RISK-BENEFIT-COST BACKGROUND REPORT:
ISSUES, TERMS, METHODOLOGIES, AND ACTIVITIES

Document developed for Risk-Benefit-Cost
Scoping Study Steering Group
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INTRODUCTION

The intent of this brief report is to bring together pertinent background information in the Risk-Benefit-Cost arena to facilitate informed decision-making by industry representatives responsible in this field. Its purpose is to serve as a beginning primer to acquaint the reader with the issues, the meanings of some of the currently used terms, the methodologies, and some of the key players or leading specialists in this area. It will attempt to identify where in government, academia, and the private sector some of the Risk-Benefit-Cost work and studies are being conducted.

Risk-Benefit-Cost analyses are used formally and informally in nearly every activity of life. In certain areas, quantification of the risks, benefits, and costs is quite rigorous. However, in health, safety, and environmental areas many of the elements of an analysis are intangible and not immediately perceivable. Believing that the interest of the Risk-Benefit-Cost Scoping Study Steering Group lies mainly in the health and safety areas, our cursory survey has confined itself, where necessary, to the following materials controlled by well defined statutes and where risk assessment is used in their regulatory practice.

Material (Media)	Statutes
Air	Clean Air Act (CAA)
Air Quality Standards	
Carcinogens	
Chemical Substances	Toxic Substance Control Act (TSCA)
Drugs	Federal Food Drug and Cosmetic Act (FFDCA)
Food	
Material and Ingredient	FFDCA
Additive	
Contaminant	

Water	Clean Water Act & Safe Drinking Water Act
Water Quality Standards	
Priority Pollutants	
Workplace	Occupational Safety & Health Act (OSHA)
Health	
Safety	

Within this framework, this report attempts to fulfill the following listed charges given by the Steering Group to the working party:

1. Develop listing of issues.
2. Identify centers and range of activities by others on these issues.
3. Develop definitions of risks, benefits, and ancillary terminology with range of use.
4. Establish what methodologies are currently used for standard setting.

The report is organized by Chapters which address the above topics. Finally, we have included reprints of selected articles which the Task Force recommends as particularly germane to the use of risk-benefit-cost analysis in regulatory practice. These four reprints include:

Bazelon, D. L. 1979. Risk and Responsibility. Science 205:277-280.

Leape, J. P. 1980. Quantitative Risk Assessment in Regulation of Environmental Carcinogens. Harvard Environmental Law Review 4:86-116.

Okent, D. 1980. Comment on Societal Risk. Science 208 (4442):372-375.

U. S. Congress. Senate. Benefits of Environmental Health and Safety Regulation. Committee on Governmental Affairs. 25 March 1980. Prepared for Committee by the Center for Policy Alternatives at the Massachusetts Institute of Technology. *Nicholas A. Ashford, Co-principal Investigator.

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CHAPTER I

Background: Legislative and Regulatory Impetus and Conflicts.

The United States, together with many developed nations, experienced rapid economic growth and improvement in our standard of living in the decades immediately following World War II. Development of the petrochemical industry contributed a major component of the growth rate. Technological innovation has resulted in rapid expansion of basic materials, an introduction of many new substances each year, and broadscale dispersion of these and older substances in wide application in industrial processes and consumer products.

Some products of technological growth have involved risks of toxicity to man and his environment. In response to society's perception of these risks, the United States Congress in the 1970's enacted several laws that govern the conditions under which chemicals or products may be introduced into the environment. (See Appendix I, Table 1.)

Paralleling this legislation is the rapid growth of the bureaucracy required to develop, administer, and enforce the regulations. The various regulatory agencies have greatly enlarged their manpower, scientific capability, and the scope of screening and monitoring programs. (See Appendix I, Table 2.)

This growth has been mainly piecemeal, incremental, responsive to crisis, and lacking in a basic policy for the coherent management of the nation's health and safety resources. As a result, a variety of problems have arisen. The nation has laws and regulations with inconsistent dictates: some too strong to be met (e.g. by marginal industries), others too weak to provide protection (e.g. to high-risk groups). There are agencies with overlapping mandates (e.g. FDA, EPA, and CPSC). There are inconsistencies between different approaches to risk assessment and risk management, and conflicts between the public, industry, and government.

The statutes are not consistent in requiring regulatory agencies to consider the economic, environmental, social, and technological costs and benefits of regulating risks. Table 3 (in Appendix I), developed for the National Academy of Sciences Study on Food Safety Policy, summarizes for eleven statutes 1) the statutory standard for regulatory action and 2) the agency concerns in regulatory action.

Health, safety and social requirements are closely linked. However, early legislation in these areas separated issues according to media of exposure, often resulting in overlapping or conflicting requirements. As recognition of these commonalities has occurred, there is a greater tendency for generic regulations encompassing broad areas of control with hundreds of materials being affected by a single sweeping regulation. To cope with the increasing complexity, modeling is used more and more to assist in the decision-making process. As the complexity of the regulatory process increases, modeling techniques as a part of

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risk-benefit-cost analysis will be extended into more areas of regulatory decision making.

As these concepts are utilized by government groups (legislative and regulatory) to fit their particular needs, inductry needs to develop unified positions on methodology and policy in order to interact effectively. Since much of the critical information in the decision making process will derive from the industry sources, insuring its proper interpretation and application can best be done with industry involved. Thus, regulatory decision making process must permit and encourage industry participation.

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CHAPTER II

Issues in Risk/Benefit/Cost Analysis

"A thing is safe if its risks are judged to be acceptable."(1)

This simple statement embodies all of the complex and controversial elements of risk/benefit analysis. The statement clearly emphasizes that two very different kinds of activities are involved: measuring the risk and judging the acceptability of that risk. The estimation of risk is basically a scientific activity, although it can be extended to include economic factors as well. The judgment of the acceptability of the risks involves value judgments in which benefits figure prominently.

The fundamental issue is how to allocate our national resources in order to obtain the greatest improvement in health and safety for the resources expended. It should be recognized, particularly at this time, that the national resources which can be expended in improving health and safety are not unlimited. We need to allocate these resources as wisely as possible with due consideration, not only for the humanistic and ethical implications, but with consideration of economics as well. Now what is needed is a process which will set national priorities, based on objective evaluation of costs, risks, and benefits. The current approach on a piecemeal, case-by-case basis has frequently led to use of resources to obtain less than optimal results.

The more detailed listing of issues which follows further subdivides the problem into three broad areas: scientific, societal, and structural/policy.

A) Scientific - Estimation of the risk involved in a particular activity is primarily a scientific exercise. The process is based on the development of the technical facts around the consequences of exposure and estimation of the means and extent to which the negative consequences will be experienced by various populations. This process, at its best, is objective and free of value judgments. Specific issues are as follows:

- How to get the highest quality and most objective scientific assessment. Both industry and regulatory scientists have been criticized for lack of objectivity. In cases of unusual importance the National Academy of Sciences, as an objective, unbiased, prestigious, scientific group, has been drawn in to make risk assessments. Even this group has not always been able to keep from letting value judgments creep into their assessments.

(1) Of Acceptable risk - Science and the Determination of Safety; Lowrance, William W., William Kaufmann, Inc.; Los Altos, California; 1976.

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- Should the scientific assessment of risk be separated organizationally from the regulatory and enforcement functions? The regulatory process needs to find a way to develop the scientific assessment of risk as free from value judgments and political pressure as possible. Furthermore, we need to improve the effectiveness of the interface between scientific assessment of risk and the political/social assessment of benefits and the balancing of these benefits against the entailed risks.

- How to handle scientific uncertainty. Even with the most conscientious effort, scientific information, particularly on chronic, long-term issues, is seldom definitive. Scientists are left with some uncertainty which is most often handled by conservatism. If the scientific uncertainties are expressed, they frequently are conveyed to the public and to regulators, and only tend to increase anxiety.

- How to update risk assessment without losing face as new scientific information becomes available.

- How to communicate conclusions based on highly technical information to the societal sector understandably and effectively.

- How to handle "trans-scientific problems." These are problems in which definitive scientific information is unobtainable, but, nevertheless, decisions must be made. It has been suggested that these kinds of problems cannot be handled by scientific means alone--there are political implications which must be integrated into the decision.

- The special case of risks from cancer. The scientific debate between the threshold theory and the one-hit theory of carcinogenesis has not been resolved. Uncertainty about the mechanism of initiation of cancer continues to complicate risk assessment in this area.

- How do we deal with remote but finite probabilities of a risk occurring? How do we determine the point at which a risk becomes so remote that it is not worth considering?

- How to quantitate the increase in probability of a risk occurring due to human error, equipment malfunction and improper maintenance and combinations of these items, e.g. Three Mile Island.

- How do we evaluate the acceptability of risks to future generations; of risks whose manifestations come only later and of combinations of hazards, e.g. cigarette smoking and asbestos exposure?

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B) Societal Issues - Once the magnitude of the risk has been established by the scientists it falls to the politicians and courts, more or less responsive to public opinion, to make the value judgments as to whether or not the risk is acceptable. These judgments are clearly influenced by advocacy groups and by lobbyists. The process generally evolves to a subjective judgment based on scientific findings, but importantly influenced by political and policy considerations. Much of the controversy over the usefulness of risk/benefit analysis and its practice in setting regulatory standards stems from the subjective value judgments which are made. The "zero risk" approach to regulation finds its roots in this part of the process. Following are some of the societal issues involved.

- How to preserve freedom of individual choice. Benefits may be valuable to some but perceived of no value, and therefore, not worthy of risk to others. How do we regulate risk while still preserving the basic democratic tenet of freedom of choice?

- How to articulate benefits which are psychological or aesthetic. In a risk/benefit analysis any risk involved must be balanced against benefits. If the benefits are intangible, they still may be of value and therefore worth some risk.

- Rather than evaluating risks and benefits on an absolute scale, would it be better to position risks relative to others with which society is familiar and which have been accepted?

- How to equitably distribute risks and benefits. Society frequently asks people to take risks while others enjoy the benefits. Should risk-takers who do not receive the benefits be compensated, and if so, how?

- How to quantitate all of the risks and all of the benefits. Any rigorous benefit/risk/cost analysis has to balance all of the consequences. The task of making a global assessment of all of the consequences most often is not possible.

- How to handle the fact that risks and benefits are in different units. Here the purely economic approach runs into the morally distasteful task of putting a dollar value on human life. Similarly, how can such intangible items as peace of mind and quality of life be evaluated in dollar terms--should we even try?

- Should we be using the concept of efficacy rather than benefit? The concept of benefit in the regulatory context implies a value judgment which someone must make on behalf of others. Would we be better off to think in terms of efficacy, as is now done in drug regulation where the question is much simpler--"Does it do the job for which it is intended?"

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- The philosophical basis for risk assessment needs to be re-examined. Should we be trying to define what is an unacceptable risk rather than trying to define which risks are acceptable?

- How should society account for risks which may be statistically remote, but the consequences if the risk is realized are huge?--e.g. a major nuclear power plant disaster.

- There is a wide range of personal acceptance between known (familiar) and unknown (not familiar) risks, and between risks voluntarily accepted and risks involuntarily imposed on us by someone else. How are these factors handled in a benefit/risk analysis?

- An analysis of the risk/benefit/costs of a given action also needs to include a similar analysis of not acting. The consequence of inaction is most frequently ignored.

C) Structural/Policy Issues - In an ideal society the consequences of a given action can be rigorously analyzed and used in legislative and regulatory decision making for the optimized good of the society. Ideally we could make a global assessment of the risks-benefits-costs, and allocate our national resources to get the best overall result. However, there are a number of other issues which need to be resolved before this can be achieved.

- Who is responsible? In times past a commercial enterprise took full responsibility for the consequences of its actions. More recently, the responsibility for protecting the society from unacceptable risk has been assumed by government stimulated by public interest groups. Much of the conflict around regulatory constraints has arisen because of the shifting responsibility.

- As government has assumed increasing responsibility in the health and safety area, the incentives for action or restraint have shifted. A business enterprise, motivated to make a profit for shareholders, draws a careful balance between risks and benefits recognizing that undue risk jeopardizes the company's reputation, the product's viability, and risks reducing profit. The government's approach has been to provide incentive for responsible action through imposition of penalties. What is the most appropriate way to encourage commercial enterprise to responsible action?

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- How can regulatory agencies avoid the personal and organizational risk-avoidance approach to regulation?

- Are the techniques of risk/benefit analysis sufficiently well developed that they can be used as a rigorous part of the decision-making process? With all the deficiencies and uncertainties described above, is our society ready to rely on risk/benefit analysis as a central part of the process? Would we be better off to recognize that risk/benefit analysis is still an imprecise science and accept that it is only a tool to help organize the analysis process as some have suggested?

- What is the media's role and responsibility in shaping a balanced opinion on risk taking?

- Labor unions appear to be violently opposed to the use of risk/benefit analysis in decision making. Would their interests be better served long term by a process which brings to the public attention such issues as jobs lost or gained as a result of proposed action?

- In the spirit of preserving the right to individual choice, what action is needed to make this choice an informed one?

- How should our society develop an enlightened policy around risk assessment and the judgment of what is an acceptable risk? If we had such an enlightened policy, how does this become a part of the legislative and regulatory processes?

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CHAPTER III

Terms and Definitions

This chapter attempts to define some of the terms commonly used in risk-benefit-cost analysis. Broadly speaking, the terms are used with consistent meaning by workers in the field. Where confusion arises, it is usually in the limitations of the scope applied in using the term--e.g. what kind of elements are considered as benefits or as risks. Value judgments may be used by the analyst or by the public, sometimes unintentionally, in defining the scope of the terms as it is used in a specific instance. The following definitions are stated in the broadest terms:

Risk: Rates of occurrence of undesirable events.

Risk Assessment: The total process of quantifying a risk.

Risk Management: A process utilizing the three elements of 1) risk assessment, 2) cost/benefit analysis, and 3) value judgment to arrive at an optimal decision.

Safety: A judgment of the acceptability of risk.

Benefit: Whatever promotes social welfare. Reductions in social costs.

Costs: Whatever outlay of time, money, labor, self-denial, etc., is required to secure benefit.

Cost-Benefit Analysis: Evaluation and comparison of costs versus benefits.

Cost/Benefit Analysis: Evaluating the ratio of costs to benefits.

Cost-Effectiveness Analysis: Comparison of alternatives to achieve lowest cost/benefit ratio.

The following are some examples of how these terms have been defined by experts to suit their specific needs:

Risk

Hazards exist (trees will fall) as possible events. "Risk is the potential for realization of unwanted negative consequences of an event." (W.D.Rowe)

"A measure of the probability and severity of harm to human health" (objective but probabilistic). (W.W.Lowrance)

Carcinogenic Risk - "A quantitative estimate in probabilistic terms of cancer occurring due to exposure to specific agents." (RARG)

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Risk Assessment

"The total process of quantifying a risk and finding an acceptable level of that risk for an individual, group, or society. It involves both risk determination and risk evaluation." (W. D. Rowe)

"Human risk assessment is a very inexact exercise, based largely upon theoretical assumptions concerning interspecies extrapolation." (Food Safety Council) (See references Chapter IV.)

Process steps are:

1. Define conditions of exposure.
2. Identify adverse effects.
3. Relate exposure with effect (Dose-Response).
4. Estimate overall risk.

"When policy decisions are based on calculated probabilities, the base numbers should be supplemented with 'confidence limits'." (J. R. Ravertz)

Safety

"A matter of personal and social value judgement." (W. W. Lowrance)

"The acceptability of risks cannot be simply derived from a scientific study of quantified probabilities, costs, and benefits. The human factor influences the analysis at every point. But fairness in discussions and effectiveness in controls of risk can be approached by the use of scientific methods among others, provided that the diversity of human interests, values and perceptions of risks is always respected." (M. Swann, et al.)

Benefit

". . . anything received that causes a net improvement to accrue to the recipient" and "a result of a specific action that constitutes an increase in the production possibilities or welfare level of society." (W. D. Rose)

Cost

"A result of a specific action that constitutes a decrease in the production possibilities or welfare level of society." (W. D. Rowe)

Cost/Benefit Analysis

"An attempt to delineate and compare in terms of society as a whole the significant effects, both positive and negative, of a specific action." (W. D. Rowe)

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Cost-Effectiveness Analysis

"A term less specific than cost/benefit analysis, usually meaning the selection of the lowest cost alternative that achieves a pre-determined level of benefits. Alternatively, the analysis and selection of the path that yields the largest social benefit for a pre-determined specified level of social costs." (W. D. Rowe)

Appendix III, Table 1 provides a more extensive glossary of terms taken from W. D. Rowe, Anatomy of Risk, (1977).

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CHAPTER IV

Methodologies in the Health and Safety Areas

A complete, full fledged risk-benefit-cost analysis is a complex, sophisticated multi-disciplined exercise, still in an evolutionary development stage. The basic elements of the analysis are: an estimate of the exposure required to produce a biological effect; an estimate (frequently in probabilistic terms) of the frequency at which the population will experience the biological effect based on projected exposure; an estimate of all costs required to limit or control the exposure; and an estimate of all the benefits expected from the expenditure required to reduce exposure.

Each step in the procedure normally involves assumptions and uncertainties which should be identified and expressed as fully as possible.

The first steps, i. e., the estimation of exposure required to produce a biological effect and an estimate of the exposure the population will experience, are basically scientific. Many techniques (listed below and more fully described in Appendix IV) have been devised to improve the quality of risk estimation. Nonetheless, many critical issues remain for investigation--the theory of cancer initiation, problems with the extrapolation from animals to man, and so forth.

The remaining steps in the process, estimation of costs and benefits, are economic and societal. Much of the controversy in interpreting results from risk-benefit-cost analysis lies in the biases and value judgments which are inevitable in the subjective part of the process.

The diagram on the following page illustrates the many elements and their sequences in a typical analysis scheme.

Two examples of risk assessment methodologies are briefly outlined in the next sections of this chapter.

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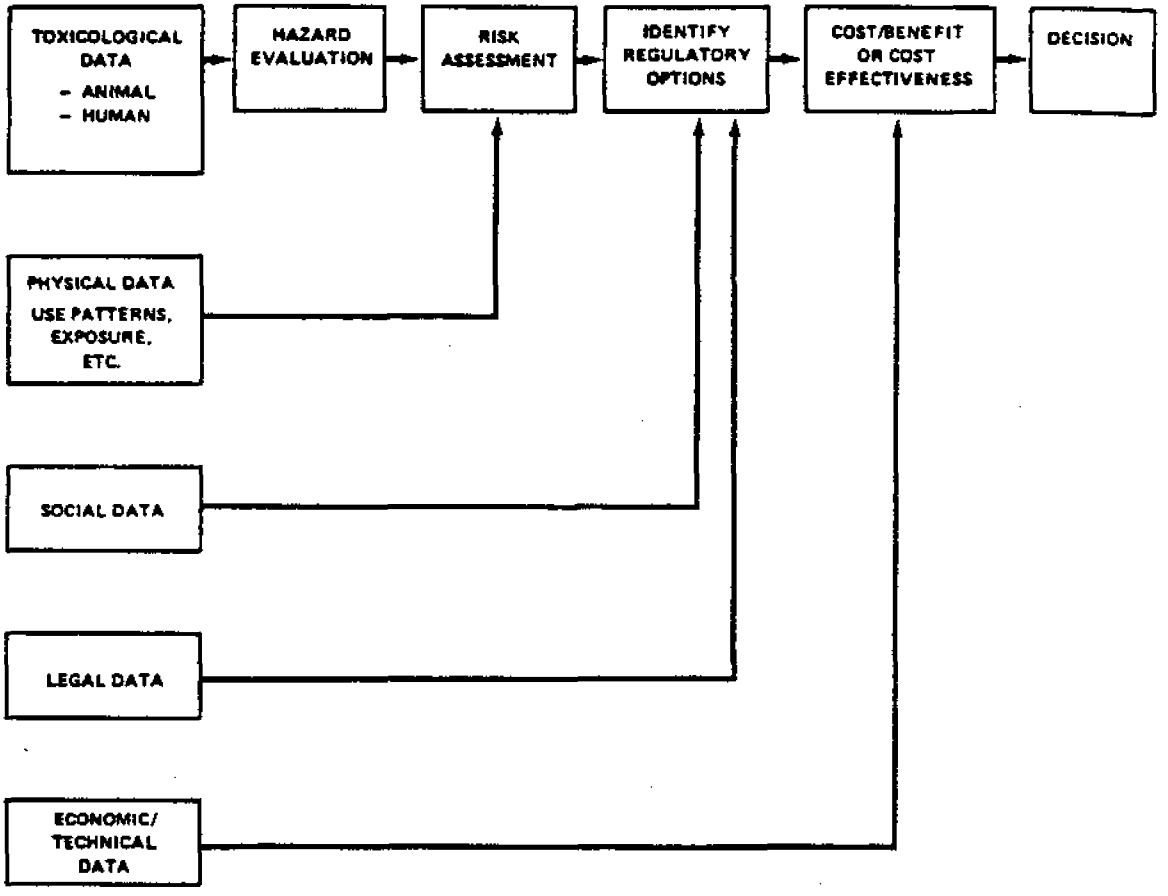
AMERICAN PETROLUEM INSTITUTE
PROJECT PROPOSAL: RESOURCE STUDY
OF RISK ANALYSIS AND DECISIONMAKING
ICOSH RISK ASSESSMENT TASK FORCE



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Food and Cosmetics Toxicology published two decision trees in 1978, which are abstracted here.

FEMA (Flavor and Extract Manufacturers Association)
FSC (Food Safety Council)

See references 1) and 2) below for a complete discussion of the methods.

FEMA DECISION TREE - See diagram on following page.

1. The decision tree consists of 33 questions, each answered "yes" or "no". Each answer leads to another question or to final classification into one of three classes (I, II, II) reflecting a presumption of low, moderate, or serious toxicity.

2. The tree is for use with all ingested, structurally defined organic and metallo-organic substances. Major chemical classifications are the organized branches of the tree.

3. Answering the questions requires chemical or biochemical training, and relies primarily on features of chemical structure.

4. The tree takes into consideration:

   - occurrence in body tissues and fluids, and
   - natural occurrence in food.

5. The logic of the tree rests heavily on known metabolic and toxicity data.

6. To establish priorities and to define tentatively the extent of appropriate testing, one can combine:

   - the classification according to presumptive toxicity, with
   - knowledge of human intake to provide for each substance a "protection index".

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1) FEMA Cramer, G. M., and R. A. Ford. 1978. Estimation of Toxic Hazard--A Decision Tree Approach. Food and Cosmetics Toxicology. 16(3):255-276.

2) FSC Food Safety Council. (Scientific Committee) 1978. Proposed System for Food Safety Assessment. Chapter 11: Quantitative Risk Assessment. Food and Cosmetics Toxicology, 16(suppl. 2): 109-136.

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FEMA DECISION TREE

(Figure 1)

Decision tree prediction of toxic risk

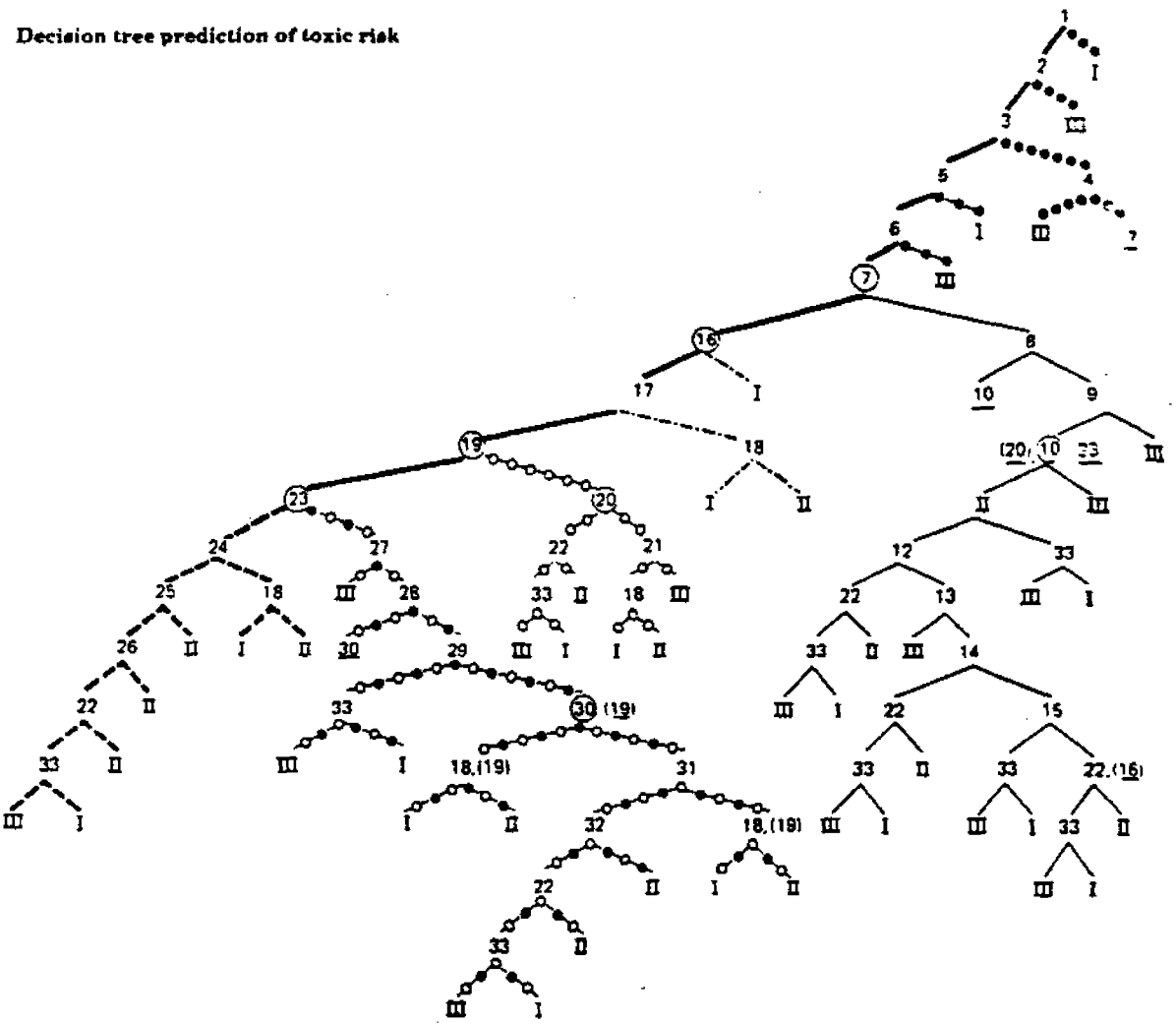

Fig. 1. A schematic diagram of a decision tree for the estimation of probable toxicity. Assessor should (a) start with question 1. (b) proceed by 'no' ↙ or ↘ 'yes', (c) move from any underscored number encountered to same circled number and (d) proceed to final classes I, II or III. Working downwards through the tree, the symbols designate the following groupings: biological normality (●●●●), high and low toxicity (●–●–●); heterocyclics (——); terpenoids (—); aliphatics (○–○–○–); aromatics (○–●–○–●); alicycles (——).

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FSC Revised Quantitative Risk Assessment[3)]

1. Introduction

2. Mathematical Models:

   - Probit Model
   - Logit Model
   - One-Hit Model
   - Gamma Multi-Hit Model
   - Armitage-Doll Model
   - Weibull Model
   - Simplified Statistico-Pharmacokinetic Model
   - Joint Effects of Two or More Agents

3. Biological Factors:

   - Evaluation of Chronic Cancer Bioassay Data
   - Evaluation of Characteristics of the Compound
   - Population at Risk

4. Methods Available for Low-Dose Risk Assessment:

   - Mantel-Bryan Procedure (most common)
   - Method Based on the One-Hit Model (low-dose linearity) (most common)
   - Methods based on the Armitage-Doll Model
   - A Method Based on the K-Hit Model
   - A Method Based on the Weibull Model
   - A Method Based on the Pharmacokinetic Model

5. Performances of the Gamma, Armitage-Doll, Weibull and One-Hit Models--Tables 2, 3, and 4. Dose-response data from 14 different experiments with the following 14 substances:

   - NTA
   - Aflatoxin B1
   - Ethylenethiourea
   - 2, 3, 7, 8-tetrachlorodibenzo-p-dioxin
   - Dimethyl Nitrosamine
   - Vinyl Chloride
   - Hexachlorobenzene
   - Botulinum toxin Type A
   - Dischloromethyl urea
   - Sodium Saccharin
   - Ethylenethiourea

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3)J. B. Cordaro--Executive Director of the Good Safety Council--provided a pre-publication draft of the substantially revised Chapter 11, "Quantitative Risk Assessment", of the Scientific Committee's report. This revised chapter is the basis of our summary. Food and Cosmetics Toxicology will publish the revised chapter in the next few months.

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- Dieldrin
- DDT
- Rapeseed (span) oil

6. Recommendations for Risk Assessment Methods:

   a. Choice of the models currently seen usable for low-dose extrapolation: (See Appendix IV for brief description.)

      - Probit
      - One-Hit
      - K-Hit
      - Armitage-Doll
      - Weibull

   b. Choice of extrapolation procedure.

      - inexactness of behavior of models in low-dose range, cannot be firmly justified on either statistical (goodness-of-fit) or biological grounds; choice of extrapolation procedure is matter of judgment.

      - pick one of models which incorporate low-does linearity as well as non-linearity, (K-Hit; Weibull; Armitage-Doll) together with extrapolation procedure with desired conservativeness.

   c. Choice of Societal Risk Level (Risk Level PO to which one extrapolates.)

7. Other Considerations of Low-Dose Risk Assessment:

   - Combination of results for two or more species.
   - Combination of separate studies on the same species.
   - Interspecies extrapolation.
   - Accounting for variations in human ingestion.
   - Multiple responses.
   - Concurrent and historic controls.
   - Confidence limits versus best estimates.

8. Summary: Risk Assessment Involves Risk and Benefit.

   a. Recommended use of calculations of VSD's (virtual safe dose) from four models:

      - One-Hit
      - Armitage-Doll
      - Weibull
      - Gamma Multi-Hit

      as inputs into the decision procedures.

   b. These calculations should be done for a variety of risk levels in the range of societal concern.

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c. Choice of estimates made should reflect the use of the more flexible models:

- Armitage-Doll
- Weibull
- Multi-Hit

when they fit better and seem appropriate biologically.

Conservative procedure: one-hit model or some other low-dose linear extrapolation procedure seems justified.

Blind use of low-dose linear extrapolations or conservative one-hit model appear scientifically indefensible.

Returning to the diagram on page 14, the areas relating to cost/benefit analysis require three areas of activity:

1. Identify the negative aspects (costs) and the positive aspects (benefits):

   - Individual - Group - Society
   - Direct - Indirect
   - Tangible - Intangible
   - Economic - Welfare

2. Measure the above factors in terms of:

   - Quality of Life
     - Health
     - Safety
     - Environmental Amenities
   - Dollars
   - Risks

3. Compare costs with benefits:

   - Explicit - Implicit
   - Ethics
   - Value Judgments
   - Discounting for Timing Differences

In the first activity, a lot of uncertainty and confusion exists. The identification of all non-trivial effects of a particular decision demands the widest possible exploration on the total system impacts by knowledgeable representatives of areas affected by the decision. Short-term and long-term effects are both possibilities. Who and what is affected, and how needs determination. Societal, group and individual impacts can by psychological and emotional as well as material.

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The application of measure, especially dollars for comparative purposes, in the second activity is heavily value-laden. Quoting B. R. Putnam, American Cyanamid, (CEP, February, 1980):

> "The most emotionally gripping argument against cost-benefit, and especially risk-benefit, is that it is impossible to put a dollar value on improvements to human safety or health. The plain fact, however, is that both industry and government make such valuations every day, whether they recognize it or not. As Robert W. Crandall, senior fellow of the Brookings Institution has asked: "Why do regulators set limits ...which are greater than zero? Why did OSHA not argue for 0 parts per million for benzene? Or why are not all of the primary ambient air standards set at 0 ppm? Surely it is not because we know with certainty that reducting current standards to 0 ppm would improve one's health. It is, quite simply, because the administrators of EPA and OSHA do not believe the additional health benefits are "worth it." Or, alternatively, they do not think that the courts will sustain such a high value placed on human health. Either way, we have social institutions reaching judgments about the value of improvements in human health. They must. They cannot avoid it.
>
> "Therefore, all a proponent of sensible judgments would ask is that they write down these values and defend them, and that they use them consistently in evaluating all regulations and options to each regulation. It is that simple."
>
> It is time for the regulatory agencies to acknowledge this responsibility publicly. That their decisions do have significant economic consequences is undeniable. That these consequences should be weighed against identified anticipated benefits is equally clear. Costs versus benefits is a process that already exists in regulatory decision making; what remains is formal <u>acceptance of the philosophy underlying the process</u>."

In the comparison activity of risk assessment, the ethical considerations arise. Are we to promote just the greatest good for the greatest number, or do we wish to see that the benefits are distributed such that all persons are as well or better off with no additional harm to anyone?

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CHAPTER IV

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CHAPTER V

Activities: Centers and/or Principal Individuals Involved in Risk-Benefit-Cost Activities.

Risk-benefit-cost activities are on an exponential growth curve. The proliferation of centers and individuals involved in these activities in the last year is tremendous now that risk assessment, risk analysis, risk-benefit analysis, and cost-benefit analysis have become "buzz" words in Washington. None of these activities are new as this report attempts to document. For example, risk assessment has replaced technology assessment -- which has not lived up to promises its advocates hoped for.

The literature is massive. The authors of this report have culled the literature, conferred with numerous individuals, and gladly accepted the Steering Group's suggestions in developing a list of centers and principal individuals involved in risk-benefit-cost activities. We have selected the following eight categories which comprise the body of this chapter as an organizational framework.

I. Washington Governmental Activities
II. Washington Quasi-Governmental Activities
III. Academia
IV. Centers, Contractors, and Organizations
V. Contractors
VI. Law
VII. Public Interest Groups
VIII. Trade Associations

We accept responsibility for those individuals and centers that we intentionally or unintentionally did not include. We welcome the Steering Group's comments and further additions and deletions to our selected listing -- as this is a working document.

In addition to the several bibliographies assembled independently by Haight, Haxby, Ifland, and Norberg, we requested two formal computer-generated literature searches: 1) Toxline using different combinations of the following sets of terms: (Risk or Risks)(Assessment or Analysis or Evaluation)(cancer or carcinogen or carcinogenic)(cost and Benefit and Analysis)(impact) and (chronic) augmented by Chemical Industry Institute, and 2) Smithsonian Science Information Exchange. These bibliographies are on file and available as well as some of the selected references, at the American Industrial Health Council, 1612 K Street NW. Washington D.C.

CMA 072809

I. Washington Governmental Activities*,°

U. S. Congress

Office of Technology Assessment

Assessment of Technologies for Determining Cancer Risks from The Environment.
Project Personnel: Michael Gough and Robert Fensterheim
Topics: Environmental cancer estimates, testing technologies, extrapolation techniques, "unreasonable risk".

Associated Conference: N.Y. Academy of Sciences Workshop on Management of Assessed Risk for Carcinogens. 17-18 March 1980.

Impacts of Applied Genetics.
Project Director: Zsolt Harsanyi
Topics: Identify, characterize, and analyze environmental social, and ethical issues accompanying the use of genetic technologies.

Environmental Contaminants in Food.
December, 1979. (GPO 052-003-00724-0) OTA-F-103.

House of Representatives:

H.R. 4939 ° Ritter 24 July 1979
"To provide for a Federal mechanism within the Office of Science and Technology policy for assessing the comparative risks involved in actions in scientific, technical, and related fields." (Referred to Committee on Science and Technology.)

H.R. 5091 ° Martin et al. 2 August 1979
"To amend the Federal Food, Drug, and Cosmetic Act to authorize the issuance of a regulation for a food additive on the basis of an evaluation of the risks and benefits of the additive. . ." (Referred to Committee on Interstate and Foreign Commerce.)

* Individuals and/or activities worthy of special attention for their current and potential future significant contributions.

° Individuals whose names appear within one or more categories indicating potential crossover influence.

CMA 072810

H.R. 6521 Wampler and Grassley 13 February 1980
"To establish the National Science Council to decide questions of scientific fact which arise in agency adjudications involving restricting the use of certain substances which are primarily used in food production, processing, or marketing, and which may be harmful to human health. . ." (Referred jointly to Committees on Agriculture, Interstate and Foreign Commerce, and Science and Technology.)

Committee on Interstate and Foreign Commerce
Subcomittees on Oversight and Investigations and/or Consumer Protection and Finance.
Hearings: Cost-Benefit Analysis by Regulatory Agencies.
Witnesses:

30 July 1979
- Lester Lave
- Robert Crandall
- Baruch Fischoff
- Nicholas Ashford

24 October 1979
- Mark Green
- James C. Miller, III
- Murray L. Weidenbaum
- Allen R. Ferguson

17 April 1980
- H. L. Krieger (GAO)
- Congressman Herbert E. Harris, III

Committee on Science and Technology

1. Risk/Benefit Analysis in the Legislative Process.
   24 and 25 July 1979. (Committee Print 71 and Serial KK)
   Joint Hearings before:
   Subcommittee on Science, Research and Technology of Committee on Science and Technology.

   Subcommittee on Science, Technology, and Space of the Senate Committee on Commerce, Science, and Transportation

   AAAS Congress/Science Forum
   Witnesses:
   - Aaron Wildavsky
     Harold P. Green (George Washington University)
     Edwin Diamond (MIT)
     Eula Bingham (OSHA)
   - Congressman James G. Martin
   - Nicholas Ashford
     Samuel W. Greenhouse (George Washington University)
     Lewis H. Sarett (Merck and Co.)
     Marvin Schneiderman (NCI)

CMA 072811

Senator Paul Tsongas
° Hon. Howard T. Markey
John H. Gibbons (OTA)
° Congressman Don Ritter
° David Okent
° Daniel Callahan
° Paul Slovic
Congressman Richard L. Ottinger
Congressman John W. Wydler
° William Lowrance
Robert P. Morgan (Washington University)
John Stewart (Senate Subcommittee)

2. Committee Report 96-61 to accompany H.R. 2729--
Appropriations to the National Science Foundation (NSF).
Recommendation by Committee that NSF:

a) "Sponsor systematic research to improve the methods for evaluation of long-term comparative risks of alternative technological solutions, including inaction, to such national concerns as energy, materials, environmental quality, food or drugs."

b) "Promote education in risk assessment methods and stimulate public and professional application of comparative risk research." (See also NSF and NRC entries.)

3. Hearing scheduled for 14 and 15 May 1980 before
Subcommittee on Science, Research, and Technology.
Potential Witnesses: FDA, EPA, CPSC, and OSHA.
Topic: H.R. 4939 (. Ritter) Federal mechanism for use of risk assessments in choosing between alternative scientific or technological options. (See Appendix V)

Committee on Judiciary.
Hearings on Regulatory Reform, H.R. 3263.

SENATE:

S. 2234 Stevenson Recombinant DNA (Referred to Committee on Labor and Human Resources.)

Committee on Governmental Affairs.
1) Hearings on Regulatory Reform Legislation.
(S. 262, S. 755, S. 445, S. 93) Parts 1 and 2.
Held in March, April, May, and June of 1979.
Over 81 witnesses testified.

2) S. 2147.

CMA 072812

3. ° Benefits of Environmental, Health, and Safety Regulation. Prepared for the Committee by the Center for Policy Alternatives (MIT). 25 March 1980. Nicholas A. Ashford, Co-principal Investigator.

4. Study on Federal Regulation. 6 vol. 1977. Committee on Commerce, Science, and Transportation; Subcommittee on Science, Technology, and Space.

See House Committee on Science and Technology joint hearings on Risk/Benefit Analysis in the Legislative Process.

Hearing scheduled for 20 May 1980 on "Industrial Applications of Recombinant DNA Techniques." (See Appendix V)

National Science Foundation (NSF)
(See previous entry under House Committee on Science and Technology)

Technology and Risk Assessment Group
Joshua Menkes and Vincent Covello
Activities: 1) Funding grants on risk assessment.
2) Requested National Research Council (NRC)
to assess the current state of knowledge concerning major issues in risk assessment, and the use of information about risk in the decision-making process, and
to develop an agenda for future research on the science and technology policy aspects of risk assessment.

Ethics and Values in Science and Technology Program
Arthur L. Norberg
Activities: Joint funding of grants with the Technology and Risk Assessment Group (NSF) and with the National Endowment for the Humanities (NEH) on ethical issues in regulation, risk assessment, and risk management.

CMA 072813

Intergovernmental Regulatory Liaison Group (IRLG)
(CPSC, EPA, FDA, and FSQS of USDA)

1. Scientific Bases for Identification of Potential Carcinogens and Estimation of Risks. Report of IRLG, Work Group on Risk Assessment.

   Federal Register. 44(131):39858-39879. 6 July 1979.
   Journal of National Cancer Institute. 63(1):242-268. July, 1979.

2. Chemical Testing Guidelines -- Acute Eye Irritation, Acute Oral Toxicity, Acute Dermal Toxicity, Acute Inhalation, Teratogenicity. Consensus Testing Requirements. 9 April 1979.

Food and Drug Administration (FDA)

1. Symposium on Risk/Benefit Decisions and the Public Health. Proceedings of the Third FDA Science Symposium. Colorado Springs, CO. 15-17 February 1978. (Conducted in conjunction with EPA, CPSC, and OSHA.)

2. Sensitivity of Method (SOM) -- ongoing.

3. Delaney Clause and other food safety aspects of the FFDCA. Modification recommendations; document for submission to Congress in response to PL 95-203.

4. Formaldehyde/IRLG.

Environmental Protection Agency (EPA)

1. See also Regulatory Council and IRLG.

2. Risk assessment:
   Mutagenicity Assessment Group (MAG)
   Carcinogenicity Assessment Group (CAG)
   Teratogenicity Assessment Group (TAG)

3. Office of Toxic Substances.
   Lets many grants and contracts.

4. Specific examples include:
   FIFRA Hazard Evaluation Guidelines.
   Federal Register 44(187):55213-55218. 25 September 1979.
   Proposed Guidelines for Registering Pesticides in the United States; Hazard Evaluation: Humans and Domestic Animals.

CMA 072814

Airborne Carcinogens
Federal Register 44(197):58642-58670. 10 October 1979.
National Emission Standards for Identifying, Assessing, and Regulating Airborne Substances Posing a Risk of Cancer.

Cancer Risk Assessment.
Federal Register 45. 29 February 1980.
Proposal to report production and exposure-related data on approximately 2300 chemicals -- for ranking chemicals for investigation and for preliminary risk assessment.

Consumer Product Safety Commission (CPSC)

1. See IRLG.

2. Selection of Chemical for Toxicological Testing:
Peter Preuss -- Health Sciences.

Occupational Safety Health Administration (OSHA)

Identification, Classification, and Regulation of Potential Occupational Carcinogens.. Final Rule. Federal Register 45(15):5001-5269. 22 January 1980.

National Toxicology Program (NTP)

1. NHS Agencies:
FDA/NCTR
NIH/NCI/NIEHS/NIOSH
CDC

2. David P. Rall, Director (NIEHS)

3. Activities: Toxicology Research and Testing Coordinative Management of Activities Annual Report of Carcinogens, mandated by PL 95-622, scheduled for release in mid-summer.

Risk Assessment Methodologies grants to academia.

Office of Recombinant DNA Activities (ORDA), NIAID, NIH.
William J. Gartland
Federal Register publishes changes in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

CMA 072815

Council on Environmental Quality (CEQ)

1. August, 1979. Toxic Substances Strategy Committee March/April, 1980 -- draft revision of above.

2. December, 1979. (released 21 April 1980.) The Benefits of Air and Water Pollution Control: A Review and Syntheses of Recent Estimates. A. Myrick Freeman, III, (Bowdoin College).

Regulatory Council

Statement on Regulation of Chemical Carcinogens; Policy Request for Public Comment. Federal Register 44(202):60038-60049.

17 October 1979.

Office of Science and Technology Policy (OSTP)

Calkins, D. R., R. L. Dixon, C. R. Gerber, G. S. Omenn, and D. Zarin. 1980 Framework for Federal Carcinogen Policy. JNCI 65(1). (Adapted from "Identification, Characterization, and Control of Potential Human Carcinogens: A Framework for Federal Decision-Making". 1 February 1979.

Office of Management and Budget (OMB)

Office of Regulatory and Information Policy (organized 1 February 1980). Jim J. Tozzi, Director.
Activities: End unnecessary regulation and develop regulatory cost-accounting system.

II. Washington Quasi-Governmental Activities

National Research Council (NRC)

1. Review of Risk Assessment in NRC Reports:
   25% of all NRC studies concerned with risk assessment;
   25% devoted to management of known hazards.

2. Perspectives on Benefit-Risk Decision Making.
   Report on a colloquium conducted by the Committee on Public Engineering Policy. 26-27 April 1971. Washington,D.C. National Academy of Engineering. 1972.

3. Food Safety Policy: Scientific and Societal Considerations.
   March, 1979. Institute of Medicine. Mandated by PL 95-203.

CMA 072816

4. Committee for a Planning Study for an Ongoing Study of Costs of Environment-Related Health Effects. Institute of Medicine. (Study mandated by PL 95-623.)
7 May 1980. Public meeting to receive views on current and future needs for information in assessing environment-related hazards to human health and in assessing costs associated with those hazards.

5. Committee on Risk and Decision Making (CORADM).
See previous entry in NSF (p. 26.) Technology and Risk Assessment Group.

Project Title: Risk and Decision Making: Development of Systematic Research to Improve Risk Analysis and Decision Making.

Public Meeting (workshops) to be held summer of 1980.

Members:

Raiffa, Howard (Chair)	Harvard University
Mosteller, Frederick C.	Harvard University
° Wilson, Richard	Harvard University
Ruina, Jack	MIT
° Schuck, Peter	Yale University
Serene, Eileen	Yale University
Lindblom, Charles E.	Yale University
° Kates, Robert W.	Clark University
Tuersky, Amos	Stanford University
Yalow, Rosalyn	Bronx Veterans Hospital
Loury, Glenn C.	University of Michigan
Coleman, James	University of Chicago
Radner, Roy	Bell Telephone
Ruckelshaus, William D.	Weyerhauser
A. Karim Ahmed	National Research Defense Council
David Cohen	Common Cause

Staff: ° James W. Vaupel and John D. Graham.

CMA 072817

III. Academia

Clark University	°*R. W. Kates and R. Kasperson
UCLA	*David Okent
Harvard University	°Richard E. Wilson
MIT (Center for Policy Alternatives)	°Nicholas Ashford
University of Maryland	°Martin J. Bailey
Georgetown University	Edward J. Burger
UC, Davis	M. Goldman
Bryn Mawr College	Jane C. Kronick
Carnegie Mellon	°Lester Lave
Stanford University	°William D. Lowrance
American University	William D. Rowe
UCLA	Rakesh Sarin
Yale University	Peter Schuck
Duke University	°James W. Vaupel
UC, Berkeley	°Aaron Wildavsky
Washington University	°Murray L. Weidenbaum
Harvard University	Richard Zeckhauser
New York University	Bernard Altschuler

°See listing of CORADM members within NRC, Section II.

University of Chicago
University of Indiana
University of North Carolina

IV. Centers, Contractors, and Organizations

Hastings Center	Daniel Callahan
Food Safety Council	J. B. Cordaro
Brookings Institution	°Robert Crandall
	°Lester Lave
The Conservation Foundation	Terry Davies
Decision Research (Perceptronics)	°Baruch Fischoff
	Sarah Lichtenstein
	°Paul Slovic
Franklin Institute	Gio B. Gori
Resources for the Future	Allen Kneese
American Enterprise Institute(AEI)	°James C. Miller
	°Martin J. Bailey
	°Murray L. Weidenbaum
Electric Power Research Institute	Chauncey Starr
	Chris Whipple
American Health Foundation	E. L. Wynder
General Motors Research Laboratory-Dept. of Societal Analysis	Walter A. Albers, Jr.
New York Academy of Sciences	

CMA 072818

V. Contractors

Clement Associates, Inc.	
Decision Research	Warner North
Engineering Science, Inc.	C. R. Barden
Arthur D. Little, Inc.	R. E. Wechsler
Mitre Corporation	
Rand Corporation	John Van Ryzin
	K. Rai
Science Research Systems	Kenny S. Crump
SRI International	M. Merkhoffer
Tracor Jitco, Inc.	

VI. Law

Franklin Pierce Law Center	M. S. Baram
U.S. Court of Appeals	°Hon. David L. Bazelon
Harvard Law School	J. P. Leape
U. S. Court of Customs and Patent Appeals	°Hon. Howard T. Markey
(Washington law firm; formerly FDA)	Richard M. Cooper
Covington and Burling	Peter Barton Hutt

VII. Public Interest Groups

Congress Watch	°Mark Green
Corporate Accountability Research Group	Norman Waitzman
Environmental Defense Fund	Robert Rousch
Environmental Law Institute	R. C. Anderson
Public Interest Economics Center	Allen F. Ferguson

VIII. Trade Associations

American Industrial Health Council (AIHC)
°American Petroleum Institute (API)
°Business Roundtable
Chemical Manufacturers Association (CMA)

CMA 072819

Two proposed business sponsored projects in the regulatory risk-benefit-cost area deserve special attention. The proposals -- developed independently by the American Petroleum Institute (API) and by the Business Roundtable--directly address many of the central interests and concerns of the Steering Group. Both projects may serve to complement and supplement the ongoing CORADM study undertaken for NSF at Congressional urging. (See pages 25, 26, 30.)

First, the American Petroleum Institute's Interdepartmental Committee on Safety and Health (ICOSH) Risk Assessment Task Force has approved funding for a one-year contract to conduct a retrospective study on the use of risk management by selected Federal regulatory agencies. (See Appendix V for a detailed summary of the API proposal. The schedule shown has been delayed by about six months, but is now underway. The objectives of the study are to:

- °isolate/identify basic principles of risk analysis and its use in decision making.
- °describe what is happening in selected Federal regulatory agencies, and
- °provide a mechanism for business, government, and academic experts to work together on these issues.

Second, the Business Roundtable Task Force on Risk, Cost, Benefit Analysis is considering publication of a book dealing with improving regulatory analysis and decision making for health and safety. Business, academia, and government will contribute articles to the document, which will serve as the basis for a Business Roundtable's position paper in this area.

The Task Force visualizes that the contributed articles will develop a set of standards for :

- °assessing scientifically the magnitude of possible health and safety hazards;
- °presenting these assessments in an informative and balanced way that places the risks in perspective;
- °appraising the economic and social benefits and costs of alternative regulations and of other approaches to reducing risks, and
- °synthesizing the available scientific, economic, and social evidence in a systematic "policy analysis" report.

Technical Publications -- Proposal to Discontinue

Problem

The Technical Publications program is not financially viable. It cannot be reviewed in accordance with outside counsel's instructions for periodic review and update without substantial increase in costs. Information which was once available only from CMA but is now available from other sources negates our need to provide this service.

Objective

CMA should continue to disseminate information, but we should use other mechanisms such as trade publications, scientific journals or other appropriate vehicles which would not require a mandatory update. The preliminary shifting of workload burden for TSCA activities to the positions previously authorized to support the Technical Publications should continue in order to relieve the external workload pressure in the high priority hazards communications and TSCA areas.

Background

Technical Publications have formed a part of CMA activities for almost forty years. Last year the Executive Committee voted to discontinue the publication of material safety data sheets, and CMA's projected revenue dropped $122,000. Our operating cost was about $260,000 (including $93,000 insurance) for FY 79-80 while our revenue from sales was reduced to $32,500.

The remaining Technical Publications include Cargo Information Cards, Chem-Cards, Safety Guides and miscellaneous publications. The cards are no longer needed based on a membership poll. The Safety Guides could and should be published in the scientific press. Over 50% of CMA's existing Safety Guides currently require major revisions. Other publications require major revisions -- the Laboratory Waste Disposal Manual will cost $63,000 to revise and approximately $5,000 to publish.

Recommendations

Discontinue CMA Technical Publications as described in the background material and continue the shift of resources to support the higher priority hazards communications and TSCA activities.

Impact

Money: CMA will need to continue the estimated $93,000 annual cost for insurance for several years and

will spend about $5,000 for advertisements notifying the public of the discontinuation of these publications. The financial impact of law suits from CMA's prior publishing activities is impossible to predict but could be substantial.

Company Personnel: More than 1.5 years of company staff time will be saved.

Staff Personnel: The full-time staff executive and support staff will be assigned to the hazards communications and other health, safety and chemical regulations activities. Publications clerks and fulfillment effort can and should be shifted to support the increasing Chem-CAP activities.

Action Required

Approval to discontinue CMA's Technical Publications activities as of this date.

*

CMA

EC - 9/8/80
BD - 9/9/80

Technical Publications

Background for Discontinuation

Technical Publications should be discontinued for the following reasons:

- without material safety data sheets, the program is not financially viable;
- the information needs that CMA previously supported are now met through other sources;
- the liability associated with the program outweighs its benefits; (Insuring against liability in this area will become increasingly expensive and possibly unobtainable with the potential of severe financial loss for CMA.)
- staff could be used more effectively in other CMA programs; and
- company participation is insufficient to meet the publications program needs.

1. Financial

In FY 79-80, the following income was recorded:

Chem-Cards	$ 9,700
Cargo Information Cards	7,000
All others	15,800
Total revenue	$32,500

The expenses for the same period were:

Direct Expenses:

Insurance	$ 93,000
Other direct expenses	113,000
Total direct expenses	$206,000
Estimated Indirect Expenses:	54,000
Total	$260,000

If Technical Publications are discontinued, the insurance policy must be continued for several years to protect liabilities. Close-out expenses must include advertisements in trade publications to limit liability from use of outdated materials. This should run approximately $5,000.

2. Information needs are met through other organizations.

CMA received only 42 responses from a survey of 240 distribution contacts, CHEMTREC Advisors and project team members. Of those responding, only one-third recommended that we continue the Chem-Card program and one-half recommended that we continue the Cargo Information Card program. Of all of the company personnel surveyed, only 6% recommended continuing the Chem-Card program and 9% recommended continuing the Cargo Information Cards.

The Department of Transportation said that cancellation would not pose regulatory problems. The trucking association supplies this information in book form.

Safety Guide materials are generally available from the professional literature. (See Appendix for list of Technical Publications to be discontinued.)

3. Liability

PRIVILEGED AND CONFIDENTIAL

We publish about 170 Cargo and Chem-Cards which cost about $1,000 each for printing. This does not include the labor to review the cards prior to publication. A $50,000 three-year revenue cannot support this.

PRIVILEGED AND CONFIDENTIAL

At present, revisions on SG-2, -4, and -17 are in draft form. SG-3, -5, -6, -7, -9, -10, -11, -18, -19, -20, -23, and -24 need revision. Each revision will cost $3,000 for publication alone.

The largest revenue item outside of the material safety data sheets ($75,000/year) was the discontinued Laboratory Waste Disposal Manual. It was discontinued because the recommendations violated the Federal Water Pollution Control Act. A contractor has bid $63,000 to revise the Manual and it would cost $5,000 to publish. If republished, it would require revision every three years plus staffing to process inventory, mailing and billing.

4. Staff could be assigned to other projects.

The personnel assigned to Technical Publications could be used for hazards communications activities and toxic substances issues. In staff's opinion, this will have a greater value for the industry than the Technical Publications.

5. Company participation is insufficient.

Our experience has shown enthusiastic support for drafting the original document, but little support for revisions. The burden falls upon CMA staff to prepare these revisions.

APPENDIX

TECHNICAL PUBLICATIONS

These are publications of particular interest to managers and operators of chemical-producing plants.

Environment

Guidelines for Chemical Plants in the Prevention, Control, and Reporting of Spills (1973)	$1.00
WR-1 A Guide for Subsurface Injection of Waste Fluids from Chemical Manufacturing Plants (1976)	$1.50

Safety and Health

Occupational Epidemiology, A Brief Overview	$1.00
Case Histories of Accidents in the Chemical Industry.	
Vol. One—1962	$3.75
Vol. Two—1966	$3.75
Vol. Three—1970	$3.75
Vol. Four—1975	$3.75
Index of Case Histories of Accidents in the Chemical Industry	$1.00
Set of All Four Volumes and Index	$15.00
Guidelines for Risk Evaluation and Loss Prevention in Chemical Plants (Revised 1976)	$2.50

CMA 072825

SAFETY SERIES

These are technical publications specifically designed to assist in the safe commercial production and transportation of chemicals.

Safety Guides
$2.50 EACH

Preplanning for safety. Practices and procedures useful to those engaged in many aspects of chemical manufacturing, but especially those at the plant level.

Health Factors in the Handling of Chemicals (1979)	SG-1
Emergency Organization for the Chemical Industry (1979)	SG-4
Electrical Switch Lockout, Tag and Try Procedures (1978)	SG-8
Maintenance and Inspection of Fire Protection Equipment (1978)	SG-13
Safety in the Scale-up and Transfer of Chemical Processes (1978)	SG-14
Training of Process Operators (1978)	SG-15
Liquid Chemicals—Sampling of Tank Car and Tank Truck Shipments (1979)	SG-16
Fire Protection in the Chemical Industry (1980)	SG-17
Safety Inspection Committee for a Small Plant (1973)	SG-20
Guidelines for a Chemical Plant Safety Program and Audit (1978)	SG-21
Siting and Construction of New Control Houses for Chemical Manufacturing Plants (1978)	SG-22

NOTE: Future issues in this series may be obtained on a continuing subscription basis, billed at the end of each year.

TRANSPORTATION EMERGENCY GUIDES
50¢ EACH

CMA CHEM-CARDS. Each card gives useful information in case of accidents involving overland shipments (truck, rail) of dangerous cargoes. Cards are 17.5 cm × 25.4 cm (7" × 10"), 3-hole punched.

Acetaldehyde	CC-49
Acetone	CC-23
Acetone Cyanhydrin	CC-34
Acetonitrile	CC-64
Acrolein (Inhibited)	CC-76
Acrylonitrile	CC-15
Allyl Alcohol	CC-35
Allyl Chloride	CC-63
Ammonia, Anhydrous	CC-44
Ammonia, Aqua	CC-66
Anhydrous Hydrazine	CC-7
Aniline Oil	CC-51
Benzene	CC-17
Benzyl Chloride	CC-54
Boron Trifluoride	CC-87

TRANSPORTATION EMERGENCY GUIDES
50¢ EACH—Continued

Bromine	CC-59
Butadiene	CC-81
Butyl Acetate	CC-60
Butyl Alcohol (Secondary or Tertiary)	CC-80
Butyllithium	CC-28
Butraldehyde	CC-50
Carbolic Acid (Phenol)	CC-48
Caustic Potash (Liquid)	CC-32
Caustic Soda (Liquid)	CC-33
Chlorine	CC-53
Chloride Trifluoride	CC-2
Chlorosulfonic Acid	CC-73
Cresol	CC-77
Cyclohexane	CC-20
Diethylamine (Anhydrous)	CC-27
Diethylenetriamine	CC-72
Dimethyl Ether	CC-61
Dimethyl Sulfate	CC-65
Epichlorohydrin	CC-29
Ethanol	CC-70
Ether (Ethyl)	CC-16
Ethyl Acetate	CC-18
Ethyl Acrylate	CC-55
Ethyl Chloride	CC-24
Ethylene Dichloride	CC-62
Ethylene Oxide	CC-36
Fluorine (Liquid)	CC-10
Formic Acid	CC-83
Hydrazine/UDMH	CC-9
Hydrochloric Acid	CC-82
Hydrofluoric Acid (Anhydrous or Aqueous)	CC-42
Hydrogen, Liquid	CC-12
Hydrogen Peroxide (High Strength)	CC-14
Isopropanol	CC-71
Isopropylamine	CC-56
Isopropyl Ether	CC-58
Methanol	CC-69
Methyl Acrylate	CC-74
Methylamines (Anhydrous)	CC-26
Methylamines (Aqueous)	CC-84
Methyl Bromide (Liquid)	CC-38
Methyl Chloride	CC-67
Methyl Ethyl Ketone	CC-22
Methyl Isobutyl Ketone	CC-57
Methyl Methacrylate	CC-43
Mixed Acid	CC-65
Monomethyl Hydrazine	CC-11
Motor Fuel Antiknock Compound	CC-30
Nitric Acid	CC-47
Nitric Acid (Red, Fuming)	CC-3
Nitrobenzol (Liquid)	CC-79

CMA 072826

TRANSPORTATION EMERGENCY GUIDES
50¢ EACH—Continued

Nitrogen, Liquid	CC-6
Nitrogen Tetroxide	CC-1
Oleum	CC-68
Oxygen, Liquid	CC-13
Pentaborane	CC-5
Peracetic Acid	CC-86
Perchloryl Fluoride	CC-4
Phosphorous Oxychloride	CC-39
Phosphorous Pentasulfide	CC-41
Phosphorus Trichloride	CC-40
Phosphorus (White or Yellow in Water)	CC-37
Sodium (Metallic)	CC-31
Sulfur Dioxide	CC-78
Sulfur Trioxide	CC-52
Sulfuric Acid	CC-25
Toluene	CC-19
Unsymmetrical Dimethyl Hydrazine	CC-8
Vinyl Acetate	CC-21
Vinyl Chloride	CC-46
Vinylidene Chloride	CC-75
Xylene	CC-45

NOTE: Future issues in this series may be obtained on a continuing subscription basis, billed at the end of each year

CARGO INFORMATION CARDS
50¢ EACH

Each card gives useful information in case of accidents involving barge shipments of dangerous cargoes. Cards are 17.5 cm × 25 × .4 cm (7" × 10") Varnish Coated.

Acetaldehyde	CIC-1
Acetic Acid	CIC-2
Acetic Anhydride	CIC-3
Acetone Cyanohydrin	CIC-4
Acetonitrile	CIC-5
Acrylonitrile	CIC-6
Adiponitrile	CIC-7
Allyl Alcohol	CIC-8
Allyl Chloride	CIC-9
Aminoethylethanolamine	CIC-10
Ammonia, Anhydrous	CIC-11
Ammonium Hydroxide	CIC-12
Aniline	CIC-13
Benzene	CIC-14
Butadiene (Inhibited)	CIC-15
n-Butyl Acrylate	CIC-16
n-Butyraldehyde	CIC-17
Camphor Oil	CIC-18
Carbolic Oil	CIC-19
Carbon Bisulfide or Carbon Disulfide	CIC-20
Carbon Tetrachloride	CIC-21

CARGO INFORMATION CARDS
50¢ EACH—Continued

Caustic Potash Solution	CIC-22
Caustic Soda Solution	CIC-23
Chlorine	CIC-24
Chlorobenzene	CIC-25
Chloroform	CIC-26
Chlorohydrins (Crude)	CIC-27
Chlorosulfonic Acid	CIC-28
Cresols	CIC-29
Crotonaldehyde	CIC-30
Dichlorodifluoromethane	CIC-31
Dichloropropane	CIC-32
Dichloropropene	CIC-33
Diethanolamine	CIC-34
Diethylenetriamine	CIC-35
Diisopropanolamine	CIC-36
Dimethylamine	CIC-37
Epichlorohydrin	CIC-38
Ethyl Acrylate	CIC-39
Ethyl Chloride	CIC-40
Ethyl Cyanohydrin	CIC-41
Ethylenediamine	CIC-42
Ethylene Dichloride	CIC-43
Ethyleneimine	CIC-44
Ethylene Oxide	CIC-45
Ethyl Ether	CIC-46
2-Ethyl-3-Propylacrolein	CIC-47
Formaldehyde Solution	CIC-48
Formic Acid	CIC-49
Furfural	CIC-50
Hydrochloric Acid	CIC-51
Hydrofluoric Acid	CIC-52
Hydrogen Chloride	CIC-53
Hydrogen Fluoride	CIC-54
Isobutyl Acrylate or Butyl Acrylate (iso)	CIC-55
Isobutyraldehyde or Butyraldehyde (iso)	CIC-56
Isoprene	CIC-57
Methyl Acrylate	CIC-58
Methyl Bromide	CIC-59
Methyl Chloride	CIC-60
Methyl Methacrylate	CIC-61
Monochlorodifluoromethane	CIC-62
Monoethanolamine	CIC-63
Monoisopropanolamine	CIC-64
Morpholine	CIC-65
Motor Fuel Antiknock Compounds	CIC-66
Oleum	CIC-67
Phenol	CIC-68
Phosphoric Acid	CIC-69
Phosphorous	CIC-70
Propionic Acid	CIC-71
Propylene Oxide	CIC-72

CMA 072827

CARGO INFORMATION CARDS
50c EACH—Continued

Styrene	CIC-73
Sulfur, Liquid	CIC-74
Sulfuric Acid	CIC-75
Sulfuric Acid, Spent	CIC-76
Triethanolamine	CIC-77
Triethylenetetramine	CIC-78
Vinyl Acetate	CIC-79
Vinylidene Chloride (Inhibited)	CIC-81
Compressed Gases	CIC-82
Cargoes with flashpoints of 20° F and lower	CIC-83
Cargoes with flashpoints above 20° F to and including 80° F	CIC-84
Cargoes with flashpoints above 80° F	CIC-85
Cargoes with flashpoints above 80° F and requiring heat for transfer	CIC-86

NOTE: CIC-82 through CIC-86 are "generic" type cards approved for use with cargoes listed in U.S. Coast Guard regulations 46 CFR. A list of applicable cargoes is given on the reverse of each card.

Future issues in this series may be obtained on a continuing subscription basis, billed at the end of the year.

CMA 072828

Exhibit K

SPECIAL COMMITTEE ON HAZARDS COMMUNICATIONS

WILLIAM C. KRUMREI

A. COMMITTEE ORGANIZATION, FORMATION OF TASK GROUPS
   ACTION REQUIRED: CONFIRM COMMITTEE NOMINEES

B. EPA CHRONIC HAZARDS LABELING RULE
   ACTION REQUIRED: APPROVE CARCINOGEN POLICY

C. EPA ACUTE HAZARDS LABELING RULE
   ACTION REQUIRED: NONE - INFORMATION ONLY

D. OSHA HAZARDS LABELING RULE
   ACTION REQUIRED: NONE - INFORMATION ONLY

Hazards Communications Special Committee
Organization and Formation of Task Groups

Problem: Both the Environmental Protection Agency (EPA) and the Occupational Safety and Health Administration (OSHA) have drafted proposed rules to regulate labeling of hazardous and toxic substances. Those rules, as initially drafted, could adversely impact the chemical industry if not mitigated. Such impacts include unnecessarily burdensome and inefficient regulations, direct costs of compliance and the potential for disclosure of trade secrets and proprietary information. Litigation of these rules may be necessary.

Background: On May 13, 1980, the Executive Committee approved the formation of and a charter for the Hazards Communications Special Committee. (See Attachment 1). On June 23, 1980, letters were mailed to each CMA Executive Contact requesting nominees for that committee. Fifteen nominees were selected, for Board confirmation, at a CMA meeting on July 23. (See Attachment 2). Mr. William C. Krumrei, Dr. Curtis Smith, Mr. Robert Roland and other CMA staff attended that meeting.

Following the tentative selection of committee nominees, the committee was structured to provide five task groups -- composed of industry experts who had been active on other CMA labeling groups -- to develop prospective CMA positions on the labeling issues. (See Attachment 3). For each task group, charters were developed, chairmen were appointed and tentative task group memberships were compiled. Those charters, approved by the Hazards Communications Special Committee at its first meeting, August 11, are included as Attachment 4.

Impact: Money — Successful completion of the project will require expenditures for legal and technical consultants. Expenditures already projected in the fiscal year-81 proposed budget should be sufficient. While there is, at this time, no basis for predicting an overrun, the committee will be notified if additional expenses are to be incurred.

Action Required: Confirm members nominated to the Committee.

Attachments

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072830

Attachment 1

HAZARDS COMMUNICATIONS SPECIAL COMMITTEE

CHARTER

Within limits of authority specified by the Executive Committee, the Special Committee will oversee Association hazards communications activities. The scope of these activities includes EPA and OSHA proposals for product labeling, in-plant labeling, material safety data sheets and substance identification lists.

Within this scope, the Special Committee will identify key issues and focus on matters of greatest significance to the chemical industry; establish specific objectives and mobilize resources to produce timely results; advocate responsible regulation within existing statutes; and seek relief from unreasonable regulation by providing alternative language to the agencies, submitting comments to proposed rulemaking, and initiating legal action where appropriate.

The Special Committee will communicate major trends and developments to the Executive Committee, the Board of Directors, the Association President, member companies and other trade associations. The Special Committee will serve for a period of two years on an ad hoc basis. At the end of two years, the Committee's status will be reviewed by the Executive Committee.

CMA
EC - 5/13/80
EC - 9/8/80
BD - 9/9/80

CMA 072831

Attachment 2

HAZARDS COMMUNICATIONS SPECIAL COMMITTEE

Nominees for Membership

Krumrei, William C. (Chairman)	The Procter & Gamble Co.
Smith, Curtis W. (Vice Chairman and Chairman - OSHA TG)	Shell Chemical Company
Arnold, Grant	Ethyl Corporation
Bittenbender William A.	Borden Chemical
Brubaker, Bruce H.	Diamond Shamrock Corporation
Carmody, Thomas W. (Chairman - Economics TG)	Union Carbide Corporation
Evans, Thomas F.	Monsanto Company
Hanes, James H.	The Dow Chemical Company
Marino, Maryann S.	Koppers Company Inc.
McMillan, Graham W.	International Minerals & Chemical Corporation
Plaut, Jonathan (Chairman - International Labeling Issues TG)	Allied Chemical Corporation
Spainhour, J. D.	Borg-Warner Chemicals
Sullivan, William F.	American Hoechst Corporation
Trexel, James J.	E. I. du Pont de Nemours & Co.
Umland, Carl W. (Chairman - EPA TG)	Exxon Chemical Company

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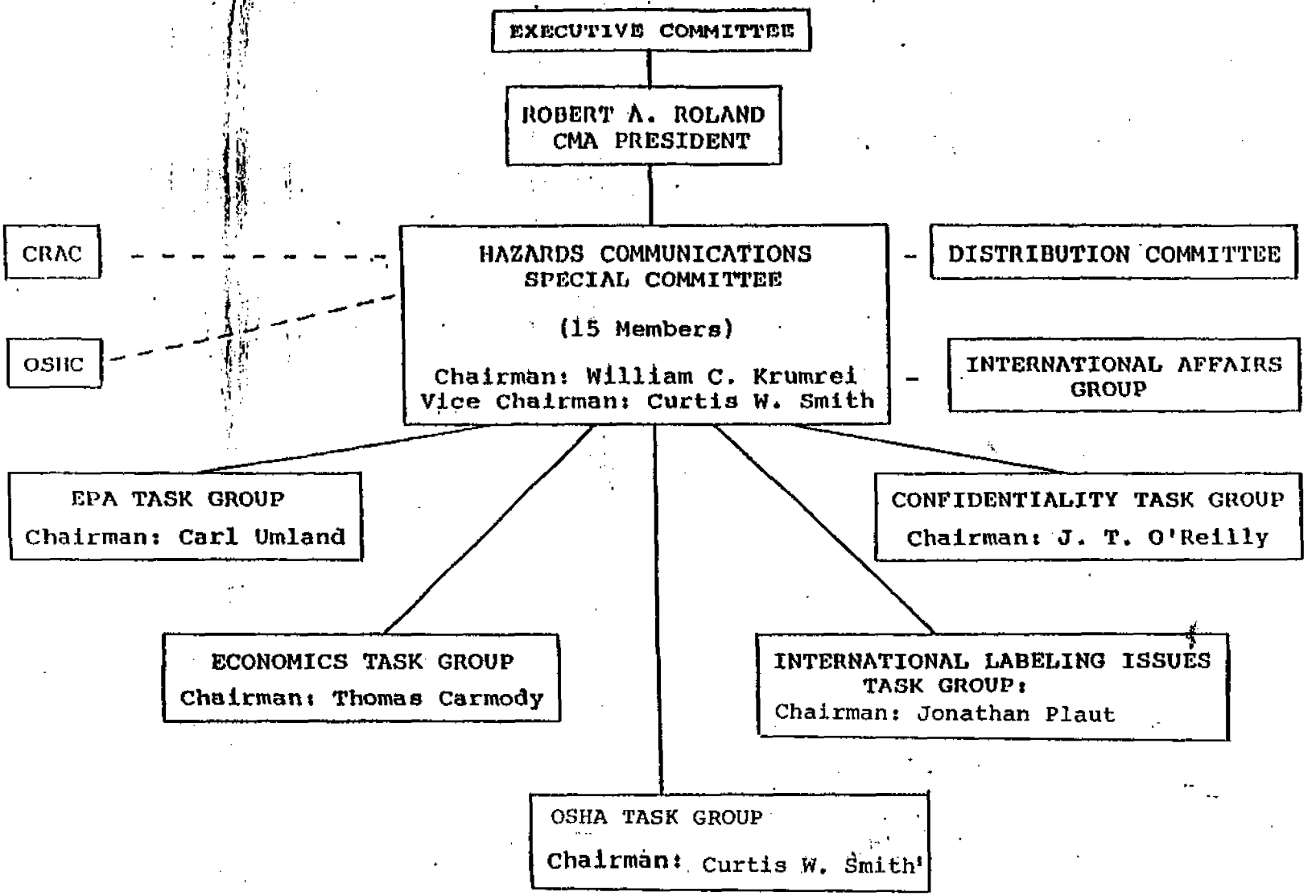
EC - 9/8/80
BC - 9/9/80

CMA 072832

Attachment 3

CMA 072833



Straight line means direct reporting and management.

Dotted line means: (1) Communication; (2) Overlapping representation;

(3) Opportunity to involve Greenbrier procedures.

A-4

CMA
EC - 9/8/80
BD - 9/9/80

Attachment 4

CONFIDENTIALITY TASK GROUP

Charter: Consider confidentiality issues raised by proposals of U.S. agencies and foreign governments and groups that may impact the U.S. chemical industry and recommend to the Hazards Communications Special Committee CMA positions on confidentiality issues.

Chairman: James T. O'Reilly

Membership: 5-10 members appointed for 12 months

Established: July 23, 1980

Sunset Date: July 23, 1982

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072834

ECONOMICS TASK GROUP

Charter: To review national proposals for labeling and determine the industry's probable costs of compliance; consider and evaluate alternative proposals, compare CMA and agency estimates of costs; and report to the Hazards Communications Special Committee its findings and recommendations.

Chairman: Thomas W. Carmody

Membership: 5 - 15 members appointed for 12 months

Established: July 23, 1980

Sunset Date: July 23, 1982

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072835

INTERNATIONAL LABELING ISSUES TASK GROUP

Charter: Monitor through liaison with the CMA/SOCMA International Affairs Group international initiatives on labeling of hazardous and toxic substances, compare those proposals to existing and proposed U.S. agency labeling rules and standards and recommend to the Hazards Communications Special Committee actions and positions necessary to protect United States chemical industry interests.

Chairman: Jonathan Plaut

Membership: 5 - 15 members appointed for 12 months

Established: July 23, 1980

Sunset Date: July 23, 1982

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072836

EPA TASK GROUP

Charter: Review EPA and other proposals for labeling of hazardous substances, acute and chronic hazards, identify key issues and develop CMA recommended positions and actions for commenting on EPA proposed rules. Meet with government representatives in concert with Hazards Communications Special Committee to negotiate final EPA hazardous substance labeling and records and reports rules acceptable to the chemical industry.

Chairman: Carl W. Umland

Membership: 5 - 25 appointed for 12 months

Established: July 23, 1980

Sunset Date: July 23, 1982

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072837

OSHA TASK GROUP

Charter: Review OSHA and other proposals for labeling of hazardous substances, acute and chronic hazards, identify key issues and develop CMA recommended positions and actions for commenting on OSHA proposed standards. Meet with government representatives in concert with Hazards Communications Special Committee to negotiate final OSHA hazardous substances labeling standards, material safety data sheets and records and reports requirements acceptable to the chemical industry.

Chairman: Curtis W. Smith

Membership: 5 - 25 appointed for 12 months

Established: July 23, 1980

Sunset Date: July 23, 1982

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072838

ENVIRONMENTAL PROTECTION AGENCY
CHRONIC HAZARDS LABELING RULE, JULY 29, 1980

SUMMARY

BACKGROUND

EPA has announced its intent to issue a regulation designating specific chemical substances as carcinogens and requiring that they be labeled as such. This concept was initially included in the February 1980 draft of a proposed regulation governing hazard warning labeling. As a first step, CMA urged EPA to separate the proposed regulations for acute hazard labeling from that for chronic hazards, because such different issues are involved. EPA has accepted this position and has separated the two proposals (although EPA states that it intends to publish both at the same time.)

The February draft would require any chemical designated as a carcinogen, or any mixture containing that chemical at a level of 1 percent or more, to be labeled "Cancer Hazard." CMA representatives met with EPA to discuss this draft proposal and suggested that (1) the determination of carcinogenicity should be made by a group of independent scientists on the basis of sound scientific data; (2) a distinction should be made between substances known to be human carcinogens and those shown to be carcinogenic in laboratory animals; and (3) some way must be found to distinguish among carcinogens on the basis of their potency.

In July, a revised draft was issued by EPA, which it states will be the version published as a proposal in the Federal Register. None of the CMA comments were accommodated. In the July draft, any designated carcinogen, or any mixture containing 0.1 percent or more of a designated carcinogen, must be labeled as "DANGER! Cancer Hazard" and "Any exposure may be harmful." No distinction is made between human and animal carcinogens and potency is not reflected in any way in labeling.

The CMA task group has worked hard in developing a consensus position on this matter. Unlike acute hazard warning labeling, for which there is a long history of chemical industry involvement, cancer warnings are a relatively new idea and the chemical industry has little experience on which to rely. Because of the importance of this matter, CMA representatives cannot take a firm position on carcinogen labeling with EPA until the Executive Committee approves such a position. It is therefore essential that the position recommended by the CMA be acted upon at the Executive Committee meeting on September 8.

CMA 072839

This will allow CMA representatives to advocate CMA's position with EPA in order to obtain some modification of the present draft. Unless a definitive CMA position is reached on September 8, CMA representatives will be in a very poor position to attempt to modify the July EPA draft proposal before it appears in the Federal Register.

The essence of the proposed CMA position is as follows:

(1) No signal word other than "cancer";

(2) Separation of human and animal carcinogens;

(3) Fully compatible with AIHC;

(4) Inclusion of potency differences; and

(5) Separation of chronic and acute labeling rules.

There should be little disagreement on #2,3,4 and 5; there is work group consensus on all of the items.

While this proposed position is specific to carcinogens, it is expected to be of value as a model for other chronic hazards as well (e.g., mutagenicity, teratogenicity, etc.).

ACTION REQUIRED

Approve CMA carcinogen policy (attached).

Attachment

CMA
EC - 9/8/80
BD - 9/9/80

CMA 072840