of experience in the panel, the consultant contract for Dr. Tabershaw has been cancelled.

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BENZENE

<u>Report Title and Contract Number</u>	<u>Contractor</u>	<u>Contract Execution Date</u>	<u>Present Level of Funding</u>	<u>Comments</u>
Survey of Benzene Emission Control Costs in the Chemical Industry (B 0.25 ECC-BAB)	Booz, Allen & Hamilton	Nov. 21, 77	\$60,000	Released in 1978
A Historical Prospective Mortality Study of Chemical Workers Exposed to Benzene	Tabershaw Occupational Medical	July 14, 78	167,300	In Progress
Determination of Time to Steady-State Level During Inhalation Exposure of Benzene by Rats & Mice (B 2.0-Hem-Ihl-B/D)	Bio/dynamics, Inc.	April 16, 79	57,620*	Final report released December 17
Determination of the Concentration of Benzene and its Metabolites in the Blood of Rats and Mice at Various Exposure Concentrations (B 2.0-Hem-Ihl-B/D)	Bio/dynamics, Inc.	April 16, 79	*	Final report released December 17
Determination of Material Balance of Benzen in Rats and Mice (B 2.0-Hem-Ihl-B/D)	Bio/dynamics, Inc.	April 16, 79	*	Final report released December 17
A Dominant Lethal Inhalation Study in Rats with Benzene and A Female Fertility Study in Rats w/Benzene (B 3.0 ff/dl-B/D)	Bio/dynamics, Inc.	Jan. 15, 80	180,000	Final report received
Audit of B 3.0 (B 5.0-Aud.-B/D-West)	Bob West Assoc., Inc.	Jan. 21, 80	7,000	Final report received
Agreement with API to Jointly Fund Benzene Inhalation Research	Hazleton Labs			Administered by API
Five-day Acute Benzene Inhalation Study		May 5, 80	30,200	
90-day Subchronic Benzene Inhalation Study		May 21, 80	459,700	
Chronic Two-year Benzene Inhalation Study		May 21, 80	1,339,100	
Pulse dose Inhalation Study of Benzene Toxicity		May 21, 80	519,800	
Intermittent Exposure/Recovery Benzene Inhalation Study		May 21, 80	166,310	
Monitoring and Auditing of API/CMA Jointly Funded Study (B 6.0)	Bob West Assoc., Inc.	May 21, 80	31,200	Administered by API

*\$57,620 tot l for three B 2.0 Hem-Ihl-B/D Studi s

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