

A REPORT
ON THE YEAR
1986-1987

SPECIAL PROGRAMS

CMA 030516

CONTENTS

Page

1	Overview
3	New Programs
5	Continuing Programs
17	Financial Resources
19	Regulatory Affairs
21	Research
22	Guidance
23	Division Staff

SPECIAL PROGRAMS

The Biomedical and Environmental Special Programs provide a mechanism for companies that wish to jointly conduct research and/or advocacy on specific chemicals.

Research is conducted to collect scientific information which will promote the health and safety of those involved in the manufacture, processing, use and disposal of chemicals. All final reports and other significant findings of CMA-managed research programs are released to the public.

Advocacy is conducted to facilitate external communications (not designed solely for information exchange) that relate to existing or developing regulations, legislation or litigation.

THE PROGRAMS

Alkanolamines	Hydroquinone/
Arsenic	Quinone
Benzene	Isopropanol
Biocides	Ketones
Butadiene	Lubricant Additives
Butylated Hydroxy- toluene	Metal Catalysts
Chlorobenzenes	Methylenedianiline
Cresols	Naphthenates
Cumene	Octylphenol
Cyclohexane	Oleylamine
Dibenzofurans/ Dibenzodioxins	Phosgene
Epoxy Resins	Phosphorus
Ethylene Dibromide	Phthalate Esters
Ethylene Dichloride	Polychlorinated Biphenyls
Ethylene Glycol	Rubber Additives
Ethylene Oxide	Toluenediamines
Ethylhexanoic Acid	Titanium Dioxide
2-Ethylhexanol	Trimellitate Esters
Fluorocarbons	Vinyl Chloride
Glycol Ethers	Vinylidene Chloride
	Water Additives

Acceleration -- aptly describes the feelings of panel members and Division staff this year while confronting the waves of new regulatory activity. If last year gave glimpses of the regulatory future for individual chemicals, this year provided action-packed previews. In particular, massive new testing programs are on the horizon. Coming events for Special Programs were much in evidence among federal and state laws, such as SARA and California's Proposition 65. TSCA and FIFRA data call-ins on large numbers of chemicals and broad-scale concerns under TSCA about the health and environmental effects of structurally related chemicals likewise indicated that more and larger testing will be required soon. All the while, the main feature — comments on current regulations and ongoing testing of products — moved panels faster toward regulatory resolution. In short, the year presented all of the challenges that we expected . . . and more.



Fast Times

To cope with the expanding regulations, Special Program panels met more frequently with agency staffs, filed more comments, presented more testimony and initiated more research. Adding to the action were new programs that required intensive member company resources for planning and organizing in their start-up phases. Not surprisingly, financial and personnel commitments by member companies to existing and new programs were considerable. Direct contact hours by the Special Programs Division staff, a measure of program activity, were up by 9% over last year.

Further additions to the resource-consuming load were the essential activities of coordination and coalition building. This year, more than ever, the focus was on coordination of industry positions among various panels, among panels and CMA committees, and among panels and other associations. The efforts of many company personnel, with a variety of skills, ensured that consistently strong industry positions are being developed to address multi-chemical regulations under TSCA, RCRA, FIFRA, the Safe Drinking Water Act and the Clean Air Act. Likewise, panel members devoted much effort to building coalitions with trade associations and environmental groups in interactions with EPA, OSHA, the Department of State

and the United Nations Environment Programme. Some of these coalitions have already produced sensible, cost-effective solutions to regulations, and others are nearing this goal. Media coverage of Special Program chemicals was unabated. Television, radio and press interests in various chemicals resulted in a large number of interviews by panel members as well as Division staff. In addition, panels constructed many press releases to address the well-publicized concerns. While some long-standing issues remain controversial, most concerns were relieved through presentations of credible data by thoroughly prepared industry spokesmen. Panels now are focusing more frequently on planning and training of spokesmen for media coverage.

Managing At High Speed

The Special Programs Division took several vital steps to support the multiple directions of the programs. High priority remained on coordination of panel activities with other groups inside and outside CMA. The Associate Directors continued their roles as principal coordinators for Special Programs interests with the Health and Safety Committee and the Environmental Management Committee. In addition, other Division staff undertook assignments as coordinators for Special Programs concerns with CMA task groups addressing RCRA, SARA and state regulations.

The new assignments reflect the wider importance of specific chemical issues in the scheme of regulations addressed by agencies and the Association. The Division coordinators ensure that impending regulations come to the attention of all potentially affected panels as soon as possible, with suggestions on actions to take. Coordinators also make sure that appropriate standing committees are aware of the effects of current or upcoming regulations on specific

chemicals and the panels' proposed responses. Dovetailing of the Association's generic and specific chemical comments on regulations is a prime objective.

As always the Division was strongly assisted by the CMA Legal Department in antitrust, research, and regulatory areas. To ensure that antitrust protection is consistently maintained, CMA attorneys counselled panel chairmen, as well as Division staff on proper procedures and reviewed all panel comments, reports, agendas, and minutes as part of routine protective measures. In research, CMA counsels increasingly supported Division staff in negotiating effective contracts with laboratories and consultants.

Rapid, informative communication of important regulatory and scientific developments also was a prime effort for the Division. The Special Programs Newsletter, now in its third year of publication, still receives acclaim from its audience for coverage of panel activities and new influences on specific chemicals. The "Spotlight" article in each issue ensures that overall accomplishments of individual panels are regularly summarized and publicized. The Special Programs Alerts continue as quick means of informing panel members and others when a time-sensitive response is needed to protect company interests. Alert subjects vary from the pressing need to submit data or comments to an agency, to the need to join other companies in a combined response to upcoming regulatory deadlines. Valuable input for CMA standing committees also came from responses to Alerts. All the while, CMA News, ChemEcology and the President's Letter performed their usual important roles in publicizing activities of Special Programs to a wide audience.

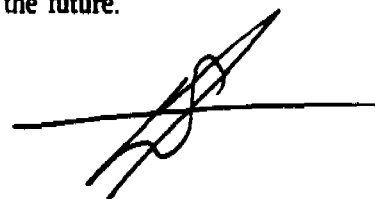
The Special Programs Leadership Session, begun experimentally last

year, became a full-fledged component in the Division's array of services. The Sessions are one-day workshops, held primarily for new panel and task group leaders. The goals are to provide advice from peers and an industry training specialist on persuasive leadership; to provide an overall view of CMA; and, to forge a bond between leaders with like interests. Ratings by this year's participants were high, and as a result, another Session is in the planning stage.

Looking Forward

We are certain that 1987-88 will at least equal and probably exceed this year's formidable pace. A stimulus to this prediction was the appearance this year of several regulations with testing and reporting requirements for large numbers of chemicals. Sections of SARA now have potential for causing large-scale testing of many chemicals some of which are the focuses of Special Programs. We expect increased activity by the affected panels first in collecting, analyzing and submitting data, and later in planning and sponsoring research. The Clean Air Act, RCRA and the continuing implementation of Proposition 65 also seem probable as generators of new Special Programs, as well as contributors to existing panel activities. And . . . in the midst of all this action, testing under TSCA Section 4 test rules will be initiated for more Special Programs chemicals than ever before.

Based on past experiences and good planning, we have confidence that our successes will continue into the future.



June 1987

During 1986-87, four new Special Programs were requested and approved. Manufacturers and users of three individual chemicals — Ethylene Glycol, 2-Ethylhexanol and Isopropanol — and one chemical category — Aromatic Diamines — organized programs to address testing needs. Impetus for formation of the new programs differed among the groups. In the first instance, manufacturers simply had a proactive interest in expanding the toxicological data base on their product. In the next two cases, the companies faced upcoming mandated testing requirements under TSCA. The driving force for the fourth program was a concern about the extent and types of EPA-required testing of new products in a category. All four panels are now fully organized and proceeding toward their initial objectives.

AROMATIC DIAMINES

Chairman:
R. Smith
Ethyl Corporation

Date Chartered:
1987

Current Task Group:
Toxicology Research

Program Manager:
C. Stack/K. Rosica



Chairman

Manufacturers of aromatic diamines are developing new products with various substituents on the aromatic ring. As part of the TSCA Premanufacture Notification process, EPA has required that each of the new products be tested for carcinogenicity because of structural similarities to 2,4-toluenediamine, a known rodent carcinogen. In February, CMA responded favorably to a request from the manufacturers to establish a special program for addressing the problem of extensive pre-marketing testing requirements.

The Panel's primary goal is to develop a strategy acceptable to EPA for achieving PMN approvals without the need for a long-term bioassay on each new product. At present, very limited structure-activity data exist to refute EPA's assumption that all substituted aromatic diamines are potentially carcinogenic. The Panel is planning research to address the question of how substitution on the aromatic diamine ring affects carcinogenic potential.

ETHYLENE GLYCOL

Chairman:
D. Macauley
Union Carbide
Corporation

Date Chartered:
1986

Current Task Group:
Toxicology Research

Program Manager:
C. Stack



Chairman

The Program was formed to clarify and expand the toxicological data base on ethylene glycol. Panel-sponsored research was initiated recently. Pharmacokinetics and material balance studies in rats, and a dermal developmental toxicity study in mice, are being conducted at the Bushy Run Research Center.

When the final reports are available, the Panel will review the results of the studies and decide where to direct future research. Possible projects include extension of the pharmacokinetics program to include mice, and conduct of oral teratology studies in rats and mice to establish No Observed Effect Levels.

2-ETHYLHEXANOL

Chairman:

R. Wise
Union Carbide
Corporation

Date Chartered:
1986

Current Task Group:
Toxicology Research

Program Manager:
E. Moran



Chairman

Budget cuts forced the National Toxicology Program to cancel a two-year rat and mouse bioassay planned for 2-ethylhexanol. NTP requested that EPA require industry to sponsor this testing by issuing a test rule under TSCA Section 4. EPA agreed to develop a proposed rule in six months, with a final rule to be published six months later.

The Panel formed to address the pending test rule. The Panel developed a bioassay test program including additional dose groups and measurements in order to understand the biological effects of 2-EH. EPA rejected the Panel's program and will publish a final rule soon requiring only traditional bioassay testing.

The Panel will conduct the testing required under the rule and will interact with EPA on a second proposed test rule. The second rule may include pharmacokinetics, teratology and reproductive effects testing. A use and exposure survey is being conducted by the Panel to aid development of relevant test protocols and to ensure that only necessary additional testing is required.

ISOPROPANOL

Chairman:

J. Quance
Exxon Chemical
Americas

Date Chartered:
1987

Current Task Group:
Toxicology Research

Program Manager:
K. Rosica



Chairman

The Panel is actively involved with EPA in developing a negotiated consent agreement for health effects testing of isopropanol under TSCA Section 4. In response to intent-to-designate status with the Inter-agency Testing Committee, the Panel proposed a testing program to EPA and awaits reactions from the Agency. If negotiations succeed, this will be among the first consent agreements effected under the new EPA procedural rules for Section 4.

The Panel formed to address concerns raised by the ITC in its 19th Report to the EPA Administrator. Designation for testing of isopropanol was included in the 20th Report released in May.

Forty Special Programs are now officially approved by CMA. Each sanctioned program operates under a charter which defines its scope within the framework of the Association's generic interests. At year's end, four new groups await official approval — Alkylphenols and Ethoxylates, Chlorine Dioxide, Fluoroalkenes, and Specialty Acrylates and Methacrylates. Special Programs membership rosters during the year included 185 companies and nine associations. Among the company members, 83 were members of CMA and 15 were non-U.S. and non-Canadian. Participating companies and associations were represented on panels and task groups by approximately 290 persons with professional skills ranging from physical and biological sciences, through engineering and industrial hygiene to legal and business areas.

ALKANOLAMINES

Chairman:
E. Bentley
Texaco Chemical
Company

Date Chartered:
1982

Current Task Group:
Toxicology Research

Program Manager:
H. Sauer



Chairman

Summaries of panel-sponsored pharmacokinetics studies on triethanolamine are to be published in Brownings', "Toxicology and Metabolism of Industrial Solvents." When the Panel presented these results to the National Toxicology Program, the NTP staff stated that the data will be used in shaping future research efforts.

The Panel formed to sponsor toxicology studies on triethanolamine in order to respond to concern raised by a Japanese study that implicates this chemical as a possible carcinogen. The Panel has tentatively planned research on other alkanolamines and is monitoring additional NTP research programs on triethanolamine, including 90-day subchronic dermal testing.

Recently, the NTP completed a 90-day subchronic dermal testing with triethanolamine and now has the chemical under review for further testing. The Panel is following these efforts as a guide to its own future testing.

ARSENIC

Chairman:
D. McGraw
Koppers Company

Date Chartered:
1981

Current Task Groups:
None

Program Manager:
H. Shah



Chairman

The Panel convened a meeting with representatives of OSHA and EPA at which Dr. Adam Taub of the University of Uppsala presented his epidemiologic research findings on Swedish smelter workers. Taub's study and earlier Panel-sponsored studies investigated whether a threshold exists for respiratory cancer related to the extent of exposure to arsenic. While the study showed that men hired before 1938 had almost twice the risk of those hired from 1938 to 1956. Taub's analysis gave no clear evidence of an exposure threshold. The Panel then hired a consulting firm to conduct alternative exhaustive analyses of the epidemiologic data to resolve the threshold issue.

The Panel was formed to address the impact of OSHA and EPA regulations on various companies manufacturing or using arsenic, and to sponsor appropriate research. In general, the Panel has accomplished its goals and objectives. Any additional Panel activities will depend on whether the epidemiological analyses indicate an arsenic threshold for respiratory cancer.

BENZENE

Chairman:
R. Daniel
Dow Chemical USA

Date Chartered:
1976

Current Task Group:
Toxicology Research

Program Manager:
C. Stack



Chairman

In March 1986, the Panel was active in OSHA hearings on the proposed reduction of the workplace standard for occupational exposure to benzene. In June, the Panel filed post-hearing comments and submitted a closing brief to OSHA. The proposal, if adopted, would reduce the permissible exposure limit from 10 ppm TWA8 to 1 ppm, with an "action level" of 0.5 ppm. The action level serves as a trigger for medical surveillance and air monitoring requirements. The Panel also actively opposed a legal challenge to EPA's final rule on benzene fugitive emissions and the Agency's decision to forego final rules on benzene emissions from ethylbenzene/styrene operations, storage vessels, and maleic anhydride production facilities. A decision is expected soon on the case pending in the U.S. Court of Appeals, District of Columbia.

Since its initiation, the Panel has pursued an active research and advocacy program. Responding to a NIOSH occupational study linking benzene exposure to leukemia, the Panel initiated an industry epidemiology study that was completed in 1983. Also, in cooperation with the American Petroleum Institute, a joint animal toxicology research program was established that produced studies examining benzene subchronic toxicity, metabolism, and possible reproductive effects.

The Panel actively participated in the 1977 OSHA proceedings to lower the current workplace standard and was a party in the

subsequent legal challenge of the 1 ppm PEL established by OSHA in 1978. The 10 ppm standard was upheld in a landmark Supreme Court decision in 1980.

An OSHA Final Rule is anticipated in June 1987. The Panel will review the provisions of the rule and then decide on future activities.

BIOCIDES

Chairman:
J. Yuster
Troy Chemical
Corporation

Date Chartered:
1986

Current Task Groups:
Regulatory
Litigation
Scientific
Specific Chemicals

Program Manager:
H. Shah



Chairman

The Panel continued to address testing issues associated with the California Department of Food and Agriculture Data Call-In on biocidal chemicals. The Panel also expanded its focus to address or monitor the following issues at the federal level: EPA Antimicrobial Data Call-In; EPA Pesticide Inerts Policy; FIFRA Registration Fees; and, FIFRA reauthorization. For the Antimicrobial Data Call-In, the Panel submitted comments outlining legal, technical, and economic problems. Specific end-use exposure assessment groups were formed by the Panel to develop the protocol for assessment. In addition, the Panel filed comments on EPA's proposed rule establishing fees for various pesticide registration activities. The Panel continued the attempt to persuade regulators at state and federal levels to distinguish industrial biocides from agricultural biocides when establishing regulatory controls. The Panel stated that the potential for human exposure to industrial biocides is limited and markets for these chemicals are small. Thus, extensive regulation has a much greater economic impact on these manufacturers and is unwarranted.

The Panel was formed in 1986 when the California Department of Food and Agriculture issued Data Call-In Notices on biocidal chemicals registered in the state. The notice required that registrants submit data on chronic toxicity, oncogenicity, reproductive effects, teratogenicity, mutagenicity and neurotoxicity. Manufacturers of many affected chemicals formed the Panel to address issues associated with this regulation and any other regulatory actions affecting biocides.

The Panel will remain active in shaping the EPA Antimicrobial Data Call-In. The new Litigation Task Force will address significant legal issues. The Panel also will monitor developments in the EPA Inerts Policy and other aspects of FIFRA reauthorization. The Panel's specific chemical task forces affected by the California Data Call-In may sponsor research as necessary. An EPA Special Data Call-In will cause the Arsenic Acid Task Force to sponsor both glove and protective clothing permeability and teratology studies.

BUTADIENE

Chairman:
J. Bonin
Shell Chemical
Company

Date Chartered:
1984

Current Task Groups:
Toxicology Research
Environmental
Industrial Hygiene

Program Manager:
R. Romano



Chairman

In January, the Panel submitted comments to OSHA on the Advance Notice of Proposed Rulemaking for 1,3-butadiene. The Panel then sponsored a tour of two butadiene plants for OSHA staff. In preparation for the proposed rule, the Panel sponsored an industrial hygiene survey of butadiene producers. This survey will be expanded to include crude butadiene producers and stand-alone terminals. Exposure data from the survey also will be used in updating workplace risk assessments. In March, the Panel participated in EPA's National Air Pollution Control Techniques Advisory Committee hearing on the "intent to list" butadiene as a Clean Air Act Section 112 hazardous air pollutant. The Panel stressed that realistic data should be used in estimating butadiene fugitive emissions.

In the aftermath of an EPA TSCA Section 4(f) consideration, the Panel formed to collect and evaluate information needed to assess the safety, environmental and health issues arising from production, storage, transportation, use or disposal of 1,3-butadiene. The Panel provided comments to EPA on two risk assessments, and worked with the Agency in assessing the "short-term" releases of butadiene. The EPA has referred butadiene under TSCA Section 9(a) to OSHA.

The Panel will review and comment on the "intent to list" proposal expected soon from EPA. In the coming year, the Panel also will actively follow development of the listing decision by the EPA and OSHA workplace standard.

BUTYLATED HYDROXYTOLUENE

Chairman:
J. Zora
Neville-Synthese
Organics

Date Chartered:
1977

Current Task Groups:
None

Program Manager:
H. Shah



Chairman

In June, the Joint Expert Committee on Food Additives of the Food and Agricultural Organization/World Health Organization lowered the temporary acceptable daily intake level for BHT. Additionally, JECFA requested information on the hepatocarcinogenicity of BHT in rats and the hemorrhagic effect of BHT in susceptible species. The Panel will generate the requested information with European manufacturers of BHT. As a first step, the Panel is reviewing current literature on the hemorrhagic effect, and European manufacturers are developing information to help understand the mechanism of hepatocarcinogenicity.

In December, the Panel filed a Citizen Petition with FDA requesting that the Commissioner issue a regulation recognizing a prior sanction for the use of BHT. The Panel has monitored scientific evaluation of BHT safety in food products for

the past decade. Submission of the Petition represents a request by the Panel that the FDA officially recognize the safety of BHT under the framework for regulation of food ingredients set forth in the Federal Food, Drug and Cosmetic Act.

The Program was, in fact, begun to conduct research and advocacy necessary to support continued use of BHT in food additive applications. In 1977, FDA published a proposal for interim regulations requiring testing to resolve safety questions on BHT. The Panel filed comments on the FDA proposal in 1978.

The Panel will cooperate with FDA in its current evaluation of BHT and may develop additional scientific information, if appropriate. The Panel also will continue its relationship with European manufacturers in developing information requested by JECFA.

CHLOROBENZENES

Chairman:
J. Bryant
Standard Chlorine
Chemical Co., Inc.

Date Chartered:
1974

Current Task Group:
Toxicology Research

Program Manager:
C. Stack



Chairman

EPA issued a TSCA Section 4(a) Final Rule in July requiring health effects testing for chlorobenzenes. The Panel complied by initiating studies on 1,2- and 1,4-dichlorobenzene, 1,2,4-trichlorobenzene, and 1,2,4,5-tetrachlorobenzene. In a separate rulemaking published in April 1986, EPA required environmental effects testing of dichlorobenzenes and trichlorobenzenes, but the Agency has yet to finalize the test standards for the testing. The Panel continued providing technical support to the Chlorobenzenes Producers Association, an affiliate of the Synthetic Organic Chemical Manufacturers Association.

In particular, the Panel and CPA have focused on regulatory proposals for 1,4-dichlorobenzene. Positive findings in an NTP study prompted the Panel, in coordination with CIIT, to investigate the rela-

tionship of tumor types found in bioassays to human risk assessment.

The Program was formed to sponsor research on chlorobenzenes. The Panel has completed investigations on the mutagenic potential of these chemicals, as well as research on developmental toxicity.

The Panel's TSCA testing program will extend through January 1991. Panel-sponsored research on 1,4-dichlorobenzene will begin in the coming year.

CRESOLS

Chairman:
J. Walbrick
Merichem Company

Date Chartered:
1984

Current Task Group:
Toxicology Research

Program Manager:
K. Rosica



Chairman

The Panel submitted comments to EPA in June on the proposed standards for testing required on cresols under TSCA Section 4. Under this rulemaking, testing will be initiated once the standards are finalized. The panel-sponsored testing, spanning a two-year period, will involve genetic, reproductive and developmental effects studies.

Since coming to CMA, the Panel has worked with EPA's Test Rules Development Branch and Office of Solid Waste, and the National Toxicology Program to ensure that logical and scientifically sound testing programs are conducted on cresols. Panel membership now includes foreign importers as well as domestic producers.

Initiation of the testing is anticipated shortly.

CUMENE

Chairman:
G. Van Gelder
Shell Chemical
Company

Date Chartered:
1984

Current Task Groups:
Toxicology Research
Mutagenicity

Program Managers:
K. Rosica/C. Stack



Chairman

The Panel completed an extensive genetic testing program on cumene and will soon submit the results to EPA. The Agency will use these data in developing a final test rule under TSCA Section 4. The testing was undertaken to clarify results of previous tests which were considered to be technically invalid.

The Program was formed because of the November 1984 Interagency Testing Committee designation of cumene for priority testing. The Panel's objective is to ensure that EPA has sufficient data to make an informed decision on health and environmental effects testing.

Final TSCA rulemaking is expected by the end of 1987. Initiation of environmental and health effects testing under the rule is planned for 1988.

CYCLOHEXANE

Chairman:
R. Cook
Phillips Chemical
Company

Date Chartered:
1985

Current Task Groups:
Toxicology Research
User Exposure Survey

Program Manager:
H. Sauer



Chairman

A Panel survey of the U.S. producers and major users indicates that cyclohexane basically is used in closed systems with monitored workplace exposures near 1 ppm TWAB. The OSHA standard is 300 ppm TWAB. Now the Panel is surveying smaller users to obtain more complete information on potential exposure risk. The Panel was

unsuccessful in negotiating a consent order testing agreement with EPA.

Manufacturers formed the Program in 1985 to address the ITC intent-to-designate cyclohexane for priority testing under TSCA Section 4. The chemical was formally designated in 1986.

Despite EPA's determination that mutagenicity data are adequate and negative, it appears that EPA will require full health effects testing, including carcinogenicity, because cyclohexane is produced in large volume. The Panel is preparing to comment on the proposed TSCA test rule.

DIBENZOFURANS/ DIBENZODIOXINS

Chairman:
K. Burgess
The Dow Chemical
Company

Date Chartered:
1984

Current Task Group:
Technology

Program Manager:
C. Stack



Chairman

Panel activities included: comments on EPA's Health Assessment Document on Dibenzofurans and Toxicity Equivalence Factor scheme for risk assessment; and, involvement in an international information exchange on dioxins and related chemicals sponsored by the NATO Committee on the Challenges of Modern Society. EPA, and the Panel as an intervenor, received a favorable federal court decision in a lawsuit filed by environmental groups. The suit sought reversal of EPA's denial of a petition to initiate TSCA Section 6 rulemaking on dioxins and furans. The decision, handed down in March, affirmed EPA's "right to set its own priorities" and held that the burden rests with the petitioner to demonstrate that a rule is required to protect against an unreasonable health or environmental risk.

The Program was formed in 1984 when the Environmental Defense Fund and the National Wildlife Federation submitted a petition to EPA under TSCA Section 21 which requested regulation of all sources and media containing furans or dioxins.

EPA shortly will publish a final rule under TSCA Sections 4 and 8 that will require analyses of 14 chemicals for the

presence of dibenzofurans and dibenzodioxins as impurities. The Agency also will issue a rule under TSCA Section 8 that will require submission of production, process, use, exposure, and disposal data on chemical products made from 12 precursor chemicals to determine if there is a need for analysis of the products. The Panel submitted comments on the proposed rule in February 1986.

Future Panel activities will address the anticipated TSCA rules and possible actions related to the court decision. Continued participation in the CCMS project is planned.

EPOXY RESINS

Chairman:
H. Flegenheimer
Interchem, Inc.

Date Chartered:
1981

Current Task Group:
Toxicology Research

Program Manager:
H. Shah



Chairman

No new activities were undertaken by the Panel this year. Earlier, the Panel collected and evaluated production, use, exposure, environmental release and health effects information on epoxy diluents represented in the category, "glycidol and its derivatives." In 1984, the Panel submitted this information to EPA in response to the Agency's Advance Notice of Proposed Rulemaking, which sought guidance on how to select representative chemicals from this large and complex category.

The Interagency Testing Committee designated the category for priority consideration by EPA under TSCA Section 4 in 1978. Testing for carcinogenicity, mutagenicity, teratogenicity, other toxic effects and epidemiology were recommended. The Panel still awaits a response from EPA.

ETHYLENE DIBROMIDE

Chairman:
V. White
Great Lakes Chemical
Corporation

Date Chartered:
1982

Current Task Groups:
None

Program Manager:
R. Romano



Chairman

The Panel is waiting to review an OSHA final rule revising the Federal Occupational Standard for EDB. The rule is imminent, but since it has not been issued, the Panel has had no need to meet this year.

The Program was formed to address the OSHA standard and its goal is to ensure that reasonable regulations are adopted. Once the OSHA rule is issued, the Panel will review the requirements and determine the effects on the industry.

ETHYLENE DICHLORIDE

Chairman:
T. Robinson
Vulcan Materials
Company

Date Chartered:
1974

Current Task Groups:
None

Program Manager:
R. Romano



Chairman

The Panel participated in the EPA Clean Air Act Section 112 NAPCTAC hearing last fall. The hearing addressed the Agency's generic Hazardous Organic NESHAP and "intent to list" eight chemicals, including EDC. The Panel opposed EPA's fugitive emissions estimates and questioned health data used to evaluate EDC. The Panel's concerns with EPA Safe Drinking Water Act regulations were incorporated into general comments, filed by the Environmental Management Committee's Safe Drinking Water Act Task Group.

The Program was formed to voluntarily sponsor an EDC toxicology study. The Panel has focused on evaluating current literature, identifying data gaps, and undertaking additional toxicological studies to improve the EDC data base. In addition, the Panel has sponsored research studies on chronic inhalation, metabolism, and teratogenicity.

The Panel will continue to work with the EPA Office of Air Quality Planning and Standards to ensure that the proposal to regulate EDC emissions is realistic. EPA's "intent to list" decision is due shortly. The Panel will review the proposal and provide comments. The Panel will also track Safe Drinking Water Act regulations of EDC in the coming year.

ETHYLENE OXIDE

Chairman:
R. Van Mynen
Union Carbide
Corporation

Date Chartered:
1981

Current Task Groups:
Scientific
Toxicology
Industrial Hygiene
Economic
Environmental
Risk Assessment

Program Manager:
R. Romano



Chairman

In October, the Ethylene Oxide Industry Council presented testimony at the EPA NAPCTAC hearing. The testimony focused on concerns with the Agency's "intent to list" EtO as a hazardous air pollutant under the Clean Air Act Section 112. The EOIC Environmental Task Group has worked closely with the EPA Office of Air Quality Planning and Standards to document EtO emissions. The EOIC also entered into the NRDC vs. EPA "intent to list" lawsuit as an amicus.

The EOIC Industrial Hygiene Task Group conducted a workplace survey of EtO producers. The survey results plus other risk assessment data will be provided to OSHA to assist development of EtO Short Term Exposure Limit. The Task Group also is sponsoring research to establish a STEL equivalency reference method for EtO monitoring.

In support of these activities, the EOIC prepared an in-depth hazard assessment on EtO that was published by CRC Publications in December.

The Clean Air Act Section 112 Hazard Air Pollutant listing decision is expected soon from EPA. The EOIC plans to review and comment on the outcome. In addition,

the EOIC will address the OSHA proposed STEL due next spring, through comments and participation in hearings. Also, the EOIC will track closely the implementation of California's Proposition 65, since EtO is included in the priority list of chemicals to be regulated.

The EOIC was formed to evaluate the results of an animal study that may affect OSHA and EPA regulatory programs. Involved in many regulatory and scientific activities, the EOIC Committees and Task Groups have worked to provide both Agencies with information to make reasonable and scientifically sound decisions on regulatory controls.

2-ETHYLHEXANOIC ACID

Chairman:
R. Gerwe
Tennessee Eastman
Company

Date Chartered:
1984

Current Task Group:
Toxicology Research

Program Manager:
H. Sauer



Chairman

The Panel asked for judicial review of EPA's finding that EHA "may present an unreasonable risk" within the context of TSCA testing provisions. The Panel feels that the requirements are not supported by "substantial evidence." The U.S. Court of Appeals denied the Panel's request for a stay of the testing pending completion of review proceedings. The Panel, therefore, initiated the TSCA testing program recently in order to meet testing deadlines in the final rule.

In 1984, the ITC designated 2-ethylhexanoic acid for priority testing under TSCA Section 4. Following this designation, the Program was formed and began submitting data to EPA that documented the use and manufacturing processes associated with EHA. Since EHA is used solely as a chemical intermediate, and is manufactured and processed in closed systems, the Panel has focused on demonstrating that there is no significant human exposure.

The TSCA testing program should be completed by June 1988. Studies include oral and dermal pharmacokinetics testing, oral subchronic testing, and oral developmental toxicity studies. The judicial review decision is still of concern to the Panel, due to the precedent-setting nature of the EPA testing decision. Also, the decision may affect any additional testing imposed by EPA.

FLUOROCARBONS

Chairman:
R. Orfeo
Allied-Signal
Corporation

Date Chartered:
1972

Current Task Groups:
Atmospheric Sciences
Effects
External Affairs

Program Manager:
E. Gormley



Chairman

The international regulatory community is showing increasing concern over the role that chlorofluorocarbons play in modifying the stratospheric ozone layer and contributing to the 'greenhouse' effect. The United Nations Environment Programme is developing a protocol to regulate CFC production under the Convention for the Protection of the Ozone Layer. In April, a tentative agreement was reached for developed countries to: cap production of some CFCs at 1986 levels by 1990; reduce production by 20% two years later; and, consider further reductions up to 50%. A firm agreement, for discussion by UNEP's diplomatic conference, is expected in September 1987. The U.S. Congress, EPA, and Department of State actively favor an eventual 95% phase-out. Production levels for developing countries are still being drafted.

Settlement of a suit filed by the Natural Resources Defense Council against EPA in 1984 was postponed to allow completion of the UNEP protocol. EPA now has until December 1987 to announce whether additional regulations are needed. A Final Rule is to be announced by August 1988.

Meanwhile, Congress continues to focus attention on this issue by hosting hearings and introducing bills. In May, Chairman S. Robert Orfeo testified at a House of Representatives hearing about research that the Panel cosponsored with NASA, NOAA and NSF on ozone changes in Antarctica.

The Program was formed to fund research on the environmental effects of CFCs. To date, the Panel has supported over \$19 million of research. Sponsored studies have addressed: atmospheric chemistry; atmospheric measurements; modeling; and, trend analysis. Since 1974, the Panel's efforts have largely centered

on the ozone depletion theory. In recent years the program has broadened to include monitoring developments in the climate/greenhouse and bio-effects areas.

In the coming year the Panel plans to fund research on: the mechanisms of the Antarctic ozone depletion phenomenon; heterogeneous and new chemistry; and, future and present day atmospheres. The Panel also will provide seed money for development of a Network for the Detection of Stratospheric Change.

GLYCOL ETHERS

Chairman:
R. Wise
Union Carbide
Corporation

Date Chartered:
1980

Current Task Groups:
Toxicology Research
Industrial Hygiene

Program Manager:
C. Stack



Chairman

Response to TSCA Section 4 rulemaking dominated Panel activities. EPA published a proposed test rule on triethylene glycol ethers in May 1986 and a proposed rule on diethylene glycol butyl ether in August. The Panel filed comments in response to both proposals. The Panel then initiated the mutagenicity testing on DGBE that was proposed by EPA.

In December, OSHA responded to EPA's TSCA Section 9(a) referral of 2-methoxyethanol, 2-ethoxyethanol and their acetates. OSHA preliminarily concluded that occupational exposures at the current permissible exposure limits may present a significant health risk, and that adoption of a revised occupational standard is economically and technologically feasible. OSHA initiated rulemaking by publishing an ANPR in April.

The Program was established to develop an adequate toxicity data base, provide information to users and government agencies on the safety of the chemicals, and promote scientifically sound regulatory action. The Panel has addressed these issues and continues to build on its accomplishments. A series of panel-sponsored subchronic and teratology studies on various glycol ethers served as indicators of comparative toxicity.

EPA recently informed the Panel of interest in initiating the consent agreement process for testing of TGEs. The Panel will be a principal party in the discussions. Future Panel activities also include further testing of DGBE, when EPA issues the final rule, and response to the OSHA ANPR.

HYDROQUINONE/QUINONE

Chairman:
R. Brothers
Eastman Kodak
Company

Date Chartered:
1984

Current Task Group:
Toxicology Research

Program Manager:
H. Sauer



Chairman

The final EPA test rule for hydroquinone under TSCA Section 4 requires oral and dermal pharmacokinetics studies, developmental toxicity, two-generation reproductive testing and neurotoxicity studies. The Panel worked closely with EPA to develop and update final test standards. In addition, the Panel recommended to EPA that hydroquinone be deleted from the listing of acutely toxic chemicals under SARA Title III because the relevant animal effects data do not satisfy the proposed listing criteria.

The Program was formed in response to the proposed TSCA Section 4 test rule published by EPA in 1984. Subsequently, the Panel submitted extensive comments to EPA and participated in the rulemaking hearing. The Panel also voluntarily sponsored a study to assess the potential developmental effects from exposure to hydroquinone. Panel comments describing these results were submitted to EPA.

The Panel's testing program under TSCA Section 4 will begin after final test standards are published. The testing program is scheduled to be completed within 29 months from the effective date of the test guidelines.

KETONES

Chairman:
J. Quance
Exxon Chemical
Americas

Date Chartered:
1980

Current Task Groups:
Toxicology Research

Program Manager:
C. Stack



Chairman

The producers challenged EPA's Final Test Rule on Mesityl Oxide under TSCA Section 4. Legal proceedings in the Fifth Circuit Court of Appeals dominated the Panel's activities over the past year. The MO producers also filed a District Court suit challenging EPA's denial of a petition to withdraw the rule; however, the Court granted a request for a stay of the proceedings until the Appeals Court case is decided.

The decision in the mesityl oxide case is expected to have a major impact on future TSCA Section 4 rulemakings. Three major issues in the case are: 1) Is EPA required to provide substantial evidence of human exposure in order to find that a chemical may present an unreasonable health risk? 2) Can EPA consider use of a chemical as a confined industrial intermediate to support a test rule? 3) Is exposure to a material used in herbicide manufacture a legitimate concern in this context, or should the chemical be excluded from coverage under TSCA?

The Program was formed to address EPA activities on methyl isobutyl ketone, methyl ethyl ketone, isophorone, and mesityl oxide under TSCA Section 4. The Panel negotiated testing programs with EPA to address the Agency's concerns about the first three ketones. Results were submitted to EPA and Agency scientists have expressed satisfaction with the data.

Oral arguments in the MO case are scheduled in July. A decision will follow shortly. The Panel may be required to start testing if EPA finalizes the test standards for the test rule before the decision, unless the Court allows a stay. Because regulatory activities on other ketones are pending, the Panel will continue to monitor activities on methyl isobutyl ketone, methyl ethyl ketone, and isophorone.

LUBRICANT ADDITIVES

Chairman:
C. Keller
Exxon Chemical
Company

Date Chartered:
1980

Current Task Groups:
Environmental Research
MARPOL Efficient
Stripping

Program Manager:
C. Stack



Chairman

The Panel completed an aquatic toxicity testing program on several classes of lubricant additives and submitted the data to the Group of Experts on the Scientific Aspects of Marine Pollution. GESAMP prepares hazard profiles on bulk chemicals in marine transport. The profiles are used by the International Maritime Organization's Bulk Chemicals Handling Subcommittee as the basis for assignment of pollution categories. The categories figure prominently in recently implemented IMO regulations governing disposal of tanker residues.

Research also was completed to show that lubricant additives, although viscous, can be efficiently stripped from ship tank surfaces. The Panel worked closely with the U.S. Coast Guard on the efficient stripping issue and the assignment of appropriate pollution categories. Liaison with the European Additives Technical Committee and CEFIC continues.

The Program was organized to address anticipated international marine pollution control regulations. An immediate concern was the need to generate marine aquatic toxicity data to support proper shipping classification. Another topic that has been addressed by the Panel is the classification of mixtures.

The IMO Subcommittee assigned, for the most part, unfavorable pollution categories to lubricant additives based on conservative GESAMP hazard profiles. The Panel, therefore, is addressing GESAMP's concerns and deciding on further testing. A Coast Guard position paper addressing the efficient stripping issue will be presented to the IMO Subcommittee shortly. If approved, the Panel will develop protocols for the required ship tank testing.

METAL CATALYSTS

Chairman:
B. Knight
United Catalysts, Inc.

Date Chartered:
1984

Current Task Groups:
Toxicology Research
Industrial Hygiene
RCRA

Program Manager:
H. Shah



Chairman

The Panel approved a toxicology research program on nickel catalysts. The program, which includes testing "generic" catalysts in two cell transformation systems at two laboratories, will begin in September 1987. The Panel also began exploring with Dr. Carlo Tamburro of the University of Louisville the feasibility of establishing an occupational health surveillance system for catalyst workers. Tamburro has successfully developed such a system for other chemicals used in industrial settings.

The Program was formed to collect and evaluate information necessary to assess safety, environmental and health issues arising out of the production, storage, transportation, use and disposal of metal-containing catalysts as heterogeneous catalysts in industrial processes. The Panel's objectives include a research program to characterize the toxicity profiles of metal catalysts.

Results from the cell transformation studies will help in determining the need for testing, if any, in the near future. Long-range testing plans will be developed after the Panel has received final reports from the National Toxicology Program's ongoing long-term inhalation studies on nickel compounds, and EPA's ongoing re-analysis of exposure data from previous epidemiology studies. These reports are anticipated in 1989.

METHYLENEDIANILINE

Chairman:
R. Daniel
Dow Chemical USA

Date Chartered:
1982

Current Task Groups:
Risk Assessment
Medical and Toxicology
Analytical and Industrial
Hygiene

Program Manager:
E. Moran



Chairman

The Panel is participating in negotiation of a workplace standard for MDA under the Occupational Safety and Health Act. The negotiations are the first of their kind and involve a 15-person Mediated Rule-making Committee. The Committee is comprised of three industry representatives, three union representatives, and nine government agency representatives. The CMA representative, Roger Daniel, is also the Panel Chairman. The other two industry representatives were appointed by trade associations that also are members of the Panel.

The Committee has met monthly to discuss toxicology, risk assessment, workplace practices, medical surveillance and economic impact. The Panel developed data on economic impact and prepared comments on toxicology and risk assessment. Although some areas of disagreement remain, the Committee has developed a workplace standard that meets the needs of OSHA, industry, and labor unions. The Committee Report is due to be published this July.

The Program was formed in response to the ITC recommendation that 4,4'-methylenedianiline be considered for health and environmental effects testing under TSCA Section 4. In 1983, EPA decided that no additional testing was necessary, but designated MDA as the first "significant risk" chemical under TSCA Section 4 (f). Ultimately in 1985, EPA announced its decision to refer MDA to OSHA, under referral authority provided by TSCA Section 9.

Following publication of the Mediated Rulemaking Report, OSHA will have 30 days to issue the workplace standard as a proposed rule. Although OSHA is not committed to adopt the Committee-developed standard, the proposed rule is not expected to deviate much from the recommendations in the Report. Barring objections to the proposal, the final rule will be published by the end of 1987. The Panel will comment on the proposed rule only if it differs from the mediated standard.

NAPHTHENATE METAL SOAPS

Chairman:
M. Scott
Mooney Chemicals, Inc.

Date Chartered:
1983

Current Task Groups:
None

Program Manager:
H. Shah



Chairman

In April, the Panel received from Shell Oil Company the final report of a study undertaken by Shell, U.K., to evaluate the toxicity potential of an oil additive product that contained calcium naphthenate and calcium carbonate in mineral oil. The study results were submitted to EPA by Shell and the Panel.

The Program was formed as a result of an ITC recommendation that calcium, cobalt and lead naphthenates be considered for testing under TSCA Section 4 for effects on human health and the environment. Since then the Panel has expanded its scope of activities to include addressing EPA concerns in the pesticide area.

The Panel will decide on a course of action when it receives EPA's evaluation of a dermal absorption study that the Panel conducted. The study was part of a voluntary testing program that the Panel worked with EPA to develop. The Panel also awaits a response from the Agency on its comments concerning the need for additional testing of copper and zinc naphthenates under FIFRA.

OCTYLPHENOL

Chairman:
R. Keener
Rohm and Haas
Company

Date Chartered:
1983

Current Task Groups:
None

Program Manager:
H. Sauer



Chairman

Under a TSCA Section 4 agreement, the Panel submitted a final report to EPA on the results of an environmental effects study which involved early-life-stage rainbow trout. The study confirmed a maxi-

mum acceptable toxicant concentration range and identified the no-observed effect level.

In 1982, the ITC designated octylphenol for priority consideration by EPA under TSCA Section 4 and recommended studies on health and environmental effects and chemical fate. The Program was formed to respond to EPA's request for this information.

The Panel will sponsor a chronic life cycle test with rainbow trout to complete the series of studies under a voluntary negotiated testing agreement with EPA. Recently, the EPA Office of Solid Waste expressed an interest in regulating the class of chemicals to which octylphenol belongs. The Panel plans to join with producers of nonylphenol and alkylphenol ethoxylates to form a new Special Program for a coordinated industry response to EPA regulation of the class.

OLEYLAMINE

Chairman:
L. Metcalfe
Alzo Chemie America

Date Chartered:
1984

Current Task Groups:
None

Program Manager:
H. Shah



Chairman

Discussions with EPA continued in this year on the proposed test rule for oleylamine under TSCA Section 4. The Agency now is alert to the complex problems involved in testing this chemical due to its highly corrosive nature and cytotoxicity. EPA, therefore, requested suggestions from the Panel on a feasible research program for subchronic and mutagenicity testing. The Panel has provided these suggestions and awaits the Agency's response.

The Program was formed in response to EPA's TSCA proposed rule requiring data on oleylamine in the areas of pharmacokinetics, genetic effects, and teratogenicity. The Panel will continue working with EPA in developing a scientifically sound testing program.

PHOSGENE

Chairman:
W. Irby
Bayer USA, Inc.

Date Chartered:
1972

Current Task Groups:
Engineering and Safety
Practices
Industrial Hygiene
Medical and Toxicology
Regulatory

Program Manager:
R. Romano



Chairman

The first year of the Panel-sponsored research project on treatment methods for accidental exposures to phosgene was completed at Johns Hopkins University. The research shows several promising leads. The Panel, therefore, approved continuation of the research for another year. In addition, the Panel continued exploring feasibility of a program for evaluating different means of controlling phosgene releases. Enhancing the ability to model a phosgene release is a complementary goal.

The Panel also submitted comments to EPA on the Phosgene Health Assessment Document. In April, members of the Panel's Regulatory Task Group briefed staff of the EPA Office of Air Quality, Planning and Standards at an information exchange meeting. The OAQPS is quickly gathering information in preparation for proposing a hazardous air pollutant regulation in the near future.

The Program was formed to improve industry's ability to safely manufacture, handle and use phosgene. Predicting and controlling ambient concentrations of phosgene from accidental releases has become an important Panel objective.

The Panel will continue information exchange and cooperation with OAQPS. In addition, the Panel will closely monitor other increasing regulatory interest in phosgene. Besides continuing research on exposure treatments, the Panel also plans to develop a phosgene mitigation data base and a field testing program to assess mitigation devices.

PHOSPHORUS (Closed Program)

Chairman:
W. Carpenter
Monsanto Company

Date Chartered:
1985

Current Task Groups:
None

Program Manager:
R. Romano



Chairman

The Program, which terminated in February, was organized to advise the Department of State during development of a U.S. position on the international treaty to control chemical warfare agents. The Panel focused on the potential impact of treaty provisions on the production, distribution in commerce, and use of phosphorus compounds. In this capacity, the Panel held briefings for DOS and Department of Defense personnel and sent representatives to international meetings.

Early in 1987, the list of substances affected by the treaty expanded to include over fifty different chemicals, many of which were not phosphorus-based. The program was therefore closed and the advisory function transferred to the Chemical Warfare Disarmament Work Group of CMA's Health and Safety Committee. The Work Group continues to provide DOS with advice for industry on potential effects of various controls and requirements for inspection and reporting.

PHthalate Esters

Chairman:
D. Finney
Eastman Chemical
Company

Date Chartered:
1973

Current Task Groups:
Toxicology Research
Environmental Research
Industrial Relations
Liaison
Food and Drug
Applications
FDA Toxicology
Research

Program Manager:
E. Moran



Chairman

The Panel worked with EPA in evaluating the health effects testing program that was completed as part of a Negotiated

Testing Agreement under TSCA Section 4. As part of this effort, the Panel sponsored a two-day symposium in Washington on the mechanism of action and species differences in the carcinogenic response of phthalate esters and related compounds. The objective was to put into perspective for FDA, EPA and CPSC, the relevance of rodent bioassay results to man. The proceedings of the symposium, "Recent Advances in Phthalate Esters Research," were published in the Journal of Toxicology and Industrial Health.

The Panel submitted comments on the inclusion of three phthalate esters on the Acute Hazards List of SARA Title III, Section 302. Emergency Planning and Community Right-to-Know. As a result, EPA proposed to remove the phthalate esters from the list. The Panel also filed comments with the NTP requesting removal of di-2-ethylhexyl phthalate from the Fifth Annual List of Carcinogens. Removal would be based upon the likelihood that di-2-ethylhexyl phthalate, although a rodent carcinogen, is not a carcinogen in man. NTP has not announced a decision.

The Program was formed to address environmental issues. In 1976, the alkyl phthalate category was placed on the first ITC list for test rule development under TSCA Section 4. Following the release of results on an NTP bioassay on DEHP and di-2-ethylhexyl adipate, EPA included health effects testing in its concerns. In 1980-81, the Panel worked with EPA to develop the first Negotiated Testing Agreement in lieu of a TSCA Section 4 test rule. The environmental portion of the testing was completed in 1984 and the results were submitted to the Agency along with a proposal for further environmental testing. Unfortunately, the decision in a lawsuit made it impossible for EPA to act on the Panel's proposal.

In 1981, FDA became interested in the indirect food additive uses of DEHA and DEHP, in light of the NTP data. In 1985, FDA became concerned about the levels of DEHP reported in some foods. This year, the Panel conducted a market survey in which milk, meat and cheese samples from different regions of the country were analyzed for DEHP content. The level of DEHP in all test foods was in the range of laboratory control samples. The Panel also designed and now is conducting studies on the pharmacokinetics and liver effects of di-2-ethylhexyl adipate. This program arose from FDA questions on a

DEHA bioassay. DEHA continues as an indirect food additive while the Panel conducts research.

In January, EPA expressed an interest in discussing additional environmental testing on phthalate esters. The Panel currently is planning a program that will include embryolaryval and adsorption/desorption studies on nine chemicals. A consent agreement is expected to be signed with EPA in late 1987. In addition to this testing, the Panel will work closely with EPA in developing the next phase of the health effects testing program.

In other regulatory activities, implementation of SARA, California's Proposition 65, and the Office of Solid Waste rule under RCRA will all require Panel positions, comments to agencies and further cooperation with other Special Programs and CMA Committees.

POlychlorinated Biphenyls

Chairman:
J. Craddock
Monsanto Company

Date Chartered:
1981

Current Task Groups:
None

Program Manager:
E. Gornley



Chairman

The Panel continued addressing PCB disposal and storage requirements as part of the Consensus Group which includes the Environmental Defense Fund, Natural Resources Defense Council, Edison Electric Institute, National Electrical Manufacturers Association and the Hazardous Waste Treatment Council. Congress and EPA believe that the requirements belong under the RCRA. The Consensus Group, however, stressed that the necessary storage and disposal controls can best be incorporated into TSCA with all other PCB regulations. The Consensus Group sees severe complications in movement of PCB controls into RCRA hazardous waste rules.

In April, the Consensus Group successfully persuaded EPA to issue a policy for cleanup of accidental PCB spills. The EPA policy provides guidance on cleanup in a variety of settings. The Group originally submitted a spill cleanup proposal to the Agency in May 1985. The Panel now is as-

sessing the policy and considering additional comments.

The Program was formed to represent the interests of the industry during implementation of the TSCA Section 6 regulations for control of PCBs. The Panel thus far has addressed inadvertent generation of PCBs, mitigation of transformer fires and retention of electrical equipment containing PCBs, as well as disposal and storage requirements and cleanup of accidental spills.

The Panel plans to continue focusing on PCB waste disposal issues and monitoring the spill cleanup policy. Tracking and commenting on the IARC review of PCBs, the implications of California Proposition 65, and the listing of PCBs for action under SARA are also planned priorities.

RUBBER ADDITIVES

Chairman:
B. Hill
Monsanto Company

Date Chartered:
1979

Current Task Groups:
Toxicology Research

Program Manager:
K. Rosica



Chairman

The Panel reviewed the draft results of NTP-sponsored chronic studies on 2-mercaptobenzothiazole. Written and oral comments were presented to NTP's Science Advisory Board in March. The Panel currently is considering further efforts to clarify the inconclusive findings of the reports. A Panel-sponsored voluntary pharmacokinetics testing program on MBT and its disulfide is near completion. The results will be submitted to EPA. The data indicate that the two chemicals are very similar in terms of absorption, distribution, metabolism and excretion.

The Panel formed to support research that would expand the rubber additives data base on safety and health issues. To date, the Panel has collected information on approximately 65 chemicals that are classified as rubber additives, and has sponsored over \$150,000 in research.

The Panel will collaborate with the German consortium, WTR, in continuing efforts to monitor, review and sponsor health and safety studies on rubber additives. The two groups will cosponsor health studies in the coming year. The Panel also will respond to a TSCA Section 4 final test rule on MBT which is expected by the end of 1987.

TITANIUM DIOXIDE

Chairman:
J. Blacker
SCM Corporation

Date Chartered:
1977

Current Task Groups:
None

Program Manager:
H. Shah



Chairman

The Panel continued monitoring the Du Pont epidemiology study on titanium dioxide and titanium tetrachloride. The final report is expected by September 1988. Based on a preliminary analysis of data, it appears that titanium dioxide and titanium tetrachloride do not pose significant adverse health risks for workers.

The Panel was formed to address concerns about potential hazards to workers in the complex atmosphere generated during formulation operations with titanium dioxide.

The Panel plans to comment on EPA's proposed rule to add titanium dioxide to the list of substances identified in the Preliminary Assessment Information Rule. The Rule would require manufacturers and importers to submit production volume, end use, and exposure data to EPA for risk assessment. In the comments, the Panel will maintain that EPA already has appropriate information for risk assessment and thus it is unnecessary to include titanium dioxide in the Rule.

The member companies plan to file petitions for delisting titanium dioxide from the SARA Title III Toxic Chemicals List. The Panel also will track state regulations that have added or plan to add titanium dioxide to their toxic chemicals lists. In a complementary effort, the Panel will continue to work with the National Cancer Institute on its proposal for an epidemiology study at other titanium dioxide plants. The Panel will step up efforts, based on epidemiology study results, to prevent further listings and petition for delisting where necessary.

TOLUENEDIAMINES

Chairman:
Vacant

Date Chartered:
1980

Current Task Groups:
Toxicology
Survey

Program Manager:
C. Stack

The Panel continues to monitor activities within EPA and OSHA on toluenediamines. There has been little action within either Agency over the past year. Through the Panel, TDA manufacturers received a Chemical Advisory issued by the EPA Chemical Control Branch. Manufacturers, in turn, complied with the Agency's request to distribute copies to their customers.

Although EPA is cooperating informally with OSHA under TSCA Section 9 on workplace exposure control, OSHA has not made known its intent in this matter. The Panel awaits the Agency's decision.

The Program was formed in 1982 to address aspects of an Advance Notice of Proposed Rulemaking issued by EPA on phenylenediamines. The Panel subsequently submitted comments to the Agency on sections of the ANPR related to toluenediamines. Since that time, the Panel has remained alert to EPA's concerns and data requirements, and has supplied information as needed.

TRIMELLITATE ESTERS

Chairman:
D. Finney
Eastman Chemical
Company

Date Chartered:
1983

Current Task Groups:
Toxicology Research

Program Manager:
E. Moran



Chairman

The Panel completed the final study on tri-2-ethylhexyl trimellitate that was part of a negotiated testing agreement under TSCA Section 4. The study compared the short-term

liver effects of the trimellitate with the effects of two related chemicals — di-2-ethylhexyl phthalate and 2-ethylhexanol. Results were submitted to EPA in May.

The ITC designated the trimellitate for priority testing under TSCA Section 4 in 1982 and recommended metabolism, sub-chronic, mutagenicity and environmental effects testing. The producers immediately formed a special task group under the Phthalate Esters Panel, and then subsequently formed the Program to pursue a negotiated testing agreement. The testing agreement was reached with EPA in 1984.

When EPA reviews the test data, the Panel will work with Agency scientists to aid in interpretation and in determination of any additional data needs. The Panel now awaits an EPA response.

VINYL CHLORIDE

Chairman:
W. Gaffey
Monsanto Company

Date Chartered:
1973

Current Task Groups:
Research Coordinator

Program Manager:
H. Shah



Chairman

The final report of the Panel-sponsored epidemiologic study of vinyl chloride workers from 1942 to 1982 was completed and sent to pertinent government agencies in October. The study showed an excess in mortality from causes not previously associated with vinyl chloride — non-angiosarcoma and biliary tract tumors. It is uncertain whether the excess really was due to other types of tumors or to angiosarcomas that were misdiagnosed as other liver and biliary cancers.

The Panel was formed to support activities related to the accumulation and assessment of health and safety data on vinyl chloride monomer. After funding several animal studies, emphasis on research shifted from toxicological investigations to

the early diagnosis and clinical management of vinyl chloride-related injuries. In the mid-1970s the emphasis further shifted to epidemiologic studies on vinyl chloride workers.

The Panel currently is exploring the possibility of conducting a pathology review of available tissue specimens and slides to clarify the epidemiologic findings.

VINYLDENE CHLORIDE

Chairman:
Z. Bell
PPG Industries, Inc.

Date Chartered:
1974

Current Task Groups:
Toxicology Research

Program Manager:
R. Romano



Chairman

In August, EPA proposed a TSCA Section 4 test rule on VDC requiring a two-year bioassay. The Panel provided comments on the proposed rule focusing on the lack of findings needed by the Agency to require testing of this chemical under Section 4. Because the EPA Office of Air Quality Planning and Standards referred VDC to the Test Rule Development Branch, the Panel also concentrated on persuading this Office to withdraw its request.

The Program was formed to sponsor investigations of the potential toxicologic effects and pharmacokinetics of VDC. Over the years, the Panel has also tracked significant research projects that can help define potential health and environmental effects of VDC.

The Panel will continue to meet with TRDB and OAQPS in efforts to educate both groups and convince them that an additional bioassay on VDC is unnecessary.

WATER ADDITIVES

Chairman:
J. Gallagher
American Cyanamid
Company

Date Chartered:
1985

Current Task Groups:
None

Program Manager:
R. Romano



Chairman

The Panel held several discussions with the National Sanitation Foundation, the organization that received an EPA grant to establish a program for setting direct and indirect water additive standards. The Panel has numerous concerns with the NSF proposed program. As a result, the Panel has sought alternative programs. It appears that the American Water Works Association will develop a viable program of standards-setting that the Panel feels comfortable in supporting.

The Program was formed to address regulations of direct and indirect potable water additives. The objectives are to monitor regulatory policies, improve communication, review available toxicology data, develop advocacy positions, ensure that any water additive program is designed and administered in a cost-effective manner, and ensure that water additives are used in a manner that does not compromise public health, safety, and the environment.

The Panel will continue to work with all organizations that are developing water additive standards programs in our attempt to find the best one. The Panel soon will participate in the annual AWWA meeting where this organization's standards program will be further discussed and defined.

TABLE 1

FINANCIAL STATUS

For the Twelve Months Ended May 31, 1987

Programs	Balance June 1, 1986	Contribution Receipts	Interest Revenue	Expenditures	Balance May 31, 1987
Alkanolamines	\$ 67,400	\$ -0-	\$ 3,900	\$ 2,700	\$ 68,700
Aromatic Diamines	-0-	10,000	-0-	2,100	7,900
Arsenic	60,100	9,000	2,000	46,900	24,200
Benzene	604,900	-0-	33,300	66,300	571,600
Biocides	15,700	258,100	1,200	170,800	104,200
Butadiene	121,700	159,900	5,600	164,300	119,900
Burylated Hydroxytoluene	14,400	48,000	600	35,600	27,400
Chlorobenzenes	104,300	636,300	7,400	379,700	368,700
Cresols	(14,200)	73,600	2,300	60,800	900
Cumene	126,100	21,900	6,700	80,000	74,700
Cyclohexane	9,500	96,300	1,400	55,200	52,000
Dibenzofurans/Dibenzodioxins	(8,400)	100,000	1,100	38,400	54,300
Epoxy Resins	4,000	-0-	100	1,500	2,600
Ethylene Dibromide	400	-0-	-0-	300	100
Ethylene Dichloride	22,000	-0-	1,100	9,300	13,700
Ethylene Glycol	-0-	187,700	1,400	46,700	142,400
Ethylene Oxide	86,300	297,100	7,500	156,100	234,800
Ethylhexanol	-0-	122,400	600	70,000	52,200
Ethylhexanoic Acid	(19,600)	334,300	1,400	115,800	200,300
Fluorocarbons	3,351,000	1,986,600	178,900	2,263,400	3,253,100
Glycol Ethers	349,900	309,600	21,100	212,300	468,300
Hydroquinone/Quinone	12,600	10,000	300	28,900	(6,000)
Isopropanol	-0-	21,000	100	14,100	7,000
Ketones	155,400	68,000	10,100	96,200	137,300
Lubricant Additives	25,700	74,000	900	79,300	21,300
Metal Catalysts	45,400	97,500	2,200	74,200	70,900
Methylenedianiline	76,400	167,300	500	263,100	(18,900)
Naphthenates	6,900	-0-	300	3,200	4,000
Octylphenol	25,200	-0-	600	26,300	(500)
Olefinamine	13,700	12,500	900	11,900	15,200
Phosgene	134,000	151,700	7,600	167,200	126,100
Phosphorus	6,700	1,800	100	8,600	-0-
Phthalate Esters	949,400	337,700	57,900	303,100	1,041,900
Polychlorinated Biphenyls	10,900	60,000	1,000	56,000	15,900
Rubber Additives	127,400	92,300	7,100	89,000	137,800
Titanium Dioxide	3,900	20,000	100	8,600	15,400
Toluenediamines	23,800	-0-	1,300	2,200	22,900
Trimellitate Esters	14,300	-0-	800	7,800	7,300
Vinyl Chloride	93,400	-0-	4,100	45,400	52,100
Vinylidene Chloride	37,400	-0-	1,300	45,200	(6,500)
Water Additives	7,200	55,500	(200)	52,100	10,400
Totals	\$6,665,200	\$5,817,100	\$ 374,200	\$5,361,000 =	\$7,495,500

Each program is required to maintain a CASH COMPENSATING BALANCE which recognizes that CMA signs all contracts on behalf of the panels and assumes the financial liability for panels meeting their contractual commitments. The balance permits timely honoring of financial commitments. The combined compensating balance for all Special Programs at the beginning of Fiscal Year 86-87 was nearly \$6.7 million. Compensating balances on May 31, 1987 totalled approximately \$7.5 million. On this date, CMA had financial liabilities totalling about \$7.4 million under 195 executed contracts on behalf of the various panels.

INTEREST on the unexpended cash balance provides supplemental revenue for each Special Program. This year, programs earned a combined total of approximately \$374 thousand in interest income.

EXPENDITURES of Special Programs are based on budgets approved by each panel. In Fiscal Year 86-87, programs spent a collective total of \$5.4 million for research, consultants, legal counsel and program management.

Figure 1

SPECIAL PROGRAMS FINANCIAL ALLOCATIONS

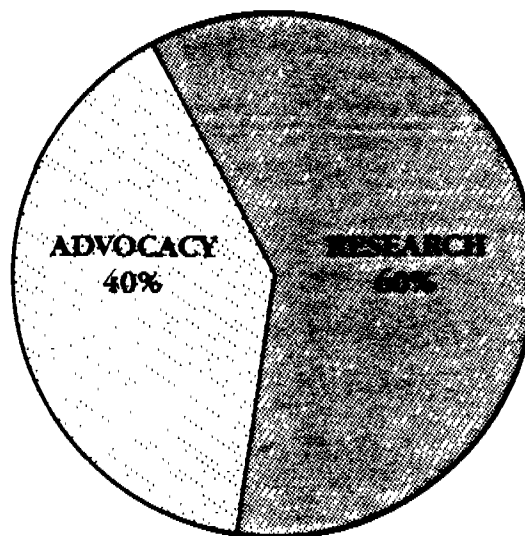


Figure 2

SPECIAL PROGRAMS

SUBMISSIONS TO GOVERNMENT AGENCIES

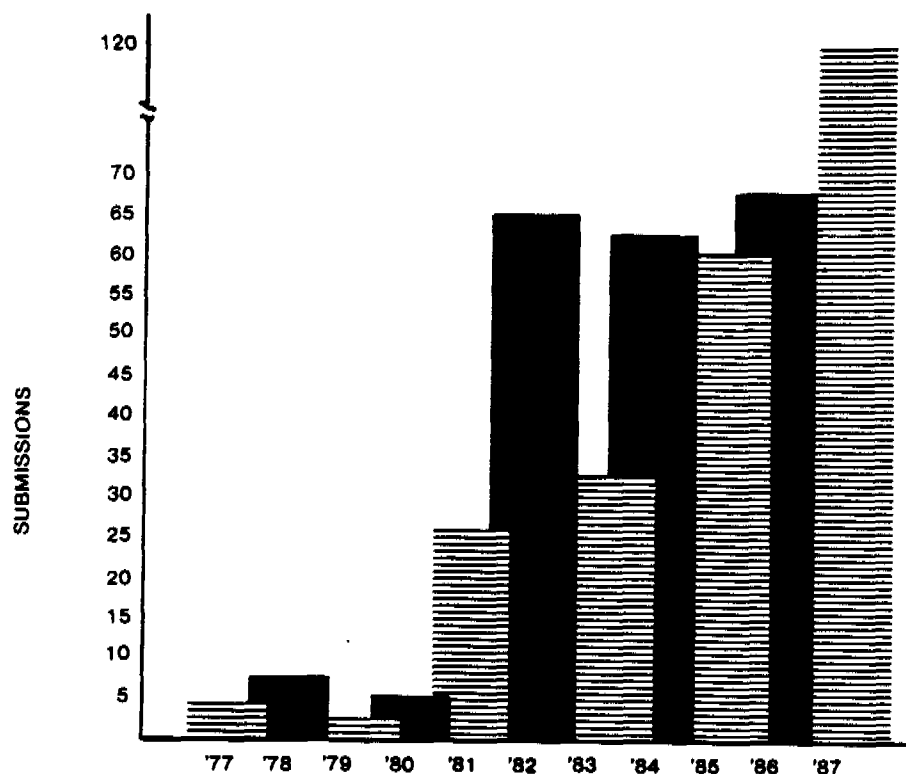
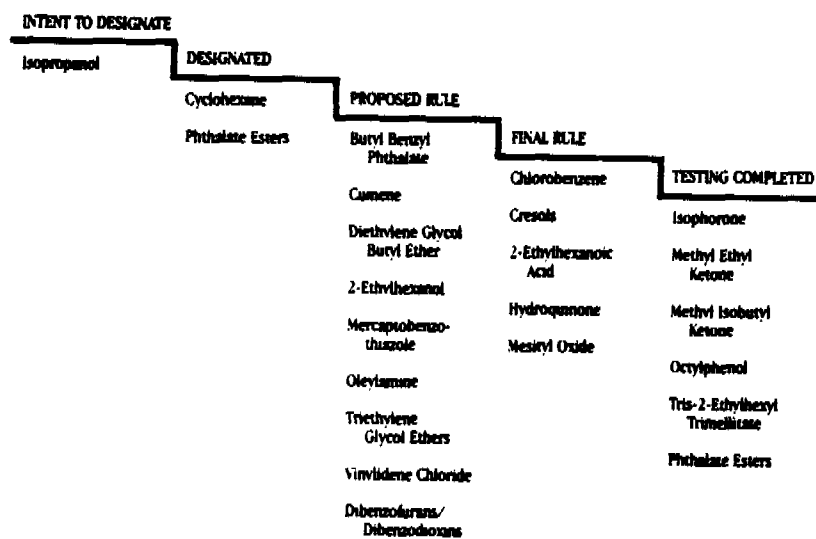


Figure 3

SPECIAL PROGRAMS

STATUS OF CHEMICALS UNDER TSCA SECTION 4



In all, 35 Special Programs worked directly on regulatory issues this year.

Panels, as usual, submitted comments on pending regulations and research data to a wide variety of federal, state and international agencies.

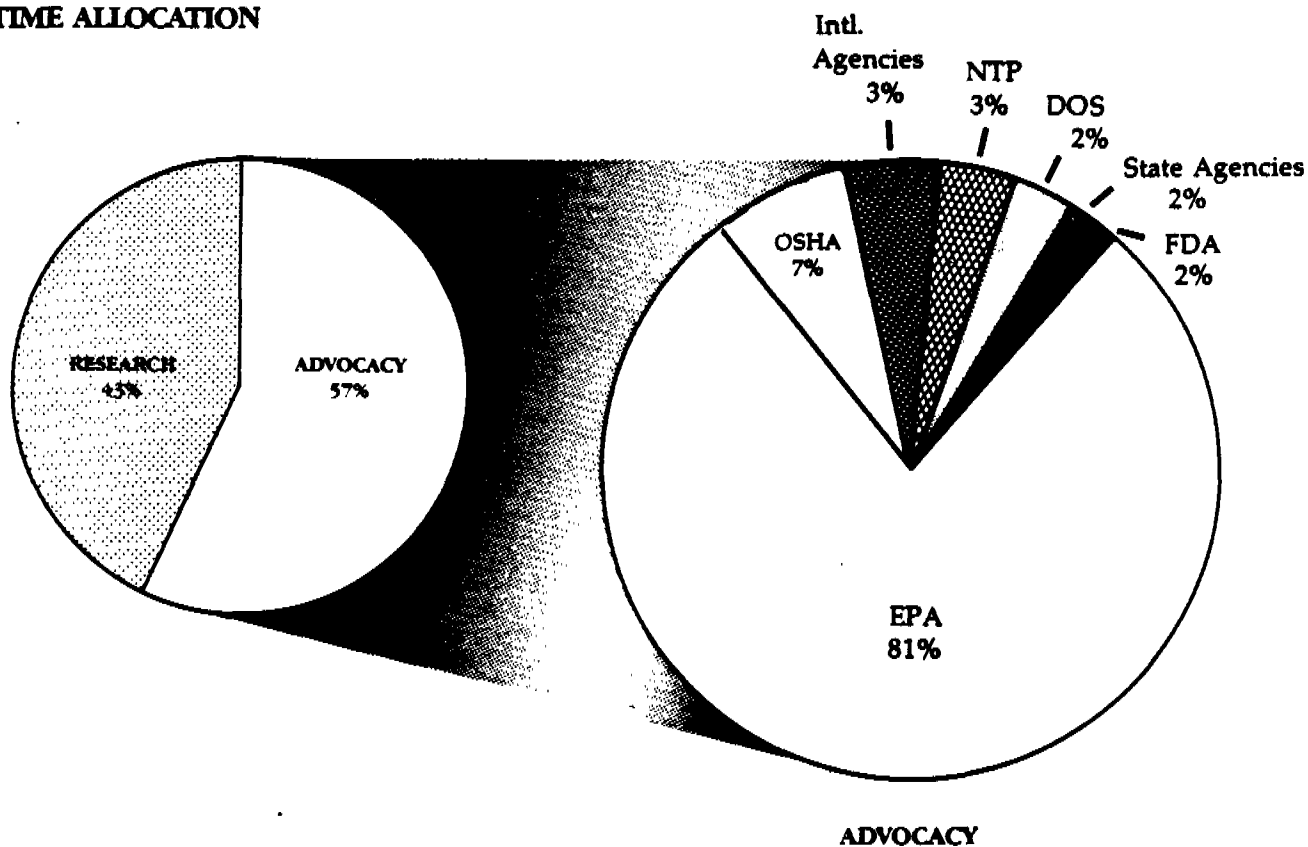
Foremost in attention among federal agencies was EPA. TSCA Section 4 testing is a major emphasis of 24 panels (Figure 3). Environmental regulations that caused increased efforts were the Clean Air Act, Safe Drinking Water Act, and RCRA. In an emerging interest, panels increasingly addressed FIFRA concerns. During the year, other federal agencies that panels cooperated with were the Food and Drug Administration, Occupational Safety and Health Administration, National Toxicology Program, and the National Cancer Institute.

Among state agencies, the California Department of Food and Agriculture commanded the most attention because of Proposition 65 implementation and data call-ins on industrial chemicals. In the international area, the United Nations Environment Programme, U.S. Department of State, International Maritime Organization, and the Food and Agriculture Organization/World Health Organization were principal focuses.

Figure 4

SPECIAL PROGRAMS

STAFF TIME ALLOCATION



The launching of the ozonesonde at McMurdo Station (picture) is one example of panel-sponsored research. The Fluorocarbon Program Panel co-sponsored atmospheric measurements in the 1986 Antarctic Ozone Campaigns with NASA, NOAA, NSF, the British Antarctic Survey, and the Lauder Group. Fluorocarbon Program research funds also are used to sponsor chemical kinetics studies, atmospheric and climate modeling, biological effects monitoring, and other studies related to the atmospheric fate of chlorofluorocarbons.



Thirty-three Special Programs sponsored some form of research. The trend this year was toward fewer, but larger, projects.

Health effects studies were a major focus. Toxicological research involved subchronic/chronic, mutagenicity, teratogenicity, oncogenicity and pharmacokinetics studies. Direct effects on humans were investigated by several programs through epidemiology and clinical research. Risk assessments and exposure surveys were other forms of research undertaken by nearly a quarter of all Special Programs. Environmental studies, including the atmospheric sciences, increased this year, reflecting greater interest in air and water regulations, in particular.

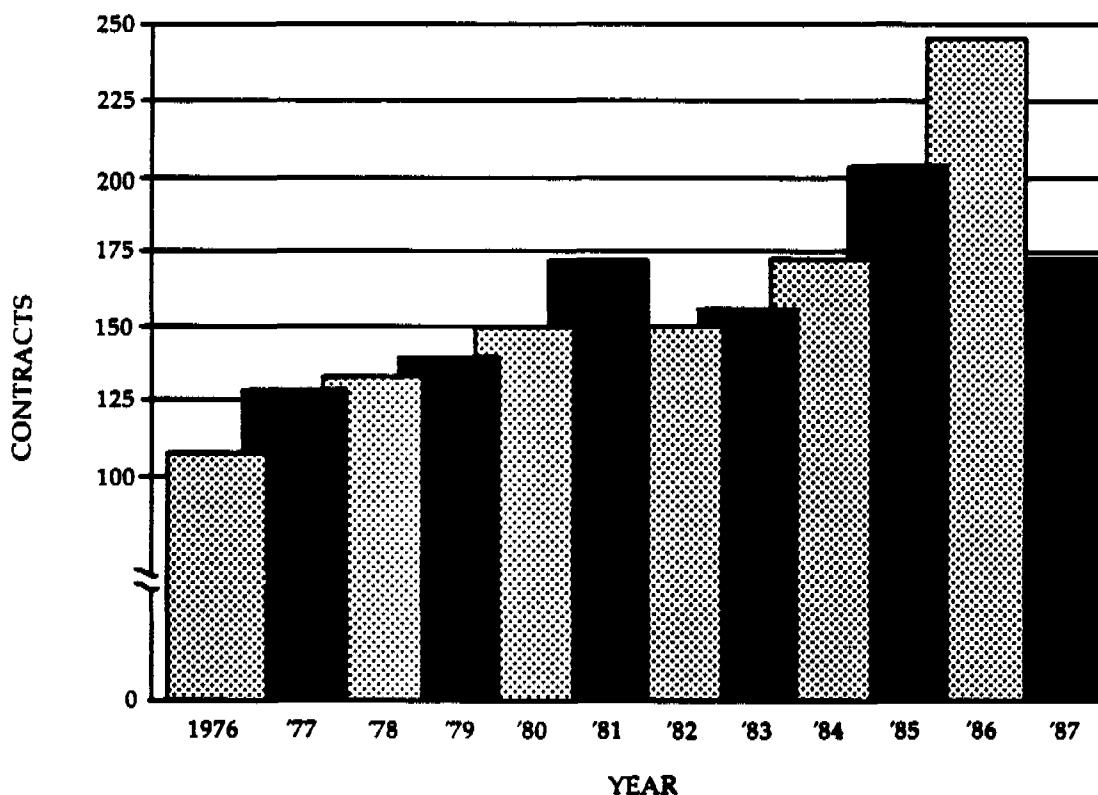
Testing required under TSCA Section 4 was initiated by several Special Programs. Mainly, the tests are large-scale efforts lasting several years. The testing schemes include many decision points where EPA and industry scientists must interpret data and decide on next steps.

As in the past, some panels undertook studies simply because of research findings rather than direct regulatory concerns. "Proactive" research of this kind continues to be a significant part of Special Programs scientific efforts.

Figure 5

SPECIAL PROGRAMS

SUMMARY OF CONTRACTS MANAGED FOR THE SPECIAL PROGRAMS



The Special Programs Policy Committee ensures that all Special Programs are conducted in a manner consistent with Association Policy, and with the Special Programs Guidelines; counsels with Special Programs regarding new and revised operating needs; and, reviews and makes recommendations on all advocacy programs on individual chemicals requested by a program panel or staff.

SPECIAL PROGRAMS POLICY COMMITTEE MEMBERS



Chairman:
Harry Corless
ICI Americas Inc.



Vice Chairman:
Keith R. McKennon
The Dow Chemical Company



Geraldine V. Cox
Vice President-
Technical Director
CMA



Gary C. Herrman
Vice President-Treasurer
CMA



David F. Zoll
Vice President-
General Counsel
CMA

Langley A. Spurlock
Staff Executive
CMA

For 1987-88:

Chairman:
Edwin L. Stenzel
BASF Corporation

Vice Chairman:
Earnest W. Deavenport, Jr.
Eastman Kodak Company

Figure 6

SUMMARIES OF PRINCIPAL GUIDANCE STATEMENTS FOR THE SPECIAL PROGRAMS

SPECIAL PROGRAMS OPERATING PRINCIPLES

The Principles present the general statement of policies and procedures for operation of all Special Programs. They address:

- Program Authorization
- Participant Financial Obligations
- Policy Coordination
- Research Output

SPECIAL PROGRAMS GUIDELINES

The Guidelines provide details of policies and procedures that are generally stated in the Operating Principles. This document is the primary reference for specific operations of special programs and the Special Programs Division. Topics covered include:

- Program Initiation Procedures
- Membership Criteria
- Responsibilities of Panel and Task Group Participants
- Financial Administration and Budgeting
- Contracting Procedures
- Information Handling
- Oversight Mechanisms

The Division staff managed more Special Programs during 1986-87 than ever before. The full staff complement of seventeen persons did not increase during the year. The managing staff underwent no changes from the previous year.

DIRECTOR

Langley A. Spurlock, Ph.D.

Dr. Spurlock marked his fifth year as Director of the Biomedical and Environmental Special Programs Division. He is responsible for oversight of all Special Programs.

Before joining CMA, Dr. Spurlock held an appointment in the U.S. Government Senior Executive Service at the National Science Foundation. During his tenure at NSF he served as Senior Staff Associate for Operations, Directorate for Mathematical and Physical Sciences, Special Assistant to the Director, Office of Planning and Resources Management, and as Oversight Coordinator and Special Assistant to the Director, Office of Audit and Oversight. Previously, Dr. Spurlock received an appointment as U.S. Department of Health, Education and Welfare Fellow, and served as Special Assistant in the Immediate Office of the Secretary of HEW. Earlier, he was Assistant to the President at the American Council on Education. Before coming to Washington, Dr. Spurlock held an appointment as Associate Professor of Chemistry at Brown University and earlier was Assistant Professor of Chemistry at Temple University. Previously, he served as Senior Research Chemist in the General Chemical and Agricultural Chemical Divisions of Allied Corporation. Dr. Spurlock received a Ph.D. in Organic Chemistry from Wayne State University.

ASSOCIATE DIRECTORS

Robert R. Romano, Ph.D.

Dr. Romano joined CMA in 1980 as a manager in the Environmental Division where he was responsible for the water and air programs. In February 1985, he joined the Special Programs Division as an Associate Director. He continued this year as manager of the programs on butadiene, ethylene dibromide, ethylene dichloride, ethylene oxide, phosgene, water additives, and vinylidene chloride. Recently he also assumed management of the program on chlorine dioxide.

Dr. Romano came to CMA from the U.S. Nuclear Regulatory Commission, where he worked as an Associate Project Director. Previously, he worked on a school fluoridation project for Indiana State Board of Health. He has also taught at Del Mar College and American University. Presently, Dr. Romano is an adjunct Environmental Engineering Professor at George Washington University and teaches a course in environmental management. He received a Ph.D. in Environmental Sciences from Purdue University.

Carol R. Stack, Ph.D.

Dr. Stack joined CMA and the Special Programs Division in 1980 and was promoted to Associate Director in 1985. She is currently responsible for management of the programs on ethylene glycol, glycol ethers, benzene, chlorobenzenes, ketones, lubricant additives, dibenzofurans/dibenzodioxins and toluenediamines.

Before joining CMA, Dr. Stack was employed in the Toxicology and Biomedical Science Department at Equitable Environmental Health, where she served as an Assistant Project Director responsible for the preparation of NIOSH multi-chemical criteria documents. Earlier, she served as Visiting Scientist at the Neurological Institute of Bogota, Colombia, where she investigated central auditory pathways in echolocating birds. Dr. Stack received a Ph.D. in Biology from New York University.

PROGRAM MANAGERS

Elizabeth Festa Gormley, B.A.

Ms. Festa Gormley joined CMA and the Special Programs Division in 1983. She is responsible for the management of the fluorocarbons and polychlorinated biphenyls programs.

Prior to joining CMA, she was Section Staff Executive with the National Electrical Manufacturers Association.

ciation, where she was responsible for the Nuclear Magnetic Resonance Imaging Section with the Diagnostic Imaging and Therapy Systems Division. Previously, Ms. Festa Gormley worked in the Endocrine Biochemistry section of the National Institute of Arthritis and Metabolic Diseases at the National Institutes of Health, and held the position of Research Chemist at both the CENTEC Corporation and Radian Corporation. She was also a recipient of a National Science Foundation Assistantship. Ms. Festa Gormley earned a B.A. in Chemistry from Albertus Magnus College.

Elizabeth J. Moran, Ph.D., D.A.B.T.

Dr. Moran joined CMA and the Special Programs Division in 1981. She continued this year as manager of the programs on phthalate esters, trimellitate esters and methylenedianiline and assumed management of two new programs on 2-ethylhexanoic acid and specialty acrylates and methacrylates.

Dr. Moran is a biochemist and Board Certified toxicologist. She is currently on the Editorial Board of the Journal of Toxicology and Environmental Health. Before coming to CMA, she was a program manager at JRB Associates. Earlier, Dr. Moran directed the Flavor Safety Program at International Flavors and Fragrances, Inc., where she was responsible for toxicological testing on new chemicals. Previously, Dr. Moran conducted lipid nutrition research at the U.S. Department of Agriculture and was a visiting professor at the University of Maryland. Dr. Moran received a Ph.D. in Biochemistry from the University of Maryland.

Henry J. Sauer, MBA

Mr. Sauer joined the Special Programs Division in May 1986. He had been Manager of the CMA Energy and Engineering Section since 1984, and the Energy Committee Staff Executive since he joined CMA in 1977. At CMA he also served as Manager of the Solid Wastes Management Committee; Manager of the Environmental Management Committee Task Groups on New Source Performance Standards for Industrial Boilers and Process Emission Regulations; Manager of the Insurance Committee, and Manager of the Special Program on Benzene. He is responsible for management of the programs on cyclohexane, alkanolamines, hydroquinone, ethylhexanoic acid, and octylphenol. He is also actively involved in management of the program on fluorocarbons.

Prior to joining CMA, Mr. Sauer had chemical industry experience in sales, marketing research, applications research and commercial development. Just before joining CMA, he was Development Manager, Fine Chemicals Group, Great Lakes Chemical Corporation. Earlier, he was employed at PPG Industries as Marketing Research Representative in the Industrial Chemical Division and the Coatings and Resins Division, and as Assistant to the Sales Manager and Technical Sales Representative. He previously served as First Lieutenant in the U.S. Army Corps of Engineers. Mr. Sauer holds an M.B.A. from the University of Pittsburgh, and a B.S. in Chemical Engineering from Carnegie Mellon University.

Hasmukh C. Shah, Ph.D., D.A.B.T.

Dr. Shah joined CMA and the Special Programs Division in 1979. He is responsible for management of the programs on arsenic, biocides, butylated hydroxytoluene, metal catalysts, titanium dioxide, vinyl chloride, oleylamine, and naphthenate metal soaps.

Dr. Shah is a Board Certified toxicologist. Before coming to CMA, he was the Director of the Toxicology and Biomedical Sciences Department of Equitable Environmental Health. He was also the Project Director for the National Institute for Occupational Safety and Health's criteria document project, and for the "Profiles on Occupational Hazards for Criteria Document Priorities." Earlier, at the Stanford Research Institute, Dr. Shah was a Project Coordinator, and served as a Senior Toxicologist. He previously was a Visiting Fellow Scientist at the National Institute for Environmental Health Sciences. Dr. Shah received a Ph.D. in Pharmacology and Toxicology from the University of Rhode Island.

MANAGER

Kathryn A. Rosica, B.S.

Ms. Rosica joined CMA and the Special Programs Division staff in 1986. She is responsible for management of the programs on cresols, isopropanol, cumene, aromatic diamines, and rubber additives. She is also actively involved in management of the programs on phthalate esters and hydroquinone.

Before coming to CMA, Ms. Rosica was a staff toxicologist for the Region I Superfund Division of the NUS Corporation, where she prepared risk assessments of hazardous waste sites in New England. Previously, she was employed as a toxicologist at General Electric Company, ICI Americas Inc. and SISA Pharmaceuticals, Inc. Ms. Rosica holds a B.S. in Toxicology from Northeastern University.



Bottom to top, left to right: Langley A. Spurlock, Haemuldh C. Shah, Carol R. Seack, Kathryn A. Rosica, Henry J. Sauer, Elizabeth F. Gormley, Robert R. Romano, and Elizabeth J. Moran.