DRAFT 12/23/83

SPECIAL PROGRAMS ADVISORY COMMITTEE
1983 REPORT TO THE
BOARD OF DIRECTORS

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I: INTRODUCTION

Division Mission

The Biomedical and Environmental Special Programs Division provides strategic planning, technical, management, and administrative services to companies that jointly conduct programs of advocacy and research on specific chemicals that fit within the framework of generic industry concerns. The focuses of program activities are outlined in Figures 1 and 2.

Advocacy programs promote information exchange with regulatory agencies and legislative bodies in order to aid development of efficient, effective regulations and laws. Research programs expand the data base for improving the workplace and general environment. Research programs also support advocacy by generating the high-quality scientific information on which regulatory and legislative decisions should be based.

The Division's goal is to ensure that companies achieve their advocacy and research objectives while maintaining the high standards and consistent approaches prescribed by CMA policies.

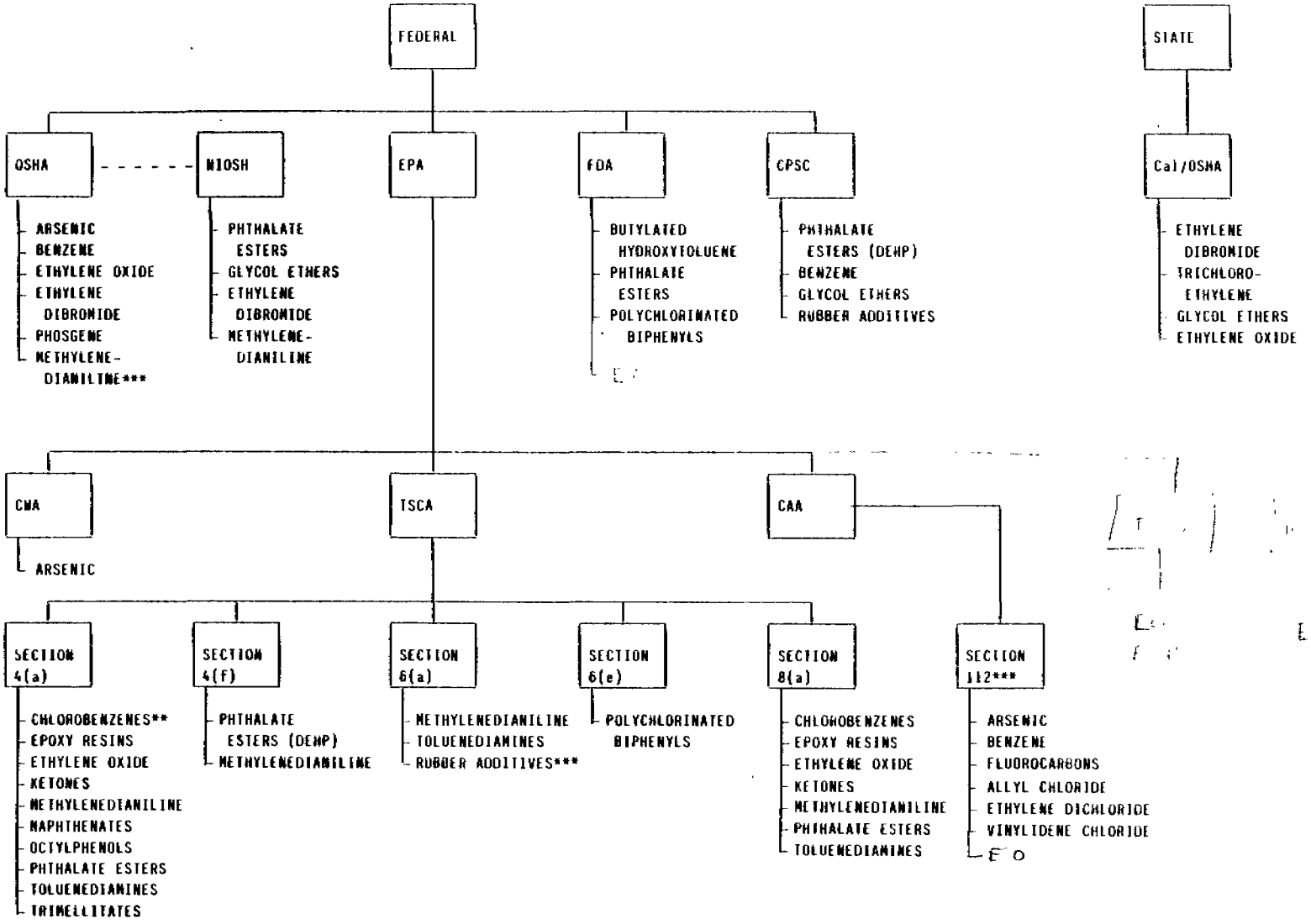
SPAC Mission

The CMA Executive Committee has given the Special Programs Advisory Committee (SPAC) a mandate to serve in an advisory capacity to ensure that all special programs are conducted in a manner consistent with CMA policy and the Special Programs Guidelines.

Over the past year SPAC has been performing its mandated function by conducting program reviews and by reviewing and making recommendations on the Special Programs Division management and planning.

BIOMEDICAL AND ENVIRONMENTAL SPECIAL PROGRAMS DIVISION

Summary of Regulatory Activities*



* For details, see Program Summaries.
** Advocacy Under SOCMA.
*** Being considered for regulation.

Figure 1

CMA 053985

BIOMEDICAL AND ENVIRONMENTAL SPECIAL PROGRAMS

Summary of Research Activities

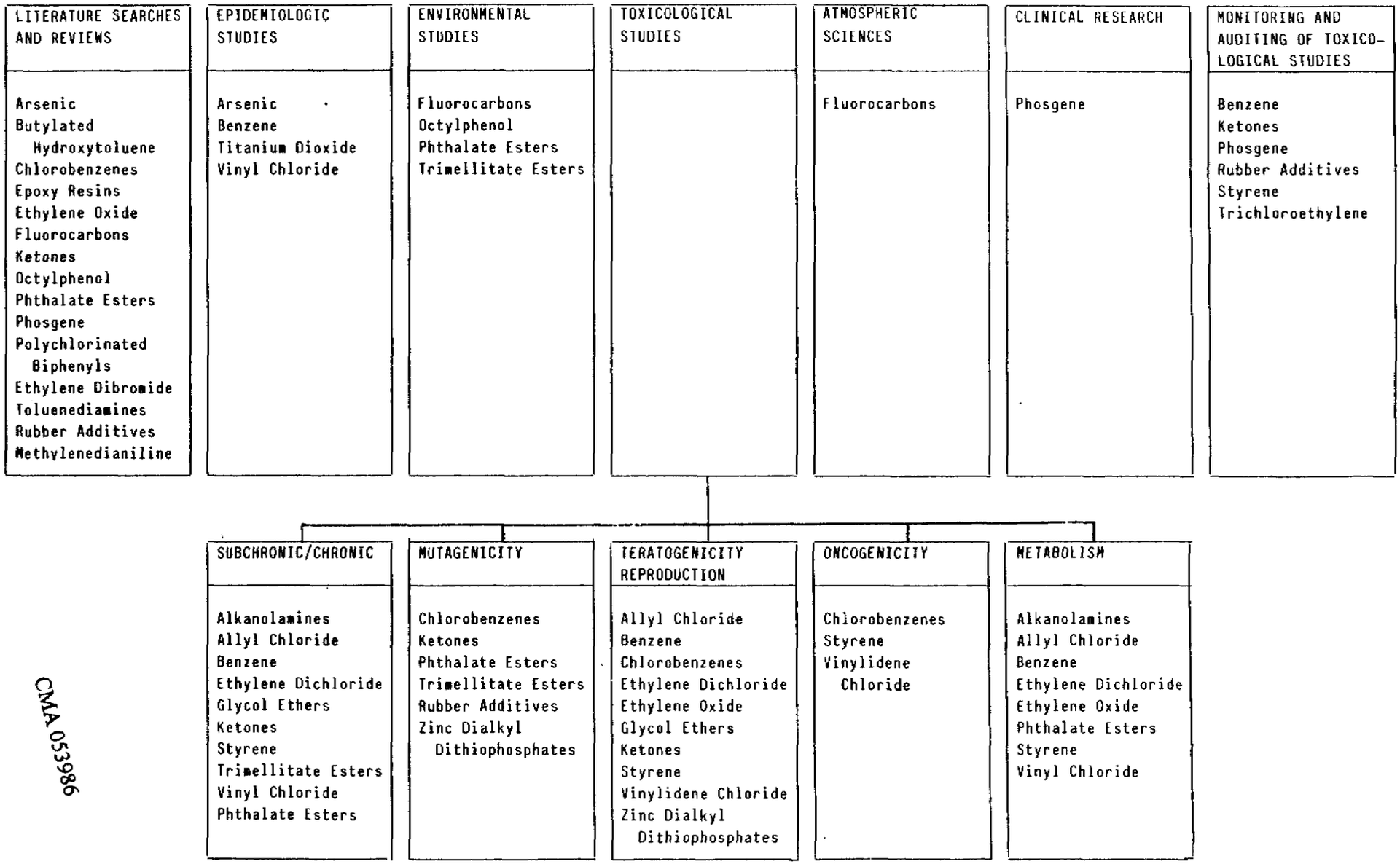


Figure 2

II: ALLOCATION OF RESOURCES

Finances

During FY 82/83, 24 research and advocacy programs spent a total of $4,593,000. The current Fiscal Year began with a balance-due on active contracts of $7,214,300. Figure 3 illustrates the financial status of all programs on November 30, 1983.

For its services in FY 82/83 the Division received $980,200, acquired through direct charges and interest on undisbursed program funds. The Division budget for FY 83/84 projects $1,272,000 in revenue, which must compensate all operating expenses incurred.

Research and Advocacy

Figure 4 indicates the distribution of collected funds between research expenditures and advocacy expenditures in the past year. Figure 5 reflects the sustained high level of research contract activity over the past several years.

Figure 6 illustrates the allocation of time by Division staff members to advocacy and research and, within advocacy, to various government agencies.

Personnel

Approximately 300 panel members represent 120 companies and associations on Special Programs panels. The Special Programs Division employs a staff of 15.

CHEMICAL MANUFACTURERS ASSOCIATION
Special Programs
Five Months Ended October 31, 1983

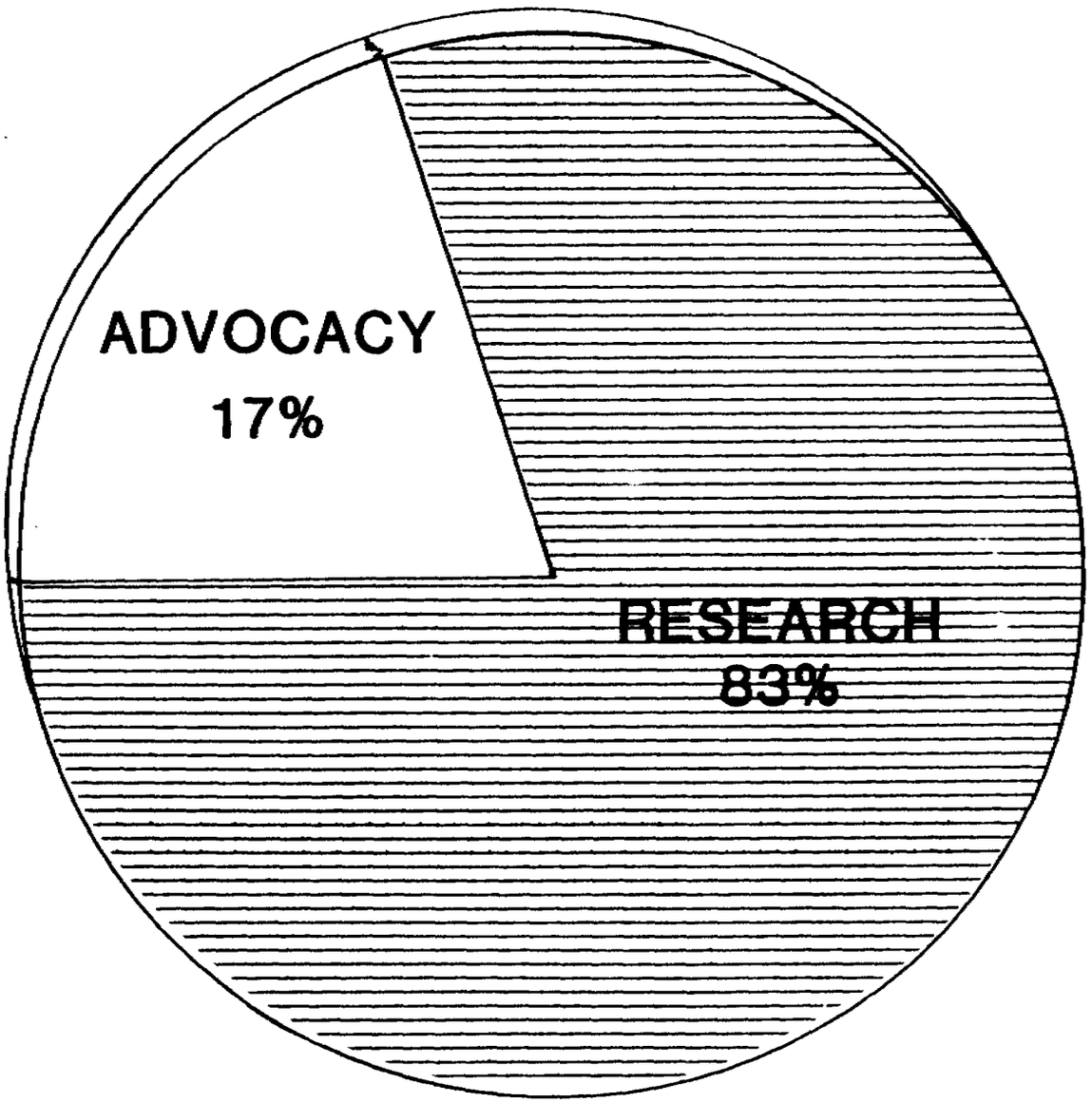
(Rounded to Nearest Hundred)

SPECIAL PROGRAM	Balance June 1, 1983	Contribution Receipts	Interest Revenue	Disbursements	Balance October 31, 1983
Biomed. & Envtl. Research					
Acrylonitrile	$ 23,800	(-1,629. $ 79) --	$ 900	$ 1,600	$ 23,100
Alkanolamines	82,800	--	2,400	41,600	43,600
Allyl Chloride	13,400	(13,400) --	500	100	13,800
Arsenic	145,600	65,000	4,800	102,700	112,700
Benzene	1,054,800	(120,350) --	37,400	117,400	974,800
Butyl Hydroxytoluene	14,600	(14,600) 3,000	500	6,000	12,100
Chlorobenzenes	176,300	5,800	6,300	19,900	168,500
Epoxy Resins	12,600	4,000	300	12,200	4,700
Ethylene Dibromide	29,900	7,600	1,100	13,300	25,300
Ethylene Dichloride	35,100	(12,600) --	1,200	10,400	25,900
Ethylene Oxide	368,700	175,600	13,600	295,100	262,800
Fluorocarbons	2,927,800	900,000	111,200	666,600	3,272,400
Glycol Ethers	512,500	139,800	17,500	214,000	455,800
Ketones	225,300	256,900	10,400	58,600	434,000
Methylenedianiline	22,600	7,000	400	32,300	(2,300)
Naphthenates	--	14,000	--	13,300	700
Octylphenol	7,600	3,100	(100)	22,000	(11,400)
Phosgene Safety	60,000	--	1,800	29,500	32,300
Phthalate Esters	931,700	--	32,000	149,200	814,500
Polychlorinated Biphenyl	78,400	12,000	2,600	20,800	72,200
Rubber Additives	38,100	--	1,100	14,800	24,400
Styrene Monomer	33,200	--	1,200	300	34,100
Titanium Dioxide	3,800	(5,000) --	100	4,400	(500)
Toluenediamine	31,200	--	1,100	2,000	30,300
Trichloroethylene	(300)	(40,700) --	(100)	3,200	(3,600)
Trimellitate	1,000	12,000	200	5,400	7,800
Vinyl Chloride	234,500	--	8,700	21,500	221,700
Vinylidene Chloride	33,600	(-68,540) --	1,100	7,400	27,300
Zinc Dialkyl Dithiophosphates	145,700	5,000	4,100	57,900	96,900
Total Biomed. & Env. Related	$7,244,300	$1,610,800	$ 262,300	$1,943,500	$7,173,900

CMA 053988

Figure 3

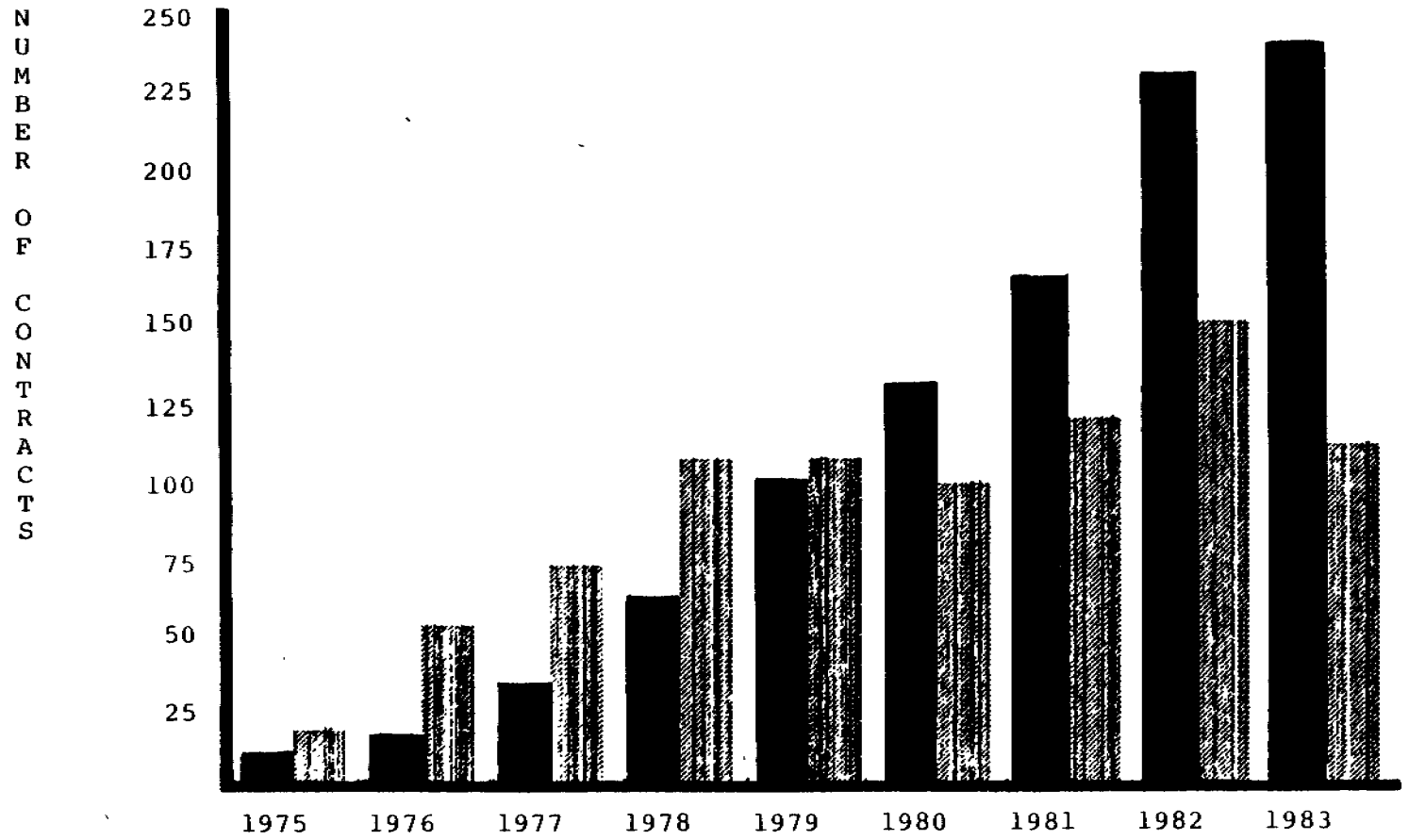
SPECIAL PROGRAMS FINANCIAL ALLOCATIONS



CMA 053989

Figure 4

IN PROGRESS AND COMPLETED CONTRACTS



CMA 053990

Figure 5

BIOMEDICAL AND ENVIRONMENTAL SPECIAL PROGRAMS DIVISION

STAFF TIME ALLOCATION 1983

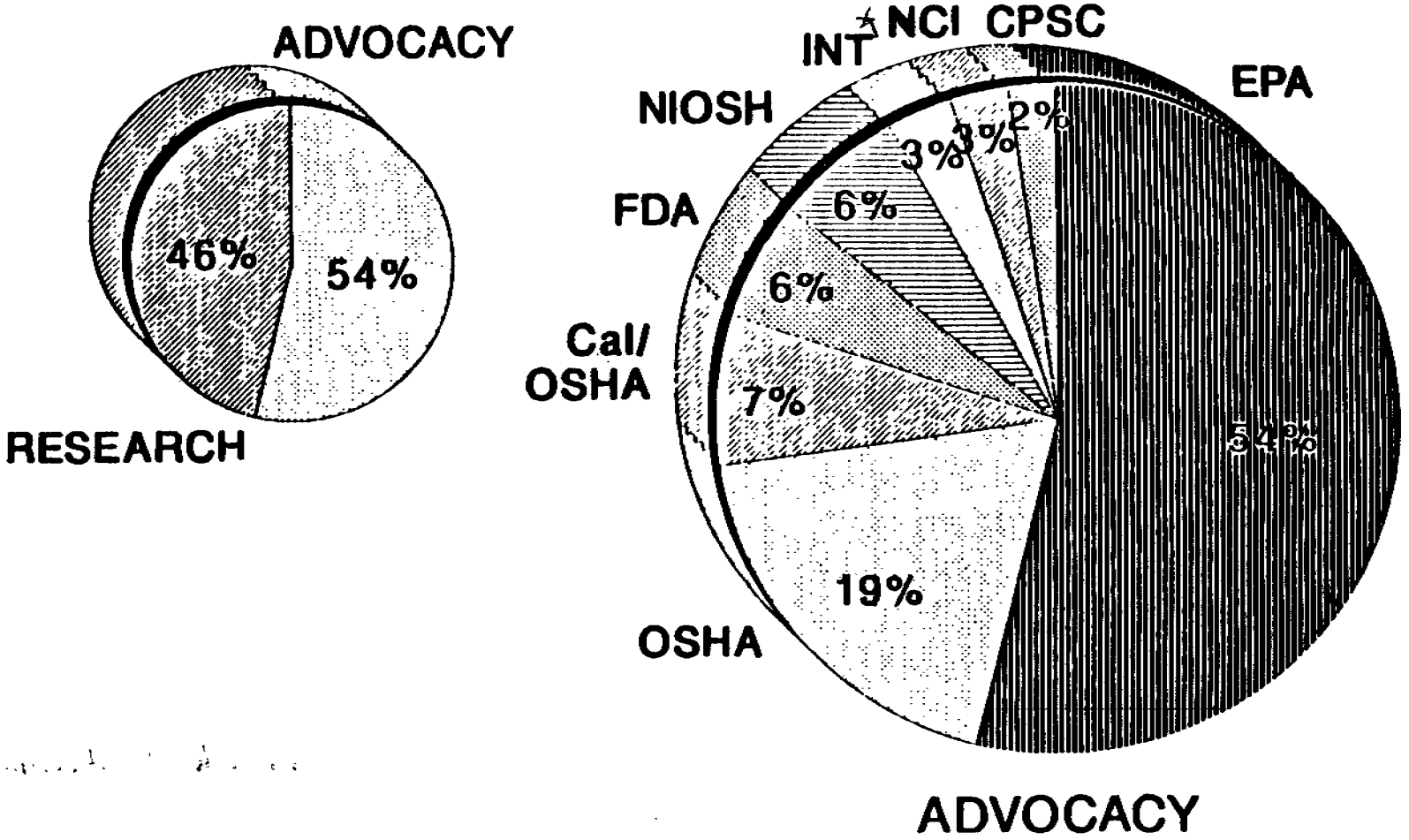


Figure 6

CMA 053991

III: PROGRAM HIGHLIGHTS

CMA and Environmental Groups Submit Proposal to EPA

CMA, the Environmental Defense Fund and the Natural Resources Defense Council jointly submitted to EPA a proposal for regulating the inadvertent generation of PCBs. PCBs can be unintentionally generated during the manufacture of many industrial chemicals. EPA relied on the Consensus Proposal as the framework for its proposed rule, published on December 8, 1983.

EPA Designates the First "Significant Risk" Chemical

4,4'-Methylenedianiline (MDA) was the first chemical designated by EPA under Section 4(f) of TSCA. Subsequently, EPA and OSHA published Advance Notices of Proposed Rulemaking (ANPRs). The MDA Panel filed comments in response to the Section 4(f) designation and to the ANPRs. As a further response the Panel initiated an extensive survey of MDA users. The purpose of the survey is to collect current information on the use, exposure and environmental release of MDA. The results of the survey will be submitted to EPA and OSHA.

Panel has Major Impact on International Research

The Balloon Intercomparison Campaign was conceived by the Fluorocarbon Panel to calibrate the best instruments available in the U.S., Europe and Japan for measuring critical trace species in the stratosphere. After a successful Phase I in Fall 1982, Phase II flew in Spring 1983. A total of 17 instruments were carried to a height of 20 Km on four huge ballons. Despite delays caused by bad weather, and the malfunctions of the two balloons, sufficient data was collected to indicate a tremendous success for the experiment. Publication of results is expected in 1984.

Twice annually the Fluorocarbon Panel holds Science Sessions at Panel meetings outside the U.S. Each Session addresses a topic such as, modeling of the stratosphere (France-April 1983), and atmospheric measurements (Germany-October 1983). A variety of experts are invited by the Panel to make presentations and participate in lively, informative discussions.

Scientists from around the world have also participated in Workshops sponsored by the Panel. These workshops fulfill two functions: they encourage discussion and dissemination of information among investigators; and they aid the Panel in determining directions for future efforts. Most recently the Panel cosponsored a Workshop with the National Bureau of Standards (NBS) on Atmospheric Spectra. NBS will publish the proceedings.

Panel Completes First Phase of Voluntary Testing Program

The Phthalate Esters Panel completed Phase I of its research program which was conducted under a Negotiated Testing Agreement with EPA. In Phase I of the environmental effects program, 14 phthalate esters were tested in a battery of environmental fate and acute aquatic toxicity studies. The Phase II environmental effects proposal has been accepted by EPA. Testing will include chronic toxicity tests in aquatic organisms and bioconcentration studies in two species on five phthalate esters. The Phase II Health Effects proposal, which was also accepted by EPA, includes mutagenicity and subchronic studies.

Panel Begins EPA-Approved Programs

The Ketones Panel successfully negotiated testing agreements with EPA on three ketones, methyl isobutyl ketone (MIBK) methyl ethyl ketone (MEK) and isophorone. Teratology and mutagenicity tests were intitated in 1983. The subchronic study on MIBK was completed and submitted to EPA.

Voluntary Testing Agreements Successfully Negotiated with EPA

The Trimellitate Esters Panel completed negotiations with EPA for a voluntary testing program on tri-2-ethylhexyl trimellitate. The program includes environmental fate studies, a chronic aquatic toxicity study, mutagenicity tests and a rat subchronic feeding study. A Federal Register notice proposing acceptance of the program was published recently.

EPA has tentatively accepted a voluntary testing program proposed by the Octylphenol Panel in lieu of a TSCA Section 4 test rule. The program includes four environmental studies.

Panel Releases Epidemiology Study

The Benzene Panel recently completed a large-scale study on the health effects of occupational exposure to benzene.

Major findings in the study were:

- A slightly higher, though not statistically significant, mortality rate from lymphatic and hematopoietic cancer, including leukemia, among the exposed workers when compared to the U.S. population. There were no deaths from acute myelogenous leukemia, the disease most commonly associated with high levels of benzene exposure.

- The death rate from lymphatic and hematopoietic cancer, including leukemia, in exposed workers was significantly higher than the rates in the study's in-plant worker control group which displayed an unexplained, unusually low mortality rate.

- A positive relationship between cumulative exposure to benzene and deaths from lymphatic and hematopoietic cancer, including leukemia. But this observation was based on a very small number of deaths, and therefore it is impossible to draw firm conclusions on its meaning.

Copies of the study report were forwarded to a variety of government agencies and to the trade press.

Panel Cooperates with NIOSH on Scientific Symposium

In September 1983 NIOSH sponsored a three day symposium on "The Toxic Effects of Glycol Ethers." The Glycol Ethers Panel helped NIOSH plan the meeting, identify speakers, and determine topics for discussion. The Panel also participated fully in the scientific exchange by presenting the results of Panel-sponsored studies.

IV: PROGRAM SUMMARIES

On behalf of the Executive Committee, SPAC has reviewed all special programs. Figure 7 reflects the levels of activity over the past year and indicates the focus of activity. In some cases advocacy for a research program is conducted elsewhere. In these instances the organization responsible for advocacy is indicated.

As part of the review process, SPAC received written reports from each panel. The reports are summarized in this section.

BIOMEDICAL AND ENVIRONMENTAL SPECIAL PROGRAMS

Level and Focus of Activities

LEVEL / FOCUS	HIGH ACTIVITY	MODERATE ACTIVITY	LOW ACTIVITY
ADVOCACY	Polychlorinated Biphenyls Methylenedianiline	Epoxy Resins Ethylene Dibromide Toluenediamines	
ADVOCACY AND RESEARCH	Arsenic Benzene Butylated Hydroxytoluene Ethylene Oxide Glycol Ethers Naphthenates Phthalate Esters Zinc Dialkyl Dithiophosphates	Ethylene Dibromide Ketones Octylphenol	Trimellitate Esters
RESEARCH	Chlorobenzenes (CPA) Phosgene Fluorocarbons	Rubber Additives Vinyl Chloride (SPI) Titanium Dioxide Vinylidene Chloride	Alkanolamines Allyl Chloride Styrene (SPI)

Figure 7

CMA 053996

ACRYLONITRILE

Importance

EPA has indicated that acrylonitrile may be a human carcinogen, based on findings from epidemiological and mutagenicity studies, bioassays, metabolic evidence, and a structural similarity to vinyl chloride, a known human carcinogen. The Panel was formed to sponsor research aimed at clarifying the degree of hazard presented by acrylonitrile.

Status

As a result of proposed regulation by FDA during 1980, the monomer and polymer producers formed a new organization, the Acrylonitrile Group, Inc., to conduct an advocacy program with administration by La Roe, Winn & Moermann. The Panel will disband as soon as a draft research report is reviewed and approved.

ALKANOLAMINES

Importance

Alkanolamines are a class of compounds used as cosmetics additives. A recent Japanese study implicates triethanolamine (TEA) as a carcinogen in rat feeding studies. Several questions were raised about the validity of the study including the inapplicability of the oral test route and the possibility of nitrosamine formation in the feed. The Panel formed to conduct toxicology studies on TEA to address concerns raised by the Japanese study.

Status

The Panel has completed a 14-day dermal study, is currently conducting a 90-day dermal study, and has started a dermal pharmacokinetics and metabolism study.

ALLYL CHLORIDE

Importance

Concern over the carcinogenic hazard attributed to vinyl chloride raised concerns about the structurally similar allyl chloride and prompted formation of the Panel.

Status

The Panel has sponsored a subchronic inhalation study, a pharmacokinetic study, and a teratogenicity study. The National Cancer Institute (NCI) published the results of a two-year bioassay on allyl chloride and concluded that there was no convincing evidence of carcinogenicity in rats but

there was suggested evidence for such an effect in mice. Allyl chloride is on a list of 37 chemicals for potential regulation under Section 112 of the Clean Air Act; however, EPA has not yet established a schedule of activities for allyl chloride leading to regulatory action. The Panel will consider responding to EPA's proposed actions at an appropriate time in the future.

ARSENIC

Importance

OSHA has proposed to permanently lower the existing workplace standard on inorganic arsenic. EPA is considering regulating inorganic arsenic under the Clean Air Act, Clean Water Act, Safe Drinking Water Act, Resource Conservation and Recovery Act, and Federal Insecticide, Fungicide and Rodenticide Act. The Panel studies the impact of existing and proposed regulations on various companies manufacturing or using arsenic, and undertakes advocacy or sponsors research when appropriate.

Status

The Panel and the CMA Regulatory Impact Special Committee are co-sponsoring an epidemiologic study of smelter workers to investigate the potential relationship between exposure to airborne inorganic arsenic and the incidence of respiratory system cancer. The study will investigate whether a threshold exists for respiratory cancer related to exposure to arsenic. If a threshold level is observed, thresholds for exposure to other carcinogens become realistic possibilities. In this event, the results would help in convincing regulatory agencies that a zero exposure for chemicals considered to be carcinogenic is not always necessary.

BENZENE

Importance

The Panel was established to address both research needs and advocacy issues facing the benzene industry.

Status

A Panel-sponsored retrospective mortality study of nearly 8,000 workers at seven plants was recently completed. CMA and API released a jointly sponsored 90-day benzene study in the first quarter of 1983. OSHA has initiated rulemaking proceedings on benzene and the Panel is responding. The Panel is also involved with EPA activities on the regulation of benzene as a hazardous air pollutant under Section 112 of the Clean Air Act.

BUTYLATED HYDROXYTOLUENE

Importance

In 1977, FDA published a proposal to establish interim regulations requiring testing to resolve certain safety questions on butylated hydroxytoluene (BHT). Since a recent study of a related material, butylated hydroxyanisole (BHA), indicated that BHA may be a carcinogen, FDA is considering a safety review of all antioxidant additives. The Panel is constituted to conduct research and advocacy necessary to support continued use of BHT in food additive applications.

Status

The Panel filed comments on the FDA Proposed Regulation in 1978 and is awaiting publication of the final rule before proceeding with testing. In March 1983, the Panel filed comments with the Joint Expert Committee on Food Additives (JECFA) of the Food and Agriculture Organization and the World Health Organization. These comments persuaded JECFA that currently available information was adequate to characterize the effects of BHT. JECFA therefore revised its specification on the BHT Acceptable Daily Intake ADI from temporary to unconditional. In October 1983, the National Food Toxicology Institute of Denmark published preliminary findings of a long-term study which indicated that BHT at very high concentrations produced liver tumors in rats. Initial analyses by CMA of the preliminary data have raised questions on the validity of the conclusions drawn by the Danish scientists. The Panel is considering auditing the study to validate the findings.

CHLOROBENZENES

Importance

The Panel provides technical support for the industry's advocacy activities. It supports research to expand the toxicologic data base on this class of compounds.

Status

The Panel worked closely with the Chlorobenzenes Producers Association and EPA in developing a voluntary testing program for chlorobenzenes under TSCA Section 4(a). A Federal Register Notice describing the EPA-approved program is due to be published shortly.

EPOXY RESINS

Importance

The Panel is developing a response to the Interagency Testing Committee (ITC) recommendations to EPA on the category, "glycidol and its derivatives." The ITC recommended that the following studies be conducted: carcinogenicity, mutagenicity, teratogenicity, other toxic effects and epidemiology. The Panel intends to address only the epoxy diluents represented in the category.

Status

The Panel is collecting and evaluating production, use, exposure, environmental release and health effects information in order to work with EPA in developing a reasonable regulatory response to the ITC recommendation.

ETHYLENE DIBROMIDE

Importance

The Panel is focussing attention on efforts by California and Federal OSHAs to revise the occupational standard for ethylene dibromide (EDB). The Panel's goal is to ensure that reasonable regulations are adopted that will promote the safety and health of workers.

Status

In June 1982, the Panel submitted comments in response to questions raised by Fed/OSHA in an Advance Notice of Proposed Rulemaking (ANPR) aimed at revising the Federal Occupational Standard on EDB. In October 1983, OSHA issued a Proposed Rule recommending a Permissible Exposure Level and a Term Exposure Limit. The Panel submitted comments in response to OSHA's proposal and will participate in OSHA hearings on the proposed rule.

ETHYLENE DICHLORIDE

Importance

The Panel evaluates the existing literature, identifies data gaps, and undertakes additional toxicologic studies where appropriate to improve the workplace environment. EPA is considering regulation of ethylene dichloride (EDC) under the Clean Air Act and Safe Drinking Water Act.

Status

The Panel has sponsored chronic inhalation, metabolic, and teratogenic studies. Results were distributed to appropriate government agencies. The Panel also provided

comments on EPA's draft document on Locating and Estimating Air Emissions from Sources of EDC. The Panel is currently awaiting EPA's proposed standard for EDC under the Clean Air Act.

ETHYLENE OXIDE

Importance

The Ethylene Oxide Industry Council (EOIC) provides OSHA with information to support a reasonable, scientifically sound decision on the workplace standard. The EOIC also addresses EPA's concerns regarding testing requirements under TSCA Section 4(a).

Status

The EOIC submitted comments to OSHA on a proposed rule and actively participated in the subsequent hearings. The EOIC has initiated a collaborative study to establish a reference method for EO monitoring. The Council also prepared an in-depth hazard assessment document on EO.

FLUOROCARBONS

Importance

The Panel funds research in atmospheric chemistry, atmospheric measurements, modeling and ecosphere studies. The types of research vary from atmospheric measurements and monitoring, using proven techniques, to state-of-the-art scientific projects. Although the program was intitated two years before the first publication of the ozone depletion theory, its importance and urgency have been increased in recent years because of world attention to the rate and potential effects of ozone depletion.

Status

This Fall, responsibility for CFC policy within EPA changed from the Office of Toxic Substances to the Office of Air and Radiation. EPA's position on further regulation of CFCs has also changed and differs from that espoused in the Spring EPA Report to Congress, where only further study was recommended. (The industry still awaits EPA's response to the Advanced Notice of Proposed Rulemaking, published in 1980.) Meanwhile the United Nations Environment Programme is developing a convention for the protection of stratospheric ozone that is considering a global ban on CFCs for non-essential aerosol uses. The Panel continues to meet with EPA, which is responsible for the U.S. position on the convention, and the Department of State, to provide them with data, in an effort to ensure that the U.S. position will be firmly based on current scientific information.

GLYCOL ETHERS

Importance

Shortly after the formation of the Panel, studies appeared which indicated that ethylene glycol monomethyl ether (EGME) and ethylene glycol monoethyl ether (EGEE) caused teratologic and potential reproductive effects in rats and rabbits by the inhalation route. The Panel, therefore, sponsors research to assess the teratogenic and reproductive effects of several glycol ethers.

Status

The Panel has been interacting with NIOSH, OSHA, EPA and Cal/OSHA. Two glycol ethers, EGME and EGEE, are at the third stage of a five stage review procedure within the EPA Office of Pesticides and Toxic Substances as part of the new Existing Chemicals Program. The Panel is working actively with the Agency on this issue. In addition, the Panel filed comments on a draft NIOSH Current Intelligence Bulletin and participated in a recent NIOSH symposium on the "Toxic Effects of Glycol Ethers."

KETONES

Importance

The Panel conducts research to assess the potential health effects of several ketones. It also serves a mechanism for negotiations with EPA on testing under TSCA Section 4.

Status

The Panel has developed and submitted to EPA voluntary testing program proposals on three ketones: methyl ethyl ketone (MEK); methyl isobutyl ketone (MIBK); and isophorone. A Federal Register Notice announcing acceptance of the proposed programs for MEK and MIBK was published recently. A Federal Register Notice proposing acceptance of the isophorone testing program is anticipated shortly. Results from the MIBK subchronic study have already been submitted to EPA. All other tests have been initiated. The Panel elected not to propose a voluntary testing program on mesityl oxide. A proposed test rule was therefore published by EPA in July 1983. The Panel has submitted comments on the Test Rule indicating that exposures are too low to justify testing of mesityl oxide.

METHYLENEDIANILINE

Importance

The ITC recommended to EPA that 4,4'-methylenedianiline (MDA) be considered for health and environmental effects testing. In response to the ITC recommendation, the Panel proposed a voluntary testing program to EPA. In April 1983, EPA designated MDA as the first "significant risk" chemical under Section 4(f) of TSCA, because of results from a National Toxicology Program (NTP) bioassay.

Status

EPA responded to the ITC recommendations by deciding not to require further testing because of the NTP bioassay. Furthermore, EPA and OSHA published ANPRs announcing joint efforts to control exposures to MDA. The Panel filed comments on the TSCA Section 4(f) designation and the two ANPRs. The Panel is currently conducting a "Survey of Non-MDI Uses of 4,4'-Methylenedianiline" for use in making further comments to EPA and OSHA. A proposed rule is scheduled for late 1984.

NAPHTHENATE METAL SOAPS

Importance

The Panel was formed in May 1983, as a result of the ITC's recommendation to EPA that calcium, cobalt and lead naphthenates be considered for testing for effects on human health and the environment.

Status

The Panel has worked with EPA to develop a voluntary testing program. A preliminary protocol has been developed by the Panel and reviewed by EPA. The Panel is revising the protocol based on EPA comments. A Federal Register Notice announcing EPA's decision is anticipated by May 1984.

OCTYLPHENOL

Importance

The ITC recommended to EPA that 4-(1,1,3,3-tetramethylbutyl)phenol, otherwise known as octylphenol, be considered for testing to evaluate health and environmental effects. The Panel was formed in response to this recommendation.

Status

EPA responded to the ITC recommendation in November 1983 by proposing acceptance of the Panel's proposed voluntary testing program in lieu of a TSCA Section 4 test rule.

PHOSGENE

Importance

The Panel was formed to sponsor research toward development of optimum care for accidental exposure to phosgene. Improved worker safety is an important objective of the Panel. Information is compiled and disseminated through the various task groups of the Panel.

Status

Research continues on treatment of accidental exposures to phosgene. Results from the Engineering and Safety Practices surveys have been disseminated to Panel member companies, in the U.S. and abroad. The proceedings from the Panel-sponsored International Symposium on Phosgene Induced Edema: Diagnosis and Therapeutic Countermeasures are being edited for publication in the Journal of Clinical Toxicology.

PHTHALATE ESTERS

Importance

Recent studies have indicated that di-2-ethylhexyl phthalate (DEHP) and a related compound, di-2-ethylhexyl adipate (DEHA) cause a higher incidence of hepatocellular carcinomas in mice. Rats treated with DEHP showed a similar effect. With the release of these studies three regulatory agencies [EPA, FDA and the Consumer Products Safety Commission (CPSC)], began to consider changes in regulation that could affect the 14 commercial phthalates. The Panel, as a result, has an active advocacy and research program that includes interactions with all three agencies and NIOSH.

Status

A Federal Register Notice announcing EPA's acceptance of a voluntary testing program for phthalate esters, in lieu of a mandatory test rule under TSCA Section 4, was published in January 1982. The first phase of this comprehensive environmental and human health effects testing program has been completed and final reports submitted to EPA. Proposals for the next phase of testing have been accepted by EPA; phase II testing will be initiated in early 1984. CPSC, meanwhile, has decided to convene a Chronic Hazard Advisory Panel (CHAP), the first step in regulation. The Panel has expressed reservations with the exposure studies and requested that CPSC have the studies audited to determine their validity. The Panel will work closely with the CHAP to provide test data on phthalate esters.

POLYCHLORINATED BIPHENYLS

Importance

The Panel is responding to EPA's efforts to issue new regulations on polychlorinated biphenyls (PCBs). The Panel's goal is to persuade EPA to permit the continued use of electrical equipment containing PCBs and to provide support for a reasonable regulatory cut-off level for inadvertently generated PCBs. Because of the widespread use of PCBs in electrical equipment and the potential inadvertent generation of PCBs during the manufacture of many industrial chemicals, the Panel's efforts approach a generic concern for the chemical industry.

Status

The Panel responded to three ANPRs, three proposed rules and participated in two regulatory hearings. In April 1983, CMA, NRDC and EDF jointly submitted to EPA a recommendation for regulating the inadvertent generation of PCBs. EPA issued a Proposed Rule, in December 1983, which relies on this Consensus Proposal as a framework for regulating inadvertent generation of PCBs.

RUBBER ADDITIVES

Importance

The Panel was formed to evaluate and sponsor research that will expand the toxicological data base on rubber chemicals. The Panel serves as a mechanism for reviewing information compiled by EPA on rubber chemicals.

Status

The Panel is sponsoring research to evaluate the genotoxic properties of two rubber chemicals, 2-mercaptobenzothiazole, and 2-(morpholinothio)benzothiazole. The Panel is now reviewing draft reports on this research. These reports will be submitted to the appropriate government agencies when approved. The Panel is monitoring the activities of the National Toxicology Program (NTP) and the ITC and is responding to their requests for information. The Panel also is reviewing EPA's Chemical Hazard Information Profiles (CHIPs) on two rubber chemicals.

STYRENE

Importance

The Panel emphasizes expanding the toxicologic data base on styrene. The Panel also represents the interests of the styrene industry before Federal agencies in matters relating to safety and health.

Status

The Panel is preparing to publish the results of a two year, three-generation study of styrene in drinking water.

TITANIUM DIOXIDE

Importance

The Panel is concerned with potential hazards to workers in the complex atmosphere generated during formulating operations with titanium dioxide (TD).

Status

Du Pont recently completed a 2-year inhalation study on TD in rats and found that the chemical at very high concentration produced lung tumors in the animals. The Panel is currently considering undertaking additional toxicology studies or an epidemiology study to characterize further the health effects of TD.

TOLUENEDIAMINES

Importance

The ITC recommended to EPA that the phenylenediamine category be considered for testing to evaluate effects on human health and the environment. EPA responded by publishing an ANPR. The Panel was formed in response to the ANPR, and is addressing the toluenediamine (TDA) subcategory.

Status

The Panel's ANPR comments were aimed at convincing EPA to separate the TDAs from the rest of the category in any test rule consideration, and to accept current test data on TDA as sufficient. EPA has informed CMA that it will separate TDA from the other chemicals in the category for test rule consideration. EPA is also considering selecting TDA as the first candidate for the Agency's Negotiated Rulemaking Project.

TRICHLOROETHYLENE

Importance

The Panel was formed to ensure that governmental controls, standards, regulations and policies pertaining to trichloroethylene (TCE) are reasonable, scientifically sound, and economical. It has addressed through research and advocacy, concerns of TCE exposures in air, food, drinking water, and ground water.

Status

The Panel disbanded in October 1983. Advocacy and research activities on TCE will be conducted through the Synthetic Organic Chemical Manufacturers Association.

TRIMELLITATE ESTERS

In November 1982, the ITC designated tri-2-ethylhexyl trimellitate (TOTM) for priority testing under Section 4 of TSCA. Based upon a structural similarity to DEHP, the ITC recommended metabolism, subchronic, mutagenicity and environmental effects testing on TOTM. In January 1983, the TOTM producers formed the Panel to develop a voluntary testing program.

Status

The EPA published a Federal Register Notice, proposing acceptance of the Panel's proposed testing program in lieu of a test rule. The Panel awaits publication of the notice of final acceptance before initiating testing.

VINYL CHLORIDE

Importance

The Panel supports the accumulation and assessment of health and safety data on vinyl chloride. Emphasis in recent years has been on human health data.

Status

A Panel-sponsored epidemiology study of approximately 10,000 workers is in progress.

VINYLIDENE CHLORIDE

Importance

The Panel sponsors investigations of the potential toxicologic effects and pharmacokinetics of inhaled and ingested vinylidene chloride (VDC).

Status

EPA recently published a draft health assessment document for VDC. The Panel is reviewing this document and will provide comments to EPA, if necessary.

ZINC DIALKYL DITHIOPHOSPHATES

Importance

Company-sponsored dermal studies of zinc dialkyl dithiophosphates (ZDDP) revealed testicular effects in rabbits and limited mutagenicity tests were positive. The Panel was formed to develop a research program which further addresses reproductive effects and mutagenicity issues. The Panel also represents the industry's interests before Federal agencies on health and safety issues.

Status

Species differences related to observed reproductive effects prompted initiation of a study to evaluate the role of stress in producing testicular effects in rabbits. The study was recently completed. An *in vitro* mutagenicity/carcinogenicity testing program on representative compounds within the class is also in progress. The Panel is developing an advocacy agenda and has structured its research program to build a data base in those areas where EPA testing requirements are anticipated. Research findings have also been communicated to the Interagency Testing Committee.

APPENDIX

DIRECTOR

Langley A. Spurlock, Ph.D.

Dr. Spurlock joined CMA in June 1982 as Director of the Biomedical and Environmental Special Programs Division. He is responsible for oversight of all voluntarily-funded advocacy and research programs conducted within the Division.

Dr. Spurlock received a Ph.D. in Organic Chemistry from Wayne State University. Before joining CMA, he was Senior Staff Associate for Operations, Directorate for Mathematical and Physical Sciences at the National Science Foundation (NSF). He also served as 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 at NSF.

Previously, Dr. Spurlock was an HEW Fellow and served as Special Assistant in the Immediate Office of the Secretary. Earlier, he served as Assistant to the President at the American Council on Education. Dr. Spurlock was also Associate Professor of Chemistry at Brown University and previously Assistant Professor of Chemistry at Temple University. Earlier still, he was a senior research chemist in the General Chemical and Agricultural Chemical Divisions of Allied Corporation.

MANAGERS

Robert J. Fensterheim, M.P.H.

Mr. Fensterheim joined the CMA Special Programs staff in June 1981. He is Program Manager for the methylenedianiline, octylphenol, phosgene, polychlorinated biphenyls, rubber additives, and toluenediamines programs. Mr. Fensterheim has a masters degree in Public Health from Yale University. Prior to joining CMA, Mr. Fensterheim was a research associate at the Congressional Office of Technology Assessment (OTA) where he was responsible for writing a report for Congress which examined technologies for determining cancer risk from the environment. He was also a consultant at Clement Associates, Inc., where he prepared reviews of toxicology studies for the Interagency Testing Committee and was a Team Leader on a project to evaluate priority-setting systems to monitor environmental contaminants likely to enter food.

Elizabeth Festa Gormley

Ms. Festa Gormley earned her B.A. with a major in chemistry from Albertus Magnus College in New Haven, Connecticut. She joined CMA in July 1983 as Program Manager for the Fluorocarbon Program, replacing Mr. John C. Van Horn, who retired. Since receiving her degree, Ms. Festa Gormley has 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 the Radian Corporation. Prior to joining CMA, Ms. Festa Gormley was a Section Staff Executive with the National Electrical Manufacturers Association, where she was principal staff to the Nuclear Magnetic Resonance Imaging Section within the Diagnostic Imaging and Therapy Systems Division. Ms. Festa Gormley was also a 1967 recipient of a National Science Foundation Assistantship.

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

Dr. Moran joined the Special Programs staff in April 1981. She is the Program Manager for the ketones, phthalate esters and trimellitate esters programs. Dr. Moran is a board-certified toxicologist and biochemist. As a program manager at JRB Associates, she supervised senior scientists in the preparation of toxicology and structure-activity relationships for both initial and in-depth review of PMN chemicals under Section 5 of TSCA. Dr. Moran also spent three years directing the Flavor Safety Program at International Flavors and Fragrances. Her experience there included development of regulatory positions and safety evaluation criteria as well as development of protocols for safety testing of new chemicals, submissions to regulatory agencies, development of new test methods in neuropharmacology and basic research in sensitization and structure-activity relationships.

Lori M. Ramonas, Ph.D.

Dr. Ramonas joined CMA in September 1983 as a Program Manager and is responsible for research and advocacy programs on alkanolamines, epoxy resins, ethylene dibromide and glycol ethers. Dr. Ramonas comes to CMA from the Office of the Assistant Secretary of Health, Department of Health and Human Services, where she worked as a Health Risk Assessment Senior Advisor. Previously, Dr. Ramonas was an American Chemical Society Congressional Science Fellow, and served as a Staff Investigator and Legislative Assistant to Rep. Albert Gore, Jr. She has also held the positions of Senior Staff Fellow in the Laboratory of Chemical Pharmacology at the National Cancer Institute, Post-Doctoral Scholar in the Department of Medicine at the University of California Medical Center and Instructor of the Advanced

Freshman Physical Chemistry Laboratory at Yale University. Dr. Ramonas holds a Ph.D. in Chemistry from Yale University, where she received a National Science Foundation Traineeship.

Hasmukh C. Shah, Ph.D.

Dr. Shah joined CMA in 1979 and is currently Program Manager for allyl chloride, arsenic, ethylene dichloride, butylated hydroxytoluene, titanium dioxide, vinylidene chloride, and naphthenate metal soaps programs. Before joining CMA, Dr. Shah was the Director of the Toxicology and Biomedical Sciences Department of Equitable Environmental Health (EEH). He was also the Project Director for the National Institute for Occupational Safety and Health's criteria document project. In addition, Dr. Shah served as the Project Director for the "Profiles on Occupational Hazards for Criteria Document Priorities" completed by EEH for NIOSH. Previously, at the Stanford Research Institute (SRI), Dr. Shah served as Project Coordinator for the Cancer Control Monograph of Diethylstilbestrol prepared for the National Cancer Institute. At SRI, he also worked as a Senior Toxicologist on criteria document projects for NIOSH. Dr. Shah was a Visiting Fellow Scientist at the National Institute for Environmental Health Sciences and was involved in reproductive and toxicologic studies related to diethylstilbestrol. Dr. Shah received his Ph.D. in Pharmacology and Toxicology from the University of Rhode Island in 1973. His graduate research involved inhalation toxicity of industrial organic solvents, drug interactions and drug metabolism.

Carol R. Stack, Ph.D.

Dr. Stack joined CMA in 1980 and is currently Manager responsible for research and advocacy programs on ethylene oxide, benzene, chlorobenzenes, styrene, vinyl chloride, and zinc dialkyl dithiophosphates. She received her Ph.D. in Biology from New York University in 1969. Before joining CMA, Dr. Stack was a Biologist 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 multichemical criteria documents. In 1972, she served as Visiting Scientist at the Neurological Institute of Bogota, Columbia, where she investigated central auditory pathways in echolocating birds. Her graduate research centered on histological and histochemical studies of internal auditory systems.