THE
PROCTER & GAMBLE MANUFACTURING
COMPANY

Erwin L. Behrens
Director, Industrial Health Group

November 18, 1982

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Mr. James B. Henderson
Chairman of the Board
The American Industrial Health Council
1075 Central Park Avenue
Scarsdale, NY 10583

Dear Mr. Henderson:

On May 12, 1982, the Executive Committee of the Board accepted the resignation of Mr. W. C. Krumrei of Procter & Gamble as Member of both the AIHC Board of Directors and Executive Committee. The Executive Committee and Board of Directors subsequently elected me to fill out the balance of Mr. Krumrei's term for 1982.

With the Board's concurrence that Mr. P. Ifland assume a seat on the Board to complete the balance of Mr. Krumrei's term (ending November, 1984), I am submitting my resignation from both the Board and Executive Committee of the American Industrial Health Council.

I have been privileged to represent Procter & Gamble these past several months, and it has been a pleasure working with you, in particular.

I look forward to continuing to serve the Board and Executive Committee interests, as may be appropriate, in my continued capacity as Chairman of the Public Affairs Committee.

Very truly yours,

Erwin L. Behrens

ELB:jkm

cc: R. Lang
P. Ifland

Suite 230, 1801 K Street, N.W. Washington, D.C. 20006. (202) 833-9506

Date October 13, 1982

No. 042

AIHC PROJECT REQUEST

APPROVED: 10/12/82

Project Title: Epidemiology State-of-the-Art Position Paper

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Objective: To promote the fundamental importance of sound epidemiology as a disciplined science to gain understanding of the critical factors which influence chronic disease in human populations. Epidemiology provides the only real link available for relating hazards and potential risks identified in laboratory studies to evaluations of actual risk to humans from exposures to those hazards.

Because of the often imperfect nature of available data, there continues to be either frequent misuse of epidemiological information by ex trapolation to claims far beyond the limits of the date (e.g., the "Estimates Paper") or, a tendency to discount the value of the science by placing unrealistic restrictions on its validity (e.g., the OSHA Cancer Policy).

AIHC has had to respond to both of these problems on a broad front over the past several years. Most recently, three papers have appeared under the common authorship of Dr. Marvin Schneiderman variously in a Congressional hearing, an MIT publication, and a publication of the Environmental Law Institute (ELI) called "Teratogenesis, Carcinogenesis, and Mutagenesis." The latter directly attempts to refute the Doll-Peto work undertaken for OTA and published last year in the JNCI.

The Epidemiology Subcommittee has responded forcefully to the first two publications and believes a detailed critique of the third is also required. However, we believe this information can best be used in examples of the problems to be addressed in peer-review discussions of a positive epidemiology state-of-the-art position paper. We would expect to seek the participation of eminent epidemiologists, such as Doll, Peto, Higginson, Cole, McMahon, Higgins, Tyroler, Lilienfeld, etc. for a symposium similar to those used successfully for the "Framework" and "Risk Agreement" reviews. This would be published and used to promote sound epidemiology for incorporation into emerging governmental chronic disease policy.

Strategy:
1) Epidemiology Subcommittee develop outline of position paper - Oct.
2) Contract with Environmental Health Associates (EHA) - Last Qtr. 1982
   a) Critique of ELI paper; b) Review of AIHC comments on epidemiological evidence for occupational/air/water cancer policies; c) Draft of state-of-the-art position paper.
3) Develop peer-review forum - 1st Half 1983
4) Seek publication in appropriate peer-reviewed journal - Last Qtr. 1983
5) Work with Science Policy Task Force - Ongoing

Funding Requirements: $50,000

14,000	- Contract & conslutations with EHA
32,000	- Peer-review Symposium
2,000	- Legal and general contract support
2,000	- Public Relations support

EPIDEMIOLOGY SUBCOMMITTEE

DATE: NOVEMBER 17, 1982
NO. : 043

AIHC PROJECT REQUEST

Project Title: Establishment of a State Resource Deployment Task Force

Objective: To provide appropriate AIHC assistance to state industry organizations concerned with chronic health hazard issues. (This proposal is a modified version of Project Request #034, approved May 11, 1982 and funded for 1982 at the level of $30,000. $6,657 has been expended through October 1982.)

Strategy: Legislative and regulatory activities involving chronic health hazard issues have been increasing in a number of states. Actions and decisions on some of these will have an important precedent impact throughout the country. This Task Force will help coordinate the technical and scientific resources from industry to better address the chronic health policy issues at the state and local levels.

The new Task Force would greatly facilitate availability and management of industry's scientific resources in the chronic health hazard area. Its function would be to form ad hoc groups of representatives from companies with interests in the states where chronic health policies are being developed.

The Task Force would identify key issues and assist in the coordination where assistance may be needed. The necessary inter-company liaison and detailed management of a particular issue would be handled by company representatives with direct interests in that state. AIHC's scientific resources and experience in dealing with chronic health hazard issues would be used to assist and support these ad hoc company activities with the criterion of selecting the issues being consideration for national policy implications.

The Task Force would work through and with other organizations operating at the state level, such as CIC or COC. It would coordinate its activities with national organizations including CMA, SPI and API, to avoid duplication or overlap of activities. It would work with state and local groups in the following ways:

1) Make available all relevant AIHC materials developed for addressing chronic health hazard issues, such as the "Framework Document", comments on the OSHA cancer policy and the scientific aspects of air pollution.

2) Provide advice to help local organizations manage these issues.

3) Assist in the development of industry resources to help local organizations manage these issues.

4) Provide names and promote contact of scientific experts from industry and academia who could be called upon by the ad hoc group or state organization to participate in public meetings and hearings where these issues are addressed.

5) Provide assistance and advice on dealing with the media.

6) Provide limited legal advice in relation to the above policies.

7) Provide for advice and assistance in reviewing or helping prepare scientific papers and statements which could be used at hearings, public meetings, etc.

Funding Requirements:

(Dec. 1982 - Dec. 1983)

$100,000 ($23,343 of this from project #034)

General Support	$20,000
Legal	50,000
Public Relations	10,000
Consultants, etc.	20,000

General Support: Covers meetings and general expenses for the new Task Force, air fare and travel expenses where necessary for staff to consult with state organizations and corporate ad hoc groups.

Legal: Provides for legal participation in Task Force activities, limited assistance in terms of telephone advice to state groups and help in reviewing some of the issue papers which may be needed at the state or local level. Counsel will be used as a resource to the Task Force in its adaptation of AIHC material for issues of generic concern.

Public Relations: Out-of-pocket expenses involved with providing PR advice and assistance, including some travel, in connection with state problems.

Consultants, etc.: Provides limited emergency funds where it may be desirable for AIHC to pay some expenses for a scientific consultant either in preparing a paper or appearing at a hearing. No witnesses will be provided to a state industry group in a state or local hearing unless there was prior clearance from the Task Force, and every attempt will be made to have state groups be financially independent. Also provides some reserve funds for unanticipated activities which may arise as this project develops. 15

Executive Committee

[illegible] NEWS
[illegible] 202 785-1471

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FOR FURTHER INFORMATION:

Laura Quirk Armstrong/202-785-1471
Victor Lindenheim/914-725-1492

FOR RELEASE: WEDNESDAY, NOVEMBER 17, 1982

WASHINGTON, D.C., NOV. 17 -- A group of prestigious scientists today announced strong support of a proposal calling for the formation of a "blue ribbon" central science panel to improve the scientific basis for decisions made by federal regulatory agencies.

Dr. John Higginson, Chairman of the peer review work group, told press briefing attendees, "Our group believes that if such a panel were established there would be a general improvement in the regulatory process, enhanced scientific input by agency scientists, and an improved public image of regulatory decision-making with less confrontation, and more frequent consensus between panel and agency."

The group's support is the result of an extensive scientific peer review and evaluation of "A Framework for Sound Science in Federal Decision Making," a document developed by the American Industrial Health Council (A broad-based coalition of industrial firms and trade associations). A central element of AIHC's proposal is the creation of an independent [illegible] panel. The peer review work group has put

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together a complete report on this issue.

Dr. Higginson said the proposed panel's responsibility would be to scientifically assess the human risk presented by substances under regulatory review. Government agencies would take this scientific assessment into account before making regulatory decisions.

Dr. Higginson noted that "the proposed panel would examine the validity and limitations of scientific data available on allegedly hazardous substances brought before the panel for evaluation. Hopefully this would reduce regulatory and legislative actions based on deficient, inappropriate or extraneous data."

A scientific advisor to Universities Associated for Research and Education in Pathology (UAREP), Dr. Higginson is the former Executive Director of the World Health Organization's International Agency for Research on Cancer.

Dr. Higginson said he agreed to participate in the work group because, "Much of my career work has been directed at establishing a solid scientific consensus on issues where there are legitimate differences of scientific opinion and uncertainty. I think the idea of a Central Science Panel offers some real solutions in helping to solve this dilemma."

Another renowned participant, Dr. Tom Miya, described the nature of the proposed science panel. He suggested that "panel members would be selected strictly for their expertise. To the extent possible, the panel members would have to be free from political and economic pressures and should have recognized prestige and authority; this would give panel

recommendations impact in all appropriate quarters." Dr. Miya is Dean of the School of Pharmacy and Chairman of the Curriculum in Toxicology at the School of Medicine at the University of North Carolina and past president of the Society of Toxicology.

He went on to say, "The work group suggested that the Central Science Panel would be best associated with the National Academy of Sciences, although an affiliation with another institution was not excluded.

"Any individual or organization could submit an issue for consideration to the Central Science Panel. Such proposals would be considered 'discretionary' by the panel. However, Congress or heads of federal agencies could submit issues to the panel for 'mandatory' review.

"The work group also supported other aspects of the AIHC proposal including: strengthening the science panels already in place at regulatory agencies as well as general strengthening of the agency science capabilities as suggested by AIHC."

Dr. Miya noted that the announcement of the peer review is particularly timely in light of the interest generated by a recent Presidential veto of an EPA research appropriations bill on the grounds that it would detract from the role of science in EPA actions. The bill would have weakened the scientific base of the EPA's Science Advisory Board (a good example of an in-house agency science panel) by broadening Board membership to include a number of special interest groups, (including states, industry, labor, academia, consumers). This would detract from the necessary freedom from outside pressures and objectivity needed for such a panel or Board to be effective.

# # #

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL, INC.

1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

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November 4, 1982

TO: SCIENTIFIC COMMITTEE
SCIENCE POLICY TASK FORCE
EPIDEMIOLOGY SUBCOMMITTEE
MUTAGENICITY SUBCOMMITTEE
QUANTITATIVE RISK ASSESSMENT SUBCOMMITTE
PUBLIC AFFAIRS COMMITTEE
COMMITTEE AND TASK FORCE CHAIRMEN

OSTP DRAFT CANCER POLICY

Gentlemen:

The Office of Science and Technology Policy has completed the first part of a two part document to characterize and identify potential human carcinogens. Part I, which is a review of the state-of-the-art of the science underlying the methods of identification and characterization of carcinogens, is attached. Part II, which suggests the principles to guide Federal regulatory agencies in the identification and regulation of carcinogens, will be available the first part of next year.

The OSTP has requested that the review be completed by Friday, December 3, so that they can proceed with the necessary revisions to Part I prior to development of the Part II principles.

Comments should be coordinated through Dr. Robert Moolenaar, Chairman, Scientific Committee. If I can be of any further assistance, or answer any questions, please do not hesitate to call ((202) 659-0060).

Sincerely,

Leonard J. Guarraia, Ph.D.
Director, Government Affairs

Attachment

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY
WASHINGTON, D.C. 20500

November 2, 1982

NOV 2 1982

Dear Ed:

For the last several months, an interagency work group convened by this office has been developing a document the ultimate purpose of which is to guide Federal agencies in their efforts to identify and characterize potential human carcinogens. That document will comprise two parts: Part I will review the state-of-the-art of the science underlying methods of identification and characterization; Part II will suggest principles to guide Federal regulatory agencies in their use of those methods.

The first complete draft of Part I has just been prepared by the work group, and we are eager to receive comments and suggestions on this initial effort. For that reason, my colleagues have asked that I send the draft out for peer review by a limited number of individuals knowledgeable about the scientific basis for carcinogen assessment.

Accordingly, the purpose of this letter is to ask that you assist our effort to develop a more rational basis for carcinogen assessment by reviewing the draft of Part I of the document dealing with the state-of-the-science, circa 1982. We will use the comments and suggestions you provide to refine and improve this document so that, to the degree possible, it is an accurate reflection of that state.

I realize that I am requesting a considerable commitment of time and energy. Let me make several points:

- We are requesting peer review early to help guide our later efforts and to begin a dialogue intended eventually to help develop a consensus on the most appropriate approaches to assessing carcinogens.

- The enclosed is a rough draft. Each section has been written by a different individual or group, thus the variety of styles and formats and the range of specificity and depth.

- The final Part I will need to be relatively short and generally understandable by policy-makers.

° We are seeking constructive criticism and specific recommendations on how to improve the accuracy and completeness of our document. To the degree possible, Part I is to be an objective statement of the state-of-the-science from which principles on carcinogen assessment methods can be extracted.

° We would appreciate direct, crisp responses rather than dissertations. Your comments can be in any form which is understandable, including marginal comments on the draft itself.

Needless to say, my colleagues and I will greatly appreciate the time and effort you put into this review and will incorporate your recommendations as fully as possible. We hope to have all reviews in by Friday, December 3, so that we can proceed with the necessary revisions of Part I and the development of Part II principles.

Many thanks, in advance, for your contribution to this effort. Best wishes.

Denis J. Prager
Assistant Director

Enclosure

Mr. Edwin Behrens
Chairman
Public Affairs Committee
AIHC
Proctor & Gamble
1801 K Street, N.W.
Washington, D.C. 20006

cc: Jay Keyworth

DRAFT

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POTENTIAL HUMAN CARCINOGENS: METHODS FOR IDENTIFICATION AND CHARACTERIZATION

PART I: CURRENT VIEWS

DISCUSSION DRAFT

Regulatory Work Group on Science and Technology
Office of Science and Technology Policy
Executive Office of the President

October 1, 1982

DRAFT

CHAPTER I

PREAMBLE

DRAFT

The Background: Perception of Cancer

Cancer has been a major public health concern of the Federal government for many years. Data indicate (1) that this disease--the second leading cause of death in the U.S.--will, on the average, strike one of every four of our citizens and claim the life of one in five. Although heart and circulatory disease result in roughly twice as many deaths each year, cancer produces a particularly strong reaction in the public mind because of its often lengthy and progressive course, the uncertainties which surround its origins ("causes"), and the perceived lack of progress in developing reliable cures.

The picture is not as bleak as it once was. Remarkable progress has been made in a number of areas of cancer research. Through the efforts of the National Cancer Institute (NCI), founded in 1937, and other public and private institutions significant advances have been made over the years. New forms and regimens of treatment, clearer insights into the origins and mechanisms of cancer development, and introduction of new methods of detection--all combine to present an ever-changing picture which can give the American people increasing hope for the future in the battle against this disease.

At the same time public concern about cancer--its cause, prevention and cure--remains high. Data have been presented that suggest that many cancers are due to environmental, as opposed to genetic, factors (2), and, by implication, are preventable if sufficient precautions are taken. In this spirit Congress has over the years held hearings, enacted legislation, established agencies, and appropriated funds to address various aspects of the problem. (See Table I.) Besides these efforts, many of which focus on chemical substances as potential causes of cancer, the Federal government has made additional commitments to the investigation of the disease. For example, the National Cancer Act of 1971 expanded activities at NCI. The National Institute of Occupational Safety and Health (NIOSH), the National Institute for Environmental Health Sciences (NIEHS), the National Center for Toxicological Research (NCTR) have been established to conduct research on a number of health concerns, including cancer. Also, the National Toxicology Program (NTP) has been formed within the Department of Health and Human Services (HHS) to coordinate much of the Federal testing of chemicals for toxicity, including carcinogenic activity.

Each of the legislative acts in Table I contains elements which are products of the thinking which existed at the time of enactment. Because of developments in the scientific understanding of cancer, such thinking has evolved over the years. Consequently, these acts are not uniform in their view of

the disease, the role chemical substances might play in its incidence, and what ought to be done about such potential carcinogens. For example, when Congress passed the so-called Delaney amendment to the Federal Food, Drug, and Cosmetics Act (FFDCA) in 1958, the focus was on the intentional addition of cancer-causing substances (as shown in animal tests) to the food supply. This amendment reflected the general notion that the country should strive to remove carinogens from the human environment, a belief based on the concept that any exposure entails some level of risk and that all risk should be eliminated. Prevailing opinion shifted from this view in the ensuing years (3). By the 1970s, legislative thinking had reached the point that the notion of complete removal of all animal carcinogens was being replaced by consideration of risks and benefits, as reflected in acts such as the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA).

This evolution in legislative perception was contemporaneous with rapid advances in analytical chemistry made during the 1960s and 1970s. Where prudent policy might once have called for "zero" (that is, non-detectable) amounts of carcinogens, the increasing capability of scientists to detect ever smaller amounts of materials (the "vanishing zero" phenomenon (4)) called this policy into question. As residues of known and suspected carcinogens were reported in the parts per trillion (ppt) and sub-ppt range, the health implications of these data increasingly

became the subject of debate.

Even more recently, recognition of the contributions of "lifestyle" (i.e., the free choices associated with diet, drink, and personal preferences) (5) has highlighted the more complex problems which confront the regulatory agencies in playing an appropriate role in protecting people from excess risk of cancer. The judicial branch has also entered the social debate as evidenced by the Supreme Court decision on benzene (6), which points out the need for scientific judgments which are sound and objective.

The Purpose: A Consensus View of the Federal Government

Because of these developments in the legislative, scientific, and judicial scenes, the Federal government has periodically produced statements which have summarized the then current state of knowledge on cancer (7). The intent of such documents has been to generate a consensus view of the science ("principles") which would serve as a common foundation upon which to base rational regulatory cancer policy.

The present report, the latest in the continuing series of such statements, is prompted at this time by what the agencies believe to be the significant advances in science which should affect the manner in which the regulatory bodies deal with suspected carcinogens. The purpose of this document, then, is to

articulate a view of chemicals and cancer that the agencies hold in common today and that can serve as the basis for separate, but consistent, regulatory cancer policies which these agencies can tailor to meet the requirements of the legislative acts they are charged to implement.

This paper is the result of the combined efforts of the following agencies, under the direction of the Office of Science and Technology Policy (OSTP):

Consumer Product Safety Commission (CPSC)
Environmental Protection Agency (EPA)
Food and Drug Administration (FDA)
Food Safety Inspection Service (FSIS) of the US Department of Agriculture (USDA)
Occupational Safety and Health Administration (OSHA)
National Cancer Institute (NCI)
National Center for Toxicological Research (NCTR)

The Context: Risk Determination

This document is written in the context of decisions by the regulatory agencies which involve the assessment of carcinogenic risks posed by chemical substances. The scientific inputs to these evaluations can be best appreciated by examining the decision making process in slightly greater detail.

Risk can be conceived of as being composed of two aspects,

each of which can be addressed by science: hazard and exposure.* "Hazard" refers to the inherent toxicty of the substance and is deduced from the results of structure/activity relationships, in vitro tests, whole animals tests, epidemiolgical studies, and the like.* "Exposure" refers to the amount of the substance that comes into contact with an organism in the such a way that a toxic reaction can be manifested.

The "risk" is estimated by coupling the results of the exposure and hazard assessments. If either the hazard or exposure approaches zero, the risk also goes to zero. Operationally, the risk assessor must first consider the weight of the evidence that the chemical substances is likely to be a human carcinogen. The field of toxicology has accomodated itself to dealing with many of the complications which arise in this process; e.g., use of animal data to anticipate effects in humans. Next, various means are available for quantitatively estimating the dose-response relationship at low doses. Then, additional data, assumptions, and judgments are used to generate quantitative estimates of the exposures likely to be encountered. Finally, the exposure assessment is overlaid on the dose-response relationship to generate an estimate of the risk.

Some legislation calls for action in the presence of any risk. More recent forms of legislation utilize the concept of

* The European Community uses the term "risk" where we have used the term "hazard" and vice versa.

unreasonable risk, which denotes a condition in which the risks outweigh the benefits. A spectrum of approved responses may be available to bring the risks and benefits into appropriate balance.

The Content: A Consensus View of the Scientific Input to Risk Assessment

Part I of this document is divided into six separate chapters, each addressing the current information in an area of science utilized in the cancer risk assessment process. These chapters, taken in toto, provide the underlying support for the cancer risk assessment principles articulated in Part II, which are the basis for the cancer policies of the regulatory agencies. To read Part II without a full appreciation of the material in Part I is to invite oversimplification and misinterpretation.

The first chapter examines the current state of epidemiological knowledge surrounding cancer. Data collected during the past 50 years allows the construction of trends in cancer incidence/mortality. Within the past decade there has been considerable discussion about the presence or impending presence of a cancer epidemic due to the growth of the chemical industry in this country following World War II. This chapter discusses the evidence for such a phenomenon, together with evidence for other suggested etiologies of cancer.

The remaining chapters discuss recent scientific developments that impact upon the various elements of cancer risk assessment, which, in turn, leads to regulatory decisions on chemicals substances. Recent advances in our understanding of the mechanisms of carcinogenesis are treated in Chapter 2. The simplified, conservative view of cancer held by many in the regulatory agencies 15 years ago suggested direct attack on the genetic information of the organism. While the picture is far from clear today, it is increasingly evident that "all carcinogens are not created equal" and that different groups of chemicals act to generate cancer through different mechanisms. A general consensus has evolved which describes cancer as a multi-stage process involving a variety of events including metabolism, initiation, promotion, proliferation, and repair. The chapter highlights some of these advances in our understanding which have implications in the way we assess cancer risk. At the same time, the material also suggests the vast amount of information that remains to be collected and analyzed.

Chapter 3 examines short-term testing and the connection between genotoxicity and carcinogenicity. Tests for gene mutation, chromosomal aberation, DNA damage and repair, and cellular (morphologic) transformation have provided valuable information on the potential for chemical substances to cause cancer. While the field is currently characterized by great activity, the data generated must be carefully analyzed and

verified before implications for cancer risk assessment can be accurately drawn.

The fourth chapter contains a review of the long-term animal bioassay which figures so prominently in our assessment of cancer risk. The discussion includes a critical examination of problems inherent in the bioassay technique as currently practiced. These problems underlie some of the controversies and uncertainties which surround the interpretation of results of even well-planned, well-conducted studies.

In addition to these chapters which examine factors associated with hazard assessment, Part II contains a discussion of exposure assessment, the equally important consideration leading to a determination of risk. As Chapter 5 points out, following a period of initial development, the field of exposure assessment has been marked by significant progess in the areas of monitoring data, computer modeling, transformation and transport of chemicals, and laboratory approaches to determining the behavior of chemicals in the environment. At the same time uncertainties remain in the procedures used to estimate important parameters associated with particular exposure senarios. Any risk assessment will necessarily be affected by these limitations.

Chapter 6 discusses how the hazard and exposure elements of the preceding five chapters are used as inputs to the qualitative

and quantitative cancer risk assessment procedures.

A common, if not highlighted theme, of each chapter is the uncertainty surrounding some aspects of the scientific information used in risk assessment process. Some of the major data gaps leading to such uncertainties are discussed in an appendix to Part II that identifies areas in which additional research could reduce or remove some of the uncertainties. In some instances a fairly well developed data base may already exist and yet there is controversy about how to interpret the data. The Appendix identifies these areas as appropriate subjects for consensus forums which would seek to focus scientific discussion on the issues and to move toward some generally agreed upon resolution of them.

Part II contains the summary statements (principles) of science and science policy interpreration stemming from Part I that will serve as the common foundation for the cancer policies of each of the regulatory agencies. By first agreeing to this set of principles, the agencies will be able to generate policies which, while tailored to the requirements of the different legislative acts, will still be consistent with each other, providing reasonable assurances that human health will be protected from unreasonable risks posed by carcinogens.

TABLE I[1]

FEDERAL LAWS RELATED TO EXPOSURES TO TOXIC SUBSTANCES

Legislation	Agency	Area of Concern
Food, Drug, and Cosmetics Act (1932, amended 1958, 1960, 1962, 1968, 1976)	FDA	Food, drugs, cosmetics, food additives, color additives, new drugs, animal and feed additives, and medical devices
Federal Insecticide, Fungicide and Rodenticide Act (1948, amended 1972)	EPA	Pesticides
Dangerous Cargo Act (1952)	DOT-USCG	Water shipment of toxic materials
Atomic Energy Act (1954)	NRC	Radioactive substances
Federal Hazardous Substances Act (1966)	CPSC	Toxic household products
Wholesome Meat Act (1967) Wholesome Poultry Products Act (1968) Egg Products Inspection Act (1970)	USDA	Food, feed, color additives, and pesticide residues
Poison Prevention Packaging Act (1970)	CPSC	Dangerous consumer products
Clean Air Act (1970, amended 1974, 1977)	EPA	Air Pollutants
Hazardous Materials Transportation Act (1972)	DOT	Transport of hazardous materials
Federal Water Pollution Control Act (1972, amended 1977, 1978)	EPA	Water Pollutants
Marine Protection, Research and Sanctuaries Act (1972)	EPA	Ocean dumping
Consumer Product Safety Act (1972)	CPSC	Dangerous consumer products

Lead-based Paint Poison Prevention Act (1973, amended, 1976)	CPSC	Lead paint in federally-funded housing
Safe Drinking Water Act (1974, amended 1977)	EPA	Drinking water contaminants
Resource Conservation and Recovery Act (1976)	EPA	Hazardous wastes
Toxic Substances Control Act (1976)	EPA	Hazardous chemicals not covered by other laws*
Comprehensive Environmental Response, Compensation, and Liability Act (1981)	EPA	Hazardous substances, pollutants and contaminants

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* Also requires pre-market evaluation of all chemical substances except food additives, drugs, pesticides, alcohol, and tobacco.

(1) Adpated from "Chemical Substances Designation", EPA Contract No. 68-01-6038, Dec. 1981.

REFERENCES

1. Public Health Service, Healthy People: The Surgeon General's Report on Health Promotion and Disease Prevention, PHS Pub. No. 79-55-71, 1979.

2. For example,
   a. World Health Organization, Prevention of Cancer, Technical Report No. 276, 1964.
   b. Higginson, J., "Present Trends in Cancer Epidemiology", Proc. Canadian Cancer Conf., 8:40-75, 1969.
   c. Wynder, E. G. and Gori, G.B., "Contribution to Cancer Incidence: An Epidemiological Exercise", J. Nat. Canc. Inst., 58:825-832, 1977.

3. For example,
   "Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health" (Mrak Commission), US Department of Health, Education and Welfare, Dec. 1969.

4. Zweig, Gunter, "The Vanishing Zero--Ten Years Later", J. Assoc. Off. Anal. Chem., 61:229-248, 1978.

5. For example,
   Doll, R. and Peto, R., "The Cause of Cancer: Quantitative Estimate of Avoidable Risk of Cancer in the United States Today", J. Nat. Canc. Inst., 66:1191-1308, 1981.

6. Industrial Union Department, AFL-CIO vs. American Petroleum Institute et al., 448 US607, 1980.

7. a. National Cancer Advisory Board, General Criteria for Assessing the Evidence for Carcinogenicity of Chemical Substances", J. Nat. Canc. Inst., 58:541-465, 1977.
   b. Office of Science and Technology Policy, "Identification, Characterization and Control of Potential Human Carcinogens: A Framework for Federal Decision Making", Feb. 1, 1979.
   c. Interagency Regulatory Liaison Group, "Scientific Basis for Identification of Potential Carcinogens and Estimates of Risk", Fed Reg. 33:39858-39879, 1979.
   d. Office of Technology Assessment, Assessment of Technologies for Determining Cancer Risks from the Environment, June 1981.

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL

1612 K STREET, N.W., SUITE 308, WASHINGTON, D.C. • (202) 659-0060

October 27, 1982

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Mr. Geoffrey M. Karny
Project Director
Office of Technology Assessment
Washington, D.C. 20510

Re: Draft OTA Report Entitled "The Role of Genetic Testing in the Prevention of Occupational Illness"

Dear Mr. Karny:

In a separate letter of this date we are transmitting to you the preliminary comments of the AIHC Mutagenicity Subcommittee on Parts II and III of the Draft Report entitled "The Role of Genetic Testing in the Prevention of Occupational Illness".

In addition to those comments, we have one further observation concerning pages 226 and 227 of the Draft Report. The discussion on those pages concerning the Dow Chemical Company, a member of AIHC, is highly inappropriate. The discussion is easily subject to misinterpretation and, moreover, appears to be beyond the scope of the Report. We strongly urge that it be deleted.

Very truly yours,

Leonard J. Guarraia, Ph.D.
Director, Government Relations Department

Enclosure

NEW YORK OFFICE: 1075 CENTRAL PARK AVENUE, SCARSDALE, NY 10583 (914) 725-1492

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL

1612 K STREET, N.W., SUITE 308, WASHINGTON, D.C. • (202) 659-0060

October 27, 1982

Mr. Geoffrey M. Karny
Project Director
Office of Technology Assessment
Washington, D.C. 20510

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Re: Draft OTA Report Entitled "The Role of Genetic Testing in the Prevention of Occupational Illness

Dear Mr. Karny:

The enclosed memorandum summarizes a number of preliminary comments on Parts II and III of the Draft Report of the Office of Technology Assessment entitled "The Role of Genetic Testing in the Prevention of Occupational Illness".

The comments are the result of the initial expedited review of the Draft Report by the AIHC Mutagenicity Subcommittee and are not intended to encompass an exhaustive critique of the document. The Draft Report appears to be well-balanced and carefully considered. Our review has led us to make a number of suggestions, however, which we feel would improve the document and help avoid misinterpretation. Because of the limited time available, we were unable to conduct the thorough review and analysis that the document merits.

In particular, the potential use of genetic testing should not be taken out of context. There currently exists a growing body of literature concerning the toxicity of substances in animal experimentation and methods of extrapolating to estimate occupational risks. Animal testing and risk assessment will continue to be used whether or not genetic testing proves to be a useful tool in the prevention of occupational illness. The role of genetic testing must be viewed, not in a vacuum, but in a proper perspective with other available mechanisms to reduce occupational risks.

If you have any questions concerning these comments, please do not hesitate to contact Dr. Joseph Irr at: (302) 366-5293.

Very truly yours,

Lenard J. Guarraia, Ph.D.
Director, Government Relations Department

Enclosure

NEW YORK OFFICE: 1075 CENTRAL PARK AVENUE, SCARSDALE NY 10583 (914) 725-1492

AIHC

AMERICAN INDUSTRIAL HEALTH COUNCIL

1612 K STREET, N.W., SUITE 308, WASHINGTON, D.C. • (202) 659-0060

Preliminary Comments on Parts II and III
of the OTA Draft Report Entitled
"The Role of Genetic Testing in the
Prevention of Occupational Illness"

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After a preliminary review, the American Industrial Health Council ("AIHC") Mutagenicity Subcommittee has the following observations concerning the Draft Report:

1. Page 82. With regard to the first paragraph, it has been observed that skin cells in older individuals may remain viable despite changes in the number of chromosomes.

With regard to the second paragraph, there is evidence concerning the mechanism by which radiation causes chromosomal aberrations.

The second sentence in the second paragraph should be revised to delete the reference to fibroblasts, since there are no direct preparations of fibroblasts.

2. Page 83. With regard to the discussion of sister chromatid exchange, it would seem appropriate to include a more detailed description of the phenomenon. The description at page 83 is much too brief.

3. Page 88. The Draft Report fails to recognize the variations in estimates of the number of chemicals which are both carcinogens and mutagens. The Gene-Tox Program is expected to provide further information on this topic. The

NEW YORK OFFICE: 1075 CENTRAL PARK AVENUE, SCARSDALE, NY 10583 (914) 725-1492

second sentence in the second paragraph should be revised as follows: "Many of the chemicals knowo to cause cancer in animals are also known to cause mutations in in vitro test studies."

4. Page 106. Table 1 is misleading. No test has a predictive value of .99. The table suggests that an inappropriately high level of specificity is needed, which may result in the nonuse of valuable tests.

5. Page 109. The entire final paragraph should be deleted. Under the Occupational Safety and Health Act if a chemical is a potential human carcinogen and if it is known that workers are "significantly exposed" to the chemical, exposure levels will be reduced. We doubt that OTA intends to suggest that the initial response to such "significant" exposure will be to conduct a monitoring program. As noted above, the potential use of monitoring programs must be placed in its proper perspective.

6. Page 110. The first sentence in the second paragraph should be changed to recognize that only some of such agents cause mutations and chromosomal damage.

7. Page 112. The discussion of cytogenetic monitoring should be revised to put such studies in proper perspective. Such studies may be one of many mechanisms available to determine safe levels of exposure.

8. Page 113. With regard to the second paragraph, the statement about the potential use of cytogenetics may be unwarranted. Cytogenetics may not identify certain exposures which, nevertheless, are hazardous.

The first sentence in the third paragraph is highly misleading. It suggests that cancer is causally associated with chromosomal aberration. Such an association has not been demonstrated. In addition, it is debatable whether the animal literature linking mutagens with carconogens is "large".

9. Page 114. The last paragraph is internally inconsistent. The statements regarding limitations are correct. However, they do not support the reference to "good agreement" in the third sentence.

10. Page 117. In the last sentence, the reference to "expected" breast cancer seems inappropriate. We would suggest that the sentence read "the time of onset for breast cancer has not been earlier than would be predicted on the basis of studies in unexposed populations."

11. Page 119. The first full paragraph requires revision to clarify that all references are to radiation.

12. Page 120. The first full paragraph suggests human experimentation. Perhaps the reference should be to animal studies.

13. Page 127. Table 1 has a high potential to be misleading. First, it ambiguously includes such "chemicals" as

petroleum vapors, cytostatic drugs, hair dyes, pesticides and spray adhesives. Second, the results are listed as positive or negative. This unfairly suggests that these studies are equivalent and that no findings are ambiguous. The table could easily be taken out of context.

14. Page 129. The statement of conclusions is fairly stated and balanced. However, as noted above, it does not put cytogenetic testing in the context of other testing and risk assessment methodologies.

15. Page 133. Table 2 does not appear to add anything to the Draft Report. It is also easily susceptible to misinterpretation and does not appear to be explained in the text.

16. Page 151. The word "tremendous" in the second paragraph seems to be inappropriate.

17. Page 152. Table 1 needs further explanation.

18. Page 153. Table 2 repeats the error discussed above by attempting to summarize in a single table the results of a number of studies. It is also easily misinterpreted as suggesting an occupational cause for the various mutagenetic endpoints monitored in the occupationally defined populations. Many of these studies were discredited in the Dabney paper. (Dabney, Betty J., Ph.D., "The Role of Human Genetic Monitoring in the Workplace", Journal of Occupational Medicine, Vol 23, No. 9 (Septembner 1981)).

19. Chapter 11. This chapter fails to recognize the controversy surrounding the premise that enzyme level monitoring is a good indicator of disease. The studies cited have not been reproduced. Extensive review has been undertaken by J.R. Gillette of the National Institutes of Health.

20. Page 174. The discussion of other characterized genetic traits is also very controversial. The hypotheses appear to be overstated in the Draft Report.

21. Page 180. THe same comments apply to the discussion of less well characterized genetic traits.

THE WHITE HOUSE

Office of the Press Secretary

For Immediate Release October 22, 1982

TO THE SENATE OF THE UNITED STATES:

I am returning without my signature S. 2577, the "Environmental Research, Development and Demonstration Act of 1983."

It should be understood that my disapproval of this legislation will in no way interfere with the conduct of any of the research programs of the Environmental Protection Agency. Pursuant to the Department of Housing and Urban Development -- Independent Agencies Appropriations Act of 1983, which I signed into law on September 30, 1982, EPA will spend $220.8 million on its research activities in fiscal year 1983. The appropriations authorized for research in 1983 are 10 percent higher than in 1982, reflecting this Administration's commitment to putting environmental regulation on the soundest possible scientific footing.

While S. 2577 is unacceptable as a whole, I want to commend Congressman Cooper Evans of Iowa for contributing to this bill an amendment to authorize the Senior Environmental Assistance Program. Congressman Evans' amendment provides the authority for EPA to continue promoting meaningful employment opportunities for older Americans in Federal, State, and local agencies, as they accomplish important short-term environmental protection projects. The amendment is based on a highly successful demonstration project carried out by EPA in conjunction with the Administration on Aging and the Department of Labor. I believe the amendment would further this Administration's goals of providing productive, meaningful employment to older workers, and providing the benefits of a cleaner, safer environment to future generations.

Nevertheless, enactment of S. 2577 would represent a major step backward in achieving the goal of assuring that our vitally important environmental research programs reflect the best judgment of the scientific community, unhampered by partisan or interest group politics.

S. 2577 would mandate that the EPA Science Advisory Board membership include representatives from "States, industry, labor, academia, consumers, and the general public." This requirement runs counter to the basic premise of modern scientific thought as an objective undertaking in which the views of special interests have no role. The purpose of the Science Advisory Board is to apply the universally accepted principles of scientific peer review to the research conclusions that will form the basis for EPA regulations, a function that must remain above interest group politics.

In addition, under the statutes governing actual promulgation of EPA rules, the Administrator is obligated to seek public comment from any and all interested parties and to weigh such comment in shaping final rules. That is the stage of the rulemaking process at which involvement of special interest viewpoints is appropriate, not the earlier stage of developing a sound scientific understanding of the research findings that may be relevant to a particular rulemaking or class of rules.

more

(OVER)

Environmental regulation involves scientific, political, social, and economic judgments. The laws mandating protection of our air, water, and land against harmful pollution reflect this necessity to balance a wide range of factors. But for the entire regulatory process to function effectively, it must have as its starting point an objectively developed review of the state of scientific knowledge. The Science Advisory Board is vital to the preparation of this objective scientific review; to require that the Board become a political entity, with representatives from various special interests, would completely undermine the use of scientific knowledge in EPA rulemaking.

The maintenance of a free, essentially self-governing scientific research community is one of the great strengths of our Nation. To undermine this tradition by requiring that the scientists appointed to the EPA Science Advisory Board wear the label of "industry" or "labor" or "consumer" is a modern-day version of Lysenkoism to which I must strongly object.

In addition to imposing these new requirements on the procedures for selecting the EPA Science Advisory Board, S. 2577 contains a number of other objectionable features. It authorizes spending that is $46.4 million above the previously enacted appropriation bill; it mandates an increase in the proportion of funds devoted to basic research from 15 percent to 20 percent, which will take funds away from high-priority research needed for the support of regulatory proceedings; it mandates a duplicative and wasteful effort to create another national environmental monitoring network; and it mandates a number of research activities that are inconsistent with the previously enacted appropriation.

For these reasons, I am returning S. 2577 without my signature.

RONALD REAGAN

THE WHITE HOUSE,

October 22, 1982.

# # # #

SCIENCE POLICY ISSUES IN 1983 RE AIHC INVOLVEMENT DISCUSSION

BACKGROUND MATERIALS

(Re: Agenda Item 6, November 30, 1982, Board of Directors Meeting)

01

Attachments

02

September 3, 1982

TO: Committee and Task Force Chairman

FROM: The AIHC Public Affairs Committee

SUBJECT: Guidelines for Assessing Legislative Involvement

These guidelines have been prepared by the Public Affairs Committee to help provide a rationale for assessing legislative situations for likely AIHC involvement. Periodically, AIHC members express an interest in certain legislation and ask about possible AIHC involvement; AIHC is at times approached by Congressional Members or staff for appearances or other involvement in issues of legislative interest; and the potential for an increased incidence of generic science policy issues in the next Congress all suggested that guidelines for use in evaluating such involvement by AIHC would be helpful.

These guidelines are consistent with the responsibilities of the Public Affairs Committee which include, "developing appropriate strategies for responding to germane legislative, regulatory, and Administrative proposals." Nothing in these guidelines, however, is intended to alter AIHC's prescribed processes for deciding legislative involvement. For example, since AIHC is not primarily a lobbying organization, no decision for direct legislative involvement requiring registration as a lobby group can be made without prior approval by the Executive Committee.

It is expected that the primary function of these guidelines will be to facilitate communication and understanding.

E. L. Behrens, Chairman
Public Affairs Committee

ELB:jkm

GUIDELINES FOR ASSESSING LEGISLATIVE INVOLVEMENT

AIHC Public Affairs Committee

I. Occasions for potential AIHC involvement with the Congress (e.g., on legislation, visits with Members and staff, or in testimony) should be limited to instances that substantially involve generic policy issues related to chronic health concerns (e.g., carcinogenicity, mutagenicity, or similar effects).

The relationship need not be direct. For example, legislation addressing the role of science in federal regulatory decision making processes could be appropriate for AIHC involvement, if the organizational concepts or precedents would have potential application to the chronic health interests of the respective agencies (e.g., CPSC, EPA, FDA, OSHA, etc.). The generic issues should be sufficiently material to legislation so that AIHC involvement will not have the appearance of being too closely associated with federal actions related to specific materials or industry-specific concerns.

Where a science or other generic policy issue is material to a legislative interest, it is not necessary that AIHC support or oppose the total thrust of the legislation if our participation is confined to addressing issues of specific interest to AIHC.

II. Direct participation by AIHC should generally be limited to those instances of legislative involvement where there is a reasonable likelihood that the legislation will prevail.

In prevailing, it may not be necessary that the legislation actually be enacted into law, but it should stand a good chance of passage in the respective Chamber (House or Senate) where AIHC involvement is contemplated.

AIHC has unique expertise, but limited resources; so involvement in any given instance should be balanced against other opportunities for advancing AIHC's policy objectives to the interest of its total membership. Also to be balanced against the benefits likely to result from AIHC participation, should the legislation pass, are the risks attendant upon participation in any legislative effort, particularly if the effort should fail. The Public Affairs Committee is perhaps uniquely constituted to assist in these assessments.

III. For reasons of efficiency and limited resources, it will generally be found that AIHC can best serve its legislative needs by contributing to the efforts of other more broadly based organizations.

The determination of whether or not AIHC should become directly involved in an issue will have to be decided on a case-by-case basis considering AIHC's resources, interests, and overall program needs.

The resource requirements for pursuing a legislative objective can be substantial. AIHC will want to review each potential legislative involvement against the following considerations: First, is there a generic science or other policy issue represented by the legislation that is sufficiently unique to require the expertise of the AIHC? If so, what involvement by AIHC maximizes use of that expertise? For example, offering testimony may constitute an appropriate role for AIHC by providing focus for our proposals and an arena for advancing our views. But the resource-intensive follow up that lobbying entails may be better provided by those with the broader legislative issues in mind and having more extensive means.

Second, do issues, where they coincide with the interests and objectives of the AIHC, represent the major thrust of the legislation, or are they incidental to the legislation even though important to AIHC? Identifying which groups have the more preponderant stake in the outcome of a given legislation will be important in deciding whether AIHC's involvement should be direct or supportive of others.

Public Affairs Committee
September 3, 1982

AMERICAN INDUSTRIAL HEALTH COUNCIL
1075 CENTRAL PARK AVENUE • SCARSDALE, NEW YORK 10583 • (914) 725-1492

October 20, 1982

05

MEMORANDUM FOR THE AIHC EXECUTIVE COMMITTEE

Re: Scientific issues in pending third-party liability legislation

A basic objective of AIHC has been to support sound scientific principles in the determination of causality with regard to the relationship between exposure to alleged hazardous substances and human health effects. Measures replacing sound scientific principles with legal or factual presumptions have been gaining currency in regulatory legislation and legislative proposals. Examples are the listing of 65 generic compounds in § 307(a) of the 1977 Clean Water Act Amendments and the pending proposed Clean Air Act Amendments which would add a list of specific compounds under § 112 of the Clean Air Act. These same scientific issues will arise in the reauthorization next Congress of TSCA, Safe Drinking Water Act, FIFRA, RCRA, and other environmental statutes.

Similar proposals are being advanced with regard to legislation that would establish liability and/or compensation schemes governing third party injury alleged to result from exposure to hazardous substances. In pending product liability reform legislation, moreover, there are both provisions that would diminish the role of sound scientific evidence in establishing liability and provisions whose deletion from the draft legislation would further detract from the role of science in determining causality and other elements of liability. Thus, there is a clear role for AIHC in opposing provisions that replace scientific demonstration with presumptions or unwarranted uses of inadequate data.

Some key current issues are:

1. Hazardous Waste Liability

The proposals contained in the report of the Superfund § 301(e) Study Group, the "Grad Report" (see Memorandum on Legislative Concerns Arising from the "Grad Report", dated October 11, 1982) include the suggestion that, in establishing the right to Tier One no-fault compensation, the claimant be entitled to benefit from a serious of rebuttable presumptions which would ease the claimant's burden of proof. These presumptions would be based on findings by government agencies; the scientific validity of such findings cannot be assured. Neither the fact that the presumptions would be rebuttable nor the fact that the Study Group recommends that "an appropriate rule-making procedure should be

followed to assure the scientific accuracy of the results" is sufficient to guarantee that liability will not be imposed on the basis of invalid or inadequate scientific procedures. Senator Stafford (R-VT) has announced his intention to push for legislation embodying the Grad Report recommendations on compensation.

03

2. The Miller Bill

H.R. 5735, introduced by Cong. Miller (D-CA) would establish a system of workmen's compensation for disability or death arising from exposure to asbestos or uranium ore. The bill would create presumptions of causality with respect to certain diseases if exposure occurred in the course of employment. In some cases these would be irrebuttable.

3. Product Liability Legislation

The Kasten-Gorton bill, S. 2631, as reported out by the Senate Commerce Committee presents a combination of issues (attenuation of the causality showing required by current law and deletion of a requirement that expert testimony be supported by objective evidence) whose result, if not changed, could be to make findings of causality possible on a basis devoid of sound scientific support. Other provisions in the bill as reported, if they survive the legislative process, will strengthen the role of science in key elements of liability.

Conclusion

Support for sound science in these legislative initiatives is fully consistent with AIHC's position and no other group to our knowledge is focussing on these questions.

William J. McCarville
Chairman
Scientific Committee

UNIVERSITY OF CALIFORNIA, DAVIS

BERKELEY · DAVIS · IRVINE · LOS ANGELES · RIVERSIDE · SAN DIEGO · SAN FRANCISCO · SANTA BARBARA · SANTA CRUZ

DAVID S. SAXON
President of the University

EMIL M. MRAK
Chancellor Emeritus

University House
Davis, California 95616

November 2, 1982

34

Dr. M. J. Sloan, Manager
Regulatory Affairs, Health, Safety and
Environmental Support
Shell Oil Company
1025 Connecticut Ave., N.W. , Suite 200
Washington, D. C. 20036

Dear Joe:

I have been working with people at the State Chamber of Commerce and also Mr. Riley of the Pacific Gas and Electric Company in connection with the proposed actions to be taken by the Air Resources Board and the State Department of Public Health.

I have gone over their statements very carefully and I must say they are, in the least, shocking. The general attitude seems to be that there are so many uncertainties because of the lack of needed research that they are not going to wait; they are going to make their judgments in the absence of reliable information and sound science.

I have written letters to both of them and am enclosing copies that I sent to the people at the State Board of Health and Air Resources Board.

Riley, of the Pacific Gas and Electric Company, is so impressed with the results of the Aspen Conference, he would like to arrange for such a meeting in the State of California for the State of California. I would like to know how you feel about this.

A new book has just come out entitled "Genetic Toxicology--An Agricultural Perspective." This was the result of a conference held at the Davis campus some time ago and has been edited by Dr. Raymond Fleck. It is published by the Plenum Press. You might like to look at this because it overlaps with some of things we have been talking about.

In any event, Joe, I will be looking forward to hearing from you on this whole situation and whether or not you think a move in California in the direction of the Aspen activity would be desirable.

Kindest personal regards,

Emil M. Mrak

Enclosures

October 21, 1982 33

Ms. Mary Nichols
Air Resources Board
1102 Q Street
Sacramento, California 95814

Dear Ms. Nichols:

The meeting of your group to be held on October 27 has come to my attention and I would certainly like to attend, but unfortunately, I must be at another meeting in San Francisco at that time. The meeting I am referring to, of course, is the board's proposed amendment 1 to Title 17 regarding Emission of Toxic Air Contaminants.

I have read your statement and must say a great deal of work has gone into its preparation and it does contain a great deal of information.

I am concerned, however, as to whether or not the approval and acceptance of the new amendment should be done without adequate, sound, scientific review and consideration.

I feel so strongly on this, because only last July I was invited to attend a meeting in Aspen, Colorado, held under the auspices of the American Industry Health Council, and under the direction of John Higginson, formerly the head of the United Nations Cancer Research Institute at Lyon, France.

Dr. Higginson was prompted to call a group of scientists together because he saw the need for the formation and development of a prestigious, scientific group, independent of all regulatory agencies, reporting directly to Congress and the President, to review scientific matters that might result in decisions and regulations.

A good example of something that might be reviewed by such a scientific group is the amendment you are considering.

I might point out that the background for this scientific organization has been developed and I am sure you can obtain a copy of it from Dr. Higginson at Universities Associated for Research and Education in Pathology, Inc., 9650 Rockville Pike, Bethesda, Maryland 20814, if you so desire.

It is now in the hands of Dr. James Martin, or in other words Congressman Martin, who will deal with it at the Congressional level.

I think something like this is needed in California to review an amendment such as that being proposed by your organization.

Since time is a matter of importance however, I would suggest that a committee be appointed by some neutral organization, such as the University of California. I would further suggest that the President of the University be asked to call on some of his colleagues to help appoint such a committee that might review your proposal.

Most certainly we need sound science in all these matters. I am sure you would agree with me on this.

You and your colleagues have done an enormous amount of work in this area, and it does merit serious consideration by an impartial scientific panel.

Kindest personal regards,

Emil M. Mrak

October 21, 1982

33

Dr. Robert Stephens
714 P Street, Room 599
Sacramento, California 95814

Dear Dr. Stephens:

The workshop you are to hold on October 22 has just come to my attention. Most certainly I would like to attend this gathering and participate, but unfortunately I have firm commitments on October 22, and cannot possibly do it.

I am therefore, taking the liberty of writing to you and especially so since I have read the document entitled "Carcinogen Identification Policy: A Statement of Science as a Basis for Policy." I must say an enormous amount of work has gone into the preparation of this document and it does contain a great deal of information.

I am bothered by the fact that no science review committee has been proposed to review the science upon which proposed regulations would be based. I feel very strongly on this because just recently I participated in a workshop that had developed a proposal for Congress to establish a prestigious scientific panel that would be independent of all regulatory agencies and one that would report to Congress and the President.

The purpose of this panel would be to set up ad hoc committees to study scientific decisions, judgments, regulations and so forth that might be proposed by the regulatory agencies.

The scientific studies would be made public and the agencies would be informed of the scientific considerations and could accept them or reject them. In any event, the report would finally go to Congress.

I certainly think we need something like this in California and especially since some of these regulations are based on scientific information.

I would suggest that the University of California be called upon to establish an interim scientific panel of the type I have outlined. I would further suggest that the President of the University be asked to discuss the matter with other leaders on various campus' for the purpose of setting up an impartial

scientific panel that might include members not only of the University, but others in the state.

I hope you do not mind me taking the liberty of making this suggestion. I hope you find it a constructive one. 33

Kindest personal regards,

Emil M. Mrak

Appendix III

Sunset Committee Meeting Report

SUNSET COMMITTEE REPORT FOR 1982 ANNUAL MEETING

The Sunset Committee has met to consider whether AIHC should continue its existence in 1983.

The present administration has taken a number of steps which can lead to implementation of policies AIHC has long advocated. Those policies are of critical importance, and AIHC has earned a solid reputation as a credible, scientifically sound voice in their support.

In short, we believe our goals are in sight, and that AIHC must continue its work until our recommendations are adopted by Government. We hope that goal can be attained in 1983 and recommend that AIHC continue its work during the next year.

Paul F. Oreffice, Chairman
H. Barclay Morley
James B. Henderson
George J. Sella, Jr.

Appendix IV

1983 AIHC Budget

RECOMMENDED 1983 AIHC BUDGET

	Legal	PR	Expenses[1]	1983 Total	1982 Est. Exp.
Committees:	155,000	86,000	34,600	275,600	268,600
Associations			1,000	1,000	1,000
Board/Exec. Comm.[2]	44,000		22,000	66,000	65,000
Legal	4,000			4,000	3,000
Public Affairs	10,000	2,000	3,000	15,000	15,000
Public Relations	2,000	84,000	3,600	89,600	89,600
Scientific	95,000		5,000	100,000	95,000
Task Forces:	47,500		3,700	51,200	24,700
EPA	20,000		1,000	21,000	3,200
OSHA	10,000		1,000	11,000	11,000
Science Policy	11,500		500	12,000	4,500
FDA	5,000		1,000	6,000	6,000
CPSC	1,000		200	1,200	0
Administrative				569,000	567,000
Personnel/Overhead				484,000	487,000
Admin. Exp.				40,000	40,000
Legal Exp.				45,000	40,000
Projects				278,000[3]	444,537
TOTAL	202,500	86,000	38,300	1,173,800	1,304,837

[1] Staff, travel, direct expenses and hotel meeting rooms, dinners and lunches, etc.

[2] Includes administration of Finance, Nominating and Sunset Committees

[3] Funds anticipated to be allocated to 1983 projects requested by Chairmen. See attached list.

Appendix V

New Member Nominations

NEW MEMBER NOMINATIONS*

1983 BOARD OF DIRECTORS

AMERICAN INDUSTRIAL HEALTH COUNCIL

Class of 1985

Charles E. Brooks, Senior Vice President, W. R. Grace & Company

Edward W. Callahan, Vice President-Environmental Affairs, Allied Corporation

Conner M. Fay, Senior Vice President, Clairol Division-Bristol Myers

Richard H. Leet, President, Amoco Chemicals Corporation

Donald Powell, Senior Vice President, Champion International

George J. Sella, President, American Cyanamid Company

Monte C. Throdahl, Senior Vice President, Monsanto Company

*As recommended by 1982 Nominating Committee

Appendix VI

Officer and Committee Memberships

RECOMMENDATIONS

1983 OFFICERS

Chairman:
George J. Sella, Jr., American Cyanamid Company

Vice Chairman:
Richard H. Leet, Amoco Chemical Corporation

Treasurer:
Daniel McGrade, Stauffer Chemical Company

EXECUTIVE DIRECTOR

Ronald A. Lang

MEMBERSHIP OF THE 1983 EXECUTIVE COMMITTEE

Mr. Richard H. Leet, Chairman
Amoco Chemical Corporation

Mr. George J. Sella, Jr.
American Cyanamid Company

Mr. Monte C. Throdahl
Monsanto Company

Mr. Jackson B. Browning
Union Carbide Corporation

Dr. Elwood P. Blanchard
E.I. Du Pont De Nemours & Co., Inc.

Mr. Toy F. Reid
Eastman Kodak Company

Mr. Ronald A. Lang
American Industrial Health Council

MEMBERSHIP OF THE SUNSET COMMITTEE

Mr. Paul F. Oreffice, Chairman
Dow Chemical USA

Mr. James B. Henderson
Shell Chemical Company

Mr. Richard H. Leet
Amoco Chemical Corporation

Mr. George J. Sella, Jr.
American Cyanamid Company

MEMBERSHIP OF THE COMMITTEE ON NOMINATIONS

Mr. George J. Sella, Jr., Chairman
American Cyanamid Company

Mr. Richard H. Leet
Amoco Chemical Corporation

Dr. H. Barclay Morley
Stauffer Chemical Company

NOVEMBER 23, 1982

1983 DUES/MEMBERSHIP REPORT

Budgeted 1983 Dues Income		$1,129,225*
Paid Dues (5)		30,450
Commitments Received (69)		991,475
Outstanding Commitments (9)		133,950
Resignations (4)		53,000
	Projected 1983 Income	$1,155,875

Resignations

Gulf Oil
**Halcon
Hilton Davis
Hooker Chemical
Pilot Chemical
**U.S. Borax

* Provides $100,000 reserve for membership loss from 1982 dues
** Not included in 1983 income estimates

Appendix VII

Report to the Membership in 1982

Air Products

Date 17 November 1982

INTEROFFICE MEMORANDUM

Subject CMA supports EPA and OSHA Administrations

To Distribution

From A. J. Diglio — Corporate Environmental Activities (Location, Organization, or Department)

Distribution:

D. F. Baker
P. L. T. Brian
E. C. Crossland
L. Dale
E. Donley
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G. G. Handley
B. S. Horton
W. J. Kenderick
J. M. Norwood
R. Oeler
D. J. Phillips
J. K. Spata
L. Tucci

Please find attached a Chemical Week article on CMA's support of the administrations' EPA and OSHA agencies and the major issues in these areas.

A. J. Diglio

AJD:csm

Attachment

(320)

AP00036579

CMA's chief applauds the regulators

It's just as well that the Chemical Manufacturers Assn.—whose member companies account for well over 90% of U.S. production of industrial chemicals—switched to its present name. William G. Simeral, the new chairman of what several years ago was the Manufacturing Chemists Assn., is not a chemist at all—he's a PhD physicist. He's also a member of Du Pont's board of directors and of its executive committee, and one of the company's four executive vice-presidents. On top of that, Simeral is one of the chemical industry's leading authorities on the technology and economics of the plastics business, chairman of the board of the Wilmington (Del.) Medical Center, and a golfer and skier.

As CMA's chairman, the 56-year-old Simeral succeeds Paul F. Oreffice, Dow Chemical's president and chief executive officer. Like his predecessor, Simeral believes the association must push for basic changes in the laws governing various regulatory agencies, particularly the Environmental Protection Agency and the Occupational Safety and Health Administration. Meanwhile, however, he feels the industry should support the policies of the agencies' present chiefs—EPA's Anne M. Gorsuch and OSHA's Thorne G. Auchter.

EPA officials 'are running at us hard, but at least they are willing to listen'

A welcome change. Simeral, a notably articulate speaker, emphasizes CMA's backing for the two officials. "We're delighted with Anne Gorsuch and the new EPA," he says. "But it's *not* because they're pushovers. She is no pushover. Mrs. Gorsuch and the EPA are fair. We can talk to them."

Simeral complains that the media have sometimes made it seem that under Gorsuch's EPA, anything goes. "We think that EPA is moving very deliberately to enforce the law," he says. "We're finding that they're running at us hard to make sure the regulations are dealt with. But they are also trying to institute good science into technical decisions, and they are at least willing to listen to our data."

Simeral commends Auchter for improving OSHA's plant inspection policy. Formerly, the agency seemed to be indiscriminately inspecting all the plants it could. Now it's mainly inspecting the kinds of plants that have the most accidents, and it's seeking preventive measures. Says Simeral: "We think Auchter is the first [OSHA chief] who has tried to reduce the number of accidents by figuring out how to keep people safe."

Water and dollars. While the direction at both EPA and OSHA has changed, Simeral is convinced that the chemical industry must keep trying to get Congress to amend relevant laws, especially those dealing with water quality. He contends that since Congress wrote those laws, the industry's use of "best practicable technology" has generally reduced the concentration of toxic contaminants to levels that do not warrant further concern.

"Our view," Simeral explains, "is that instead of requiring every U.S. plant to install 'best available technology' on the mere assumption that it is needed, the law should be rewritten to measure the quality of the water. And if the water quality is already good enough," he pleads, "don't make us spend billions of dollars more."

A crossroad. Simeral was elected to CMA's board and to its executive committee in June 1978. That was when the 110-year-old association was being transformed from a relatively quiet, low-profile group to an advocacy organization that would defend the industry's interests on every current issue.

Right now, Simeral says, the biggest issues for the association are environmental. These include the "Superfund" program for cleaning up hazardous dump sites, the proposed revisions of the Clean Air Act and the Clean Water Act, protection of groundwater, and proposals for curbing "acid rain."

International issues represent a relatively new area for CMA, Simeral notes. In this category are foreign-trade problems, such as the alleged dumping of dyestuffs and synthetic-fiber textile goods in the U.S. The association is also concerned about the European Common Market's current consideration of the Vredling proposal, which would require multinational companies to provide more detailed disclosure of their worldwide financial and operating data.

Simeral, the younger son of a mechanical engineer, was born in Portland, Ore., but grew up in Lancaster, Pa., and entered that city's Franklin and Marshall College, which he later served as a trustee. He went on to the University of Michigan to get his MS and PhD degrees, and then in 1953 joined Du Pont to work as a physicist in the company's experimental station near Wilmington. He had never thought of working for a chemical company, but was attracted to Du Pont's basic research in polymer physics. There he helped develop a new method for making Du Pont's Butacite polyvinyl butyral, which is best known as a laminating layer in safety glass.

In 1959, he began a five-year stint in Du Pont's Washington Works at Par-

Simeral: from researcher to No. 1 industry spokesman.

kersburg, W. Va. Initially, he managed a research group supporting the startup of a plant to make the first melt-fabricable version of a Teflon fluoropolymer. By the time he left that location, he had also worked on three other major resin products: Delrin acetals, Zytel nylons, and Lucite methacrylates. He continued in research management positions for the Plastics Dept. until 1969, when he became director of the department's Commercial Resins Div. That was the first time he ran a profit center.

'If the water quality is already good enough, don't make us spend billions'

In his managerial posts after that, he alternated between corporate R&D and the Plastics Dept., which he headed in 1976 when it absorbed the Film Dept. One year later, he moved up into corporate management as a director, a member of the executive committee, and a senior vice-president.

Last year, in the reorganization that followed Du Pont's acquisition of Conoco, he was elected an executive vice-president. As an executive committee member, he handles liaison with three departments—central R&D, employee relations, and Biochemicals.

Simeral is "a tough boss, but good and fair," according to Howard E. Simmons, director of the Central Research and Development Dept. He observes that Simeral "doesn't simply operate with one or two top lieutenants; he likes to interact broadly up and down the line to get details from all levels." Noting that Simeral has been striving to get a corporate arm around the diverse research activities carried on throughout the company, Simmons remarks that "to carry this out at this time, Bill is just what Du Pont needs."

He's also just what CMA needs, according to Dow's Oreffice. "I've nothing but the highest praise for Bill Simeral," Oreffice says. "His effectiveness as a leader of the industry has been proven. He will be a very fine CMA chairman."

Simeral and his wife, the former Elizabeth Louise Ross of Beaver Falls, Pa., live in Centreville, Del., a Wilmington suburb. They have two daughters and two sons, one of whom is a Du Pont salesman. The family members occasionally gather at their vacation home in Colorado for golfing and skiing. □

Air Products

Date 16 November 1982

INTEROFFICE MEMORANDUM

Subject CMA Survey of Chemical Company Activities

To J. M. Norwood — Safety
(Location, Organization, or Department)

From A. J. Diglio — Corporate Environmental Activities
(Location, Organization, or Department)

cc: P. L. T. Brian

As requested, please find attached the completed CMA Survey on Chemical Company Activities to reduce unreasonable risk.

The survey was completed by contributions from John Barr, Ernie Blades, Gene Handwerk, and Tony Diglio.

The information will be maintained confidentially by Peat, Marwick, Mitchell and Company. It will be used by CMA solely in an aggregate form.

The survey is to be mailed directly to Peat, Marwick, Mitchell and Company by November 30, 1982 in the envelope marked Confidential provided herewith.

A. J. Diglio

AJD:csm

Attachment

(320)

SURVEY OF CHEMICAL COMPANY ACTIVITIES TO REDUCE UNREASONABLE RISK

CHEMICAL MANUFACTURERS ASSOCIATION

2501 M Street, N.W.
Washington, D.C. 20037

PURPOSE: To survey the chemical industry's commitment to reducing unreasonable risk to health and the environment.

BENEFIT: To demonstrate to policy makers and the general public the degree to which the chemical industry is ensuring the safety of chemicals.

Please return this survey form by November 30, 1982. Thank you for participating in this important effort.

SURVEY OF CHEMICAL COMPANY ACTIVITIES
TO REDUCE UNREASONABLE RISK

The U.S. chemical industry needs information to demonstrate its commitment to controlling and reducing unreasonable risk to health and the environment. This is a survey to identify that information.

The results are intended to:

- present the U.S. chemical industry's efforts to reduce unreasonable risk for the TSCA reauthorization hearings;
- support the regulatory positions of the chemical industry;
- provide performance and compliance documentation for the public; and
- provide feedback to participating companies on the industry's effort to control and reduce chemical risks.

Instructions for Completing the Questionnaire

This is a survey of the U.S. chemical industry's activities to reduce unreasonable risk in calendar year 1981. For the purposes of this survey, the industry is defined as all domestic sales plus domestic based exports of products in SIC code 28 (chemicals and allied products), excluding 283 (drugs). This definition must be used in completing the questionnaire for your U.S. chemical business, unless specific requests are made for other information.

The questionnaire contains five major sections, addressing:

I. General Company Information;

II. Chemical Hazard Assessment;

III. Chemical Hazard Communication;

IV. Chemical Hazard Control; and

V. Environmental Control Costs.

Each section contains three to eight subsections with specific instructions for completing each question. The questionnaire is printed so that the sections can be separated and distributed to appropriate personnel for completion. If you do separate the questionnaire, please copy these instructions and send them with the portion(s) of the questionnaire being distributed.

The questionnaire is designed to minimize the effort required to respond. Therefore informed estimates are acceptable where exact data is not available. We are not requesting that major internal studies be undertaken to complete the questionnaire. If you have any problems in completing the questionnaire, please call Mr. Deems Buell of Peat, Marwick, Mitchell & Co. at (202) 223-9525.

Confidentiality of Questionnaire Responses

Completing the questionnaire requires the disclosure of business information that many companies will consider confidential. To assure that responses are maintained confidentially during and after the survey, CMA is using Peat, Marwick, Mitchell & Co., a major public accounting and management consulting firm, to conduct the survey and evaluate the survey results. The information released at the conclusion of the survey will be in aggregated form to protect the identity of individual respondents. To provide additional assurance to your company, a confidentiality agreement is enclosed for your company to enter into with Peat, Marwick, Mitchell & Co. Your response will be maintained as confidential even if your company does not enter into this agreement.

Responding to the Survey

All participating companies must return their completed questionnaire by November 30, 1982. To limit follow up, a postcard is enclosed for your company to complete and return as soon as a decision has been made about participating in the survey.

A return envelope is enclosed for submitting your completed questionnaire. If you do not use this envelope, please mark your return envelope "CONFIDENTIAL" and mail it to:

Peat, Marwick, Mitchell & Co.
1990 K Street, N.W.
Washington, D.C. 20006
ATTN: Mr. Deems Buell

CONFIDENTIALITY AGREEMENT

This agreement, effective upon its execution, is between Peat, Marwick, Mitchell & Co. (hereinafter Peat Marwick) and the company below.

Peat Marwick has contracted with the Chemical Manufacturers Association (CMA) to obtain data on chemical company activities to reduce unreasonable risk. This data will be used by CMA solely in an aggregate form which precludes identification of information sources. This data will be used to comment on existing and proposed regulations and to provide feedback to participating companies.

Peat Marwick will obtain the data by means of a written questionnaire and, in a limited number of cases, will call companies who have responded to the questionnaire but clarification is required.

Peat Marwick agrees:

To use its best efforts to treat all company data obtained in the course of this survey as confidential, including but not limited to:

- storing confidential data in physically secure facilities;
- limiting access to the data solely to employees who need to see the data;
- separating and storing separately such portions of the questionnaire as may contain codes or other identification relating to the identity of the submitting company, and
- not releasing your response in an unaggregated form without your express permission.

By John Wade

Title Principal

Company Peat, Marwick, Mitchell & Co.

Date May 28, 1982

By A. J. Dreyfus

Title Director, Environmental Activities

Company Air Products and Chemicals, Inc.

Date 16 November 1982

TABLE OF CONTENTS

CURRENT ACTIVITIES TO REDUCE UNREASONABLE RISK

SECTION I. GENERAL COMPANY INFORMATION

This section will identify general information about your company. The results from this section of the questionnaire will establish the baseline for analyzing all of your survey responses.

I. A. Company Information

Specific company information is essential to the survey for standardizing responses. The questions below request information about your entire company's activities (world-wide) and your company's chemical business (world-wide and U.S.). For this survey, a chemical business is defined by products in SIC code 28, excluding 283, and a U.S. chemical business is defined as domestic sales plus domestic based exports of products in SIC code 28, excluding 283.

Your responses to the remainder of the questionnaire must be based on your U.S. chemical business, unless a question specifically states otherwise. Supporting functions provided by other areas of your company should be considered to be a part of your U.S. chemical business on a proportional basis when possible.

A.1 Provide the following information about your company's activities for the 1981 calendar year.

1.1 Total company sales (world-wide) in millions of dollars	$ 1,650 (1981$s)
1.2 Total company employment (world-wide) at calendar year end	16,200
1.3 Total world-wide chemical/product sales (all sales of products in SIC Code 28, exluding 283) in millions of dollars	$ 575 (1981$s)
1.4 Total number of employees at calendar year end associated with your world-wide chemical/product sales (ref. question 1.3)	1,900

1.5 Total U.S. chemical/product sales (domestic sales plus domestic based exports of products in SIC code 28, excluding 283) in millions of dollars $ 575 (1981$s)

1.6 Total number of employees at calendar year end associated with your U.S. chemical/product sales (ref. question 1.5) 1,900

1.7 Total number of chemical products (count all product distinctions except package size as individual products) associated with your U.S. chemical/product sales (ref. question 1.5) 325+*

1.8 Identify the major products associated with your 1981 U.S. chemical/product sales (ref. question 1.5) by checking the appropriate SIC codes below. (Consider major chemical product categories to represent at least 10% of your total U.S. chemical/product sales.)

SIC Code	Title	
281	Industrial Inorganic Chemicals	
282	Plastics and Synthetics	X
284	Toilet Preparations	
285	Paints and Allied Products	
286	Industrial Organic Chemicals	X
287	Agricultural Chemicals	X
289	Miscellaneous Chemical Products	X

A.2 What is your company's name?

Air Products and Chemicals, Inc.

A.3 Who is your company's principal contact in completing the questionnaire, their job title, and telephone number?

J. T. Barr	Mgr., Regulatory Response	(215 481-8343
Name	Job Title	Telephone Number

*Does not include special blends, formulations.

I. B. Management Attention to Health and Environmental Matters

The following questions will determine the attention that management devotes to health and environmental matters.

For each question, check (✓) all appropriate answers or provide the requested information.

B.1 What is the highest level in your company that is routinely involved in health and environmental matters concerning your U.S. chemical business? (check appropriate response)

BOARD OF DIRECTORS	____
PRESIDENT	____
CORPORATE VICE-PRESIDENT	X
VICE-PRESIDENT	____
DEPARTMENT HEAD	____
OTHER (SPECIFY):	

_____

B.2 Does your company have formal policies that address the following health and environmental concerns and are these policies publicly available? (check appropriate responses)

	INTERNAL POLICY		PUBLICLY AVAILABLE	
	YES	NO	YES	NO
MEDICAL	X	____	____	X
PRODUCT SAFETY	X	____	____	X
WORKER SAFETY	X	____	____	X
TRANSPORTATION	X	____	____	X
HAZARDOUS WASTES	X	____	____	X
ENVIRONMENT	X	____	____	X
DISASTER PLANS	X	____	____	X
OTHER (SPECIFY)				
_____	____	____	____	____
_____	____	____	____	____
_____	____	____	____	____

B.3 Please provide any specific examples that demonstrate your management's approach for dealing with health and environmental matters.

Strong emphasis on health/safety/environment at CEO level. Excellent safety and environmental records. Active corporate and divisional departments dedicated to H/S/E.

I. C. Organization

The following questions will find how companies have organized their U.S. chemical business to carry out their environmental and health policies.

For each question, check (✓) all appropriate answers or provide the requested information.

C.1 Do you have one or more groups whose sole function is dealing with health or environmental matters?

X YES _____ NO

C.2 Use the matrix below to provide a count of all the health/environmental specialists (internal personnel plus outside consultants) that your U.S. chemical business used in calendar year 1981. Present all specialists on an equivalent full-time basis according to their most appropriate health/environmental function. Do not double count.

(In completing the matrix, product safety is defined as a function that includes coordination and development of hazard communication and regulatory compliance programs making use of other health information. Worker safety is defined as a function that includes occuptional safety and employee health monitoring. Health is defined as a function that includes human, animal, and environmental research and assessment.)

FUNCTIONS	SPECIALISTS: Physician	Immunologist	Pathologist	Nurse	Epidemiologist	Toxicologist	Industrial Hygienist	Lawyer	Environmental Engineer	Other Professionals	Technicians
Product Safety						1					
Worker Safety										29	46
Health	3			11							
Legal (Env./Health)								2			
Transportation Safety										5	10
Labeling										1	
Air Pollution Control									18	3	9
Water Pollution Control									16	5	8
Hazardous Waste Management									4	1	2
Other's (Specify) _____										1	
_____										1	
_____											

Number of Equivalent Full-Time Specialists

These assignments are not always as clear-cut as shown.

SECTION II. CHEMICAL HAZARD ASSESSMENT

In this section we would like to know what your company is doing to identify chemical hazards to health and the environment within your U.S. chemical business. Hazard assessment is sometimes called loss prevention or product safety review; it involves the determination of a hazard's presence or absence through the review of available data such as toxicity, environmental fate, and physical/chemical properties to evaluate the potential for harm or need for additional information.

II. A. Chemical Hazard Assessment Review

We need to know what your company is doing to assess chemical hazards.

For each question, check (✓) all appropriate answers or provide the requested information.

A.1 Do you have a program for chemical hazard assessment?

X YES _____ NO

If the answer is NO, skip to question II.B.1.

A.2 About what percent of the time do you perform chemical hazard assessments when you have:

New Products	100 %
New Processes	100 %
Any Formulation Changes	N.A. %

A.3 Which of the following events typically trigger a chemical hazard assessment for existing products or existing processes. (Check all appropriate answers)

Routine	X
Process Change	X
New Data	X
New Product Use	X
Employee concern	
Consumer concern	
New regulatory requirements	

Other (Specify)

_____

_____

_____

A.4 What technical specialties were involved in your chemical hazard assessment program during 1981? (check all appropriate answers.)

Specialties	Internal Personnel	Outside Consultants
TOXICOLOGY	X	X
LEGAL	X	
REGULATORY	X	
ENGINEERING	X	
ENVIRONMENTAL	X	
SAFETY	X	X
ANALYTICAL (CHEMIST)	X	X
MEDICAL	X	X
INDUSTRIAL HYGIENE	X	
R & D/TECHNICAL	X	
PRODUCTION	X	
SPECIFY OTHERS:		

A.5 Do you have a chemical hazard assessment committee(s)?
X Yes _____ No

5.1 If yes, in approximately what year was your committee(s) started? 1975

A.6 Does your company conduct formal environmental health and safety reviews for the design of new plants or equipment projects?

X YES _____ NO

II. B. Testing

Toxicity testing can be helpful to determine whether a substance could pose a hazard. This testing is defined to include animal, environmental, epidemiological, clinical, toxicological, etc.

For each question, check (✓) all appropriate answers or provide the requested information.

B.1 Does your company have toxicity tests performed to evaluate the health effects or environmental effects of chemicals?

X YES _____ NO

If the answer is NO, skip to question II.C.1.

1.1 In approximately what year did your company begin performing toxicity tests? 1960's

B.2 Toxicity testing programs often overlap between testing in support of a company's U.S. chemical business and testing in support of a company's other activities. To simplify estimating U.S. chemical business toxicity testing efforts, provide the following information on the entire toxicity testing program(s) within your company in 1981 that provides all support for your U.S. chemical business. Include both human health effects and environmental effects testing.

2.1 Equivalent full-time technical staff directly involved in the toxicity testing program. 0.2

2.2 Number of new substances/products tested (don't count individual tests) 10

2.3 Number of existing substances/products tested (don't count individual tests) 2

2.4 Annual operating expense of in-house toxicity testing $ --- (1981 $s)

2.5 Annual expense of contracted toxicity testing $ 20K (1981 $s)

2.6 Annual expense of toxicity testing performed in cooperative research programs $ 80K (1981 $s)

B.3 Based on your answer to B.2, estimate the percentage of total testing expense that was attributable to your U.S. chemical business. 100 %

B.4 Estimate the replacement value of your toxicity testing facilities that were in place during 1981 for the toxicity testing program described in question B.2.

$ ---- (1981 $s)

B.5 Do you have examples which demonstrate changes in your testing program during the past ten years? (Consider planning, protocols, auditing, recordkeeping, types of studies, and reporting.)

Went to outside testing, internal auditing supported CIIT, CMA, SPI, etc.
More genetic tests and compliance tests expanded MSDS coverage, quality assurance programs, utilized computer data storage/search.

II. C. TSCA Premanufacture Notification (PMN)

The impact of PMN may be different depending on company size and the products involved. The questions below will indicate the factors that affect your U.S. chemical business.

For each question, check (✓) all appropriate answers or provide the requested information.

C.1 Do you have a procedure for determining that a PMN is required?

X YES _____ NO

C.2 Have you declined to manufacture any new chemicals because of the time or cost of PMN compliance?

_____ YES X NO

If yes, how many due to: Time _____
Cost _____

Please explain _____

C.3 How many PMN's did your company submit in:
1979 0 1980 1 1981 3

If none, skip to question II.D.1.

C.4 How many of your PMN substances, reported in C.3, have actually been or are likely to be commercialized? 3

II. D. TSCA 8(e) Reports

An 8(e) report informs EPA that a chemical may present a substantial risk to health or the environment.

For each question, check (✓) all appropriate answers or provide the requested information.

D.1 Do you have a company procedure in place for considering 8(e) reports?

X YES _____ NO

If the answer is NO, skip to question II.D.4.

1.1 What are the sources of information that initiate an 8(e) review? (Check all appropriate answers)

TOXICOLOGY	X
RESEARCH	X
PRODUCTION (EMPLOYEES)	X
CUSTOMER/CONSUMER REPORT	
DATA FROM SUPPLIERS	
OTHER (SPECIFY) Literature/other company reports.	

1.2 Approximately how many people are normally involved in your company's 8(e) review procedure? 6

D.2 Has your company filed at least one 8(e) report?

X YES _____ NO

2.1 If yes, whom do you advise of your 8(e) reports? (Check all appropriate answers)

CUSTOMERS	N.A.
CO-PRODUCERS	X
EMPLOYEES	X
OTHERS (SPECIFY)	

D.3 Has the information provided on 8(e) reports prepared by your company or any other company been used for your Material Safety Data Sheets (MSDS's)? (Check appropriate answers)

	Always	Sometimes	Never
Your own 8(e) reports		N.A.	
Other 8(e) reports		N.A.	

3.1 Has this information been used in your industrial hygiene practices? (Check appropriate answers)

	Always	Sometimes	Never
Your own 8(e) reports	X		
Other 8(e) reports	X		

SECTION III. HAZARD COMMUNICATION

This section will identify what chemical companies are doing to inform employees and customers about chemical hazards.

III. A. MSDS

The Material Safety Data Sheet (MSDS) is a source of information about a chemical. This question will determine how extensively they are used to transmit information.

For each question, check (√) all appropriate answers or provide the requested information.

A.1 What systems do you use to communicate information about chemical products. (Check all appropriate answers)

MSDS	X
LABELS	X
PRODUCT BULLETIN	X
LETTERS	X
TRAINING	X
POISON CONTROL CENTERS	
OTHER (SPECIFY)	
Chemcard, chemtrec	
video tapes	
Environmental and safety meetings	

(If you do not use MSDSs, skip to question III.B.1)

A.2 Do you send MSDSs to your customers? (Check all appropriate answers)

UPON THE FIRST SHIPMENT ONLY	X
UPON EVERY SHIPMENT	Sometimes
ON REQUEST	X
WHEN UPDATED	X
OTHER (SPECIFY)	

A.3 Approximately what percent of your purchased chemicals and chemical products were covered by MSDSs in 1981?

Purchased Chemicals	90+ %
Chemical Products	100 %

A.4 Is the information provided on your MSDS more, the same, or less then that called for on OSHA Form 20?

More	X
The Same	
Less	

A.5 How often do you review and update your MSDSs?

ANNUALLY	
AS NEW INFORMATION BECOMES AVAILABLE	X
OTHER (SPECIFY). 2-3 years routinely	

A.6 Do you maintain files of MSDS's?

X YES _____ NO

If the answer is NO, skip to question III.B.1

6.1 Are these MSDS's available to company personnel?

X YES _____ NO

6.2 Are these MSDS's available to the public?

X YES _____ NO

On request

III. B. Labels

Labeling provides information to customers and employees. The following questions will indicate the type of information transmitted and the proportion of chemical products for which such information is provided.

For this question, check (✓) all appropriate answers.

B.1 Typically, which of the following pieces of information appeared on your chemical product labels in 1981.

PRODUCT OR TRADE NAME	X
COMMON NAME	X
CODE NUMBER	X
CHEMICAL NAME	X
NAME OF MANUFACTURER	X
CAS NUMBER	
HAZARD IDENTIFICATION	X
PRECAUTIONS FOR USE	X
EMERGENCY PROCEDURES	X
CONTAINER DISPOSAL	
COMPANY ADDRESS	X
TELEPHONE CONTACT	
OTHER (specify)	
_____	
_____	
_____	

III. C. Information Systems

Information systems identify, communicate, and record information on chemicals.

For each question, check (✓) all appropriate answers.

C.1 Do you formally maintain the following information at either a corporate, divisional or local level?

	YES	NO
LISTS OF CHEMICALS USED	X	
LISTS OF CHEMICALS PRODUCED	X	
WORK HISTORY	X	
WORK SITE EXPOSURES	X	
MEDICAL RECORDS	X	
SIGNIFICANT ADVERSE EFFECTS	X	
CUSTOMER COMPLAINTS	X	
EMPLOYEE COMPLAINTS		X

C.2 Do you have procedures established to respond to health and safety questions raised by:

CUSTOMERS	X YES	___ NO
EMPLOYEES	X YES	___ NO

III. D. Training

Training frequently involves communicating information on chemical hazards and teaches people how to avoid those hazards. We would like to obtain information on the areas in which you train your employees.

For this question, check (✓) all appropriate answers.

D.1 In which areas do your chemical plant employees (hourly and supervisory) receive training? (Check all appropriate answers)

	Chemical Plant Employees	
AREAS OF TRAINING	HOURLY	SUPERVISORY
CHEMICAL HAZARDS	X	X
WORKPLACE SAFETY	X	X
HANDLING of MATERIALS	X	X
EMERGENCY RESPONSE	X	X
OFF THE JOB SAFETY	X	X
REGULATORY COMPLIANCE	X	X
OTHER (SPECIFY)		
Product Hazard Rev.		X
Transport Safety	X	X

SECTION IV. HAZARD CONTROL

This section will identify what chemical companies are doing to control hazards that have been identified.

IV. A Listing of Chemicals

Lists of chemicals are ready sources of information that management can use to control hazards. The following questions will identify items that are listed and how the information is used.

For each question, check (✓) all appropriate answers or provide the requested information.

A.1 Does your company maintain complete lists of the following materials? If yes, approximately when was this practice started?

	YES	NO	WHEN STARTED
PRODUCTS	X		long ago
RAW MATERIALS AND SEGREGATED INTERMEDIATES	X		
SOLID WASTES	X		
EFFLUENTS	X		
EMISSIONS	X		
OTHER (SPECIFY)			

If the answer is NO in each case skip to question IV.B.1

A.2 Are internal chemical lists used to:

	YES	NO
MEET REGULATORY REQUIREMENTS?	X	
MAINTAIN INTERNAL CONTROL?	X	
RESEARCH HEALTH AND SAFETY?	X	
OTHER (SPECIFY)		

IV. B. Industrial Hygiene Program

Industrial hygiene or similar programs are designed to protect workers from chemical hazards.

For each question, check (✓) all appropriate answers or provide the requested information.

B.1 Do you have an industrial hygiene program or a similar program performing the same functions?

X YES _____ NO

If the answer is NO, skip to question IV.C.1

B.2 How many total industrial hygienists and/or trained hygiene technicians were used in your U.S. chemical business in 1981 on an equivalent full-time basis?

4

B.3 What areas of operation does your industrial hygiene or similar program address? (Check appropriate items.)

MANUFACTURING	X
MAINTENANCE	X
INCOMING RAW MATERIALS	X
PROCESSING	X
PACKAGING	X
STORAGE	X
TRANSPORTATION	X
LABORATORY	X
PRODUCT USE	X
DISPOSAL	X
OTHER (SPECIFY)	

IV. C. Health Effects Monitoring

Health effects monitoring provides an early warning of work-related health problems.

C.1 Does your company perform periodic reviews of their employees' medical histories? (check appropriate answer)

_____ ALL EMPLOYEES

X SELECTED GROUP(S) OF EMPLOYEES (SPECIFY)
Exposed workers: Manufacturing, R&D, regular visitors, etc.

_____ DOES NOT PERFORM REVIEW

IV. D. Emergency Response

The following questions seek to find out the types of emergency response teams that companies maintain and the training that they receive. These teams could include fire brigades, first aid teams, or chemical spills teams.

For each question, check (✓) all appropriate answers or provide the requested information.

D.1 Does your company have emergency response teams for:

	YES	NO
Fire Control	X	
First Aid	X	
Chemical Spills or Releases	X	
Other (Specify)		
Mutual Aid		
Transportation		

If you do not have emergency response teams for chemical spills or releases, skip to question IV.E.1

D.2 Indicate the number of trained emergency response personnel for chemical spills or releases inside and outside of your facilities (emergency site activities and all activities) that your company maintained in the U.S. in 1981.

Emergency Site Activities _____ Unknown - Teams

All Emergency Activities _____ At most sites.

D.3 Do your company's emergency response teams respond to outside emergencies not involving your products?

X YES _____ NO

IV. E. Internal Health/Environmental Compliance Audits/Reviews

Internal health/environmental compliance audits/reviews are one means that companies use to ensure that they are following health and environmental policies and regulations. The following questions will determine how extensively U.S. chemical companies use this management tool.

For each question, check (✓) all appropriate answers or provide the requested information.

E.1 Does your company have an internal health, environmental, or other type of compliance audit program?

X YES _____ NO

If the answer is NO, skip to question IV.F.1

E.2 Indicate below which programs you have, the approximate year started, and approximate frequency that each type of audit is conducted on an annual basis.

	YES	NO	If yes, approx. Year Started	Frequency Audit is Conducted
Health compliance audits/reviews	X		Early 70's	Varies 1-2 years
Environmental compliance audits/reviews	X		Mid 70's	Varies 1-2 years
Other (specify)				

E.3 What skills are represented in conducting and reviewing the audits identified in E.2? (check appropriate answers)

	Health	Environmental	Others Specified in E.2		
Legal	X	X			
Technical	X	X			
Management	X	X			
Other (specify)					
Manufacturing	X	X			
Internal Audits		X			
Outside analytical		X			

IV. F. Transportation

Transportation safety is an important element in reducing the public's risk from chemicals. The following questions seek to determine what your company is doing concerning transportation.

For each question, check (✓) all appropriate answers.

F.1 Does your company train its personnel to understand transportation safety regulations and standards?

X YES _____ NO

F.2 Does your company have a transportation procedures manual?

X YES _____ NO

F.3 If you have procedures, are the following items included in the transportation procedures manual?

	YES	NO
LOADING/UNLOADING	X	
HANDLING	X	
PACKAGING	X	
LABELING	X	
PLACARDING	X	
INSPECTION	X	
SPILL/EMERGENCY	X	
OTHER (SPECIFY)		
Applicable Regulations	X	

F.4 Does your company provide precautionary information beyond Department of Transportation (DOT) standards for identifying the hazardous nature of chemicals in transit?

X YES _____ NO

F.5 Does your company use:

	YES	NO
LABELS	X	
PLACARDS	X	
WRITTEN INSTRUCTIONS	X	
VERBAL INSTRUCTIONS	X	
OTHER (SPECIFY)		
Corporate group	X	
Divisional practices	X	

F.6 Are your company products listed with CHEMTREC?

X YES _____ NO

F.7 Does your company maintain its own transportation emergency hotline?

X YES _____ NO

IV. G. Waste Disposal Procedures

We would like to determine how companies handle their chemical wastes.

For the following question, check (✓) the appropriate answers.

G.1 In recent years, has your company been using proportionately more, the same, or less of the following waste disposal methods for your chemical wastes? Indicate in the right-hand column if the method has not been used recently. (Check appropriate answers)

	RECENT USE OF DISPOSAL METHODS			
	MORE	SAME	LESS	METHOD NOT USED RECENTLY
RECYCLED	X			
STORED ON-SITE				X
STORED OFF-SITE				X
INCINERATED:				
ON-SITE	X			
OFF-SITE	X			
LANDFILLED:				
ON-SITE			X	
OFF-SITE			X	
OTHER (SPECIFY)				
Biodegradation	X			
Chemical-fixation	X			

SECTION V. ENVIRONMENTAL CONTROL COSTS

This section will serve to update the estimated cost to the U.S. chemical industry of end-of-process pollution control. Please provide the following information for your U.S. chemical business, defined as domestic sales plus domestic based exports of products in SIC code 28 (excluding 283). In cases where your pollution control facilities serve company activities beyond your U.S. chemical business, answer the following questions using appropriate estimates of the proportion dedicated to your U.S. chemical business. One source of information for this section may be submittals to the Census Bureau on Form MA-200.

For the purposes of the survey, pollution control facilities fall into three major categories; air, water, and solid waste. Use the following definitions of these pollutants to complete Section V.

Air pollutants are airborne substances including particulates (dust, fly ash, smoke), sulfur oxides, nitrogen oxides, carbon monoxide, hydrocarbons, odors, fluorides, lead and other heavy metals, radioactive and toxic substances.

Water pollutants are waterborne substances including phosphate, nitrates(trites), substances that generate chemical or biochemical oxygen demand, solids, acids, bases, heavy metals, radioactive and toxic substances, synthetic organic molecules, harmful microbes, oil, grease, dyes, and heat.

Solid waste includes garbage, trash, sewage sludge, dredged spoil, incinerator residue, wrecked or discarded equipment, biological and chemical wastes, radioactive and other toxic materials. Include solid waste produced as a result of air and water pollutant abatement.

V. A. Capital Investment

Estimate your capital investment in pollution control facilities (original installed cost) during calendar years 1981, 1980, 1979, 1978, and 1977 for end-of-process waste treatment/disposal. (Ranges may be used.)

	Air Pollution Control	Water Pollution Control	Solid Waste Disposal
1981 (installed cost)	$ 2.7 (1981 $'s)	$ 2.0 (1981 $'s)	$ 2.5 (1981 $'s)
1980 (installed cost)	$ 3.0 (1980 $'s)	$ 2.5 (1980 $'s)	$ 1.5 (1980 $'s)

(Continued to next page)

V. A. Capital Investment (Con't.)

1979 (installed cost)	$ 6.5 (1979 $'s)	$ 3.0 (1979 $'s)	$ 2.1 (1979 $'s)
1978 (installed cost)	$ 4.7 (1978 $'s)	$ 3.1 (1978 $'s)	$ 1.0 (1978 $'s)
1977 (installed cost)	$ 3.5 (1977 $'s)	$ 3.6 (1977 $'s)	$ 0.5 (1977 $'s)

V. B. Operation and Maintenance (O&M) Costs

Estimate your 1981, 1980, 1979, 1978, and 1977 annual O&M costs for end-of-process waste treatment/disposal. (Ranges may be used.)

	Air Pollution Control	Water Pollution Control	Solid Waste Disposal
1981	$ 8.8 (1981 $'s)	$ 6.0 (1981 $'s)	$ 2.6 (1981 $'s)
1980	$ 6.0 (1980 $'s)	$ 5.0 (1980 $'s)	$ 2.3 (1980 $'s)
1979	$ 4.0 (1979 $'s)	$ 4.0 (1979 $'s)	$ 1.6 (1979 $'s)
1978	$ 2.7 (1978 $'s)	$ 3.8 (1978 $'s)	$ 1.0 (1978 $'s)
1977	$ 2.5 (1977 $'s)	$ 4.0 (1977 $'s)	$ 0.5 (1977 $'s)

V. C. Staffing

Estimate the equivalent number of full-time personnel (operations, maintenance, engineering, administration, etc.) dedicated to operating and maintaining your pollution control facilities in 1981, 1979, and 1977 at calendar year end.

		Air Pollution Control	Water Pollution Control	Solid Waste Disposal
1981	80	18*	45	27
1979	78	18	45	25
1977	70	18	45	22

*Cannot assign to various sources accurately.