

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

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INDEX

INTRODUCTION	1-2
I. BACKGROUND: LEGISLATIVE AND REGULATORY IMPETUS AND CONFLICTS	3-4
II. ISSUES IN RISK-BENEFIT-COST ANALYSIS	5-9
III. TERMS AND DEFINITIONS	10-12
IV. METHODOLOGIES IN THE HEALTH AND SAFETY AREAS	13-21
V. ACTIVITIES	22-33
APPENDICES	

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
Air Quality Standards
Carcinogens

Clean Air Act (CAA)

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.

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

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, industry 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.

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.

- ° 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?

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?"

- ° 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?

- ° 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?

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)

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)

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.

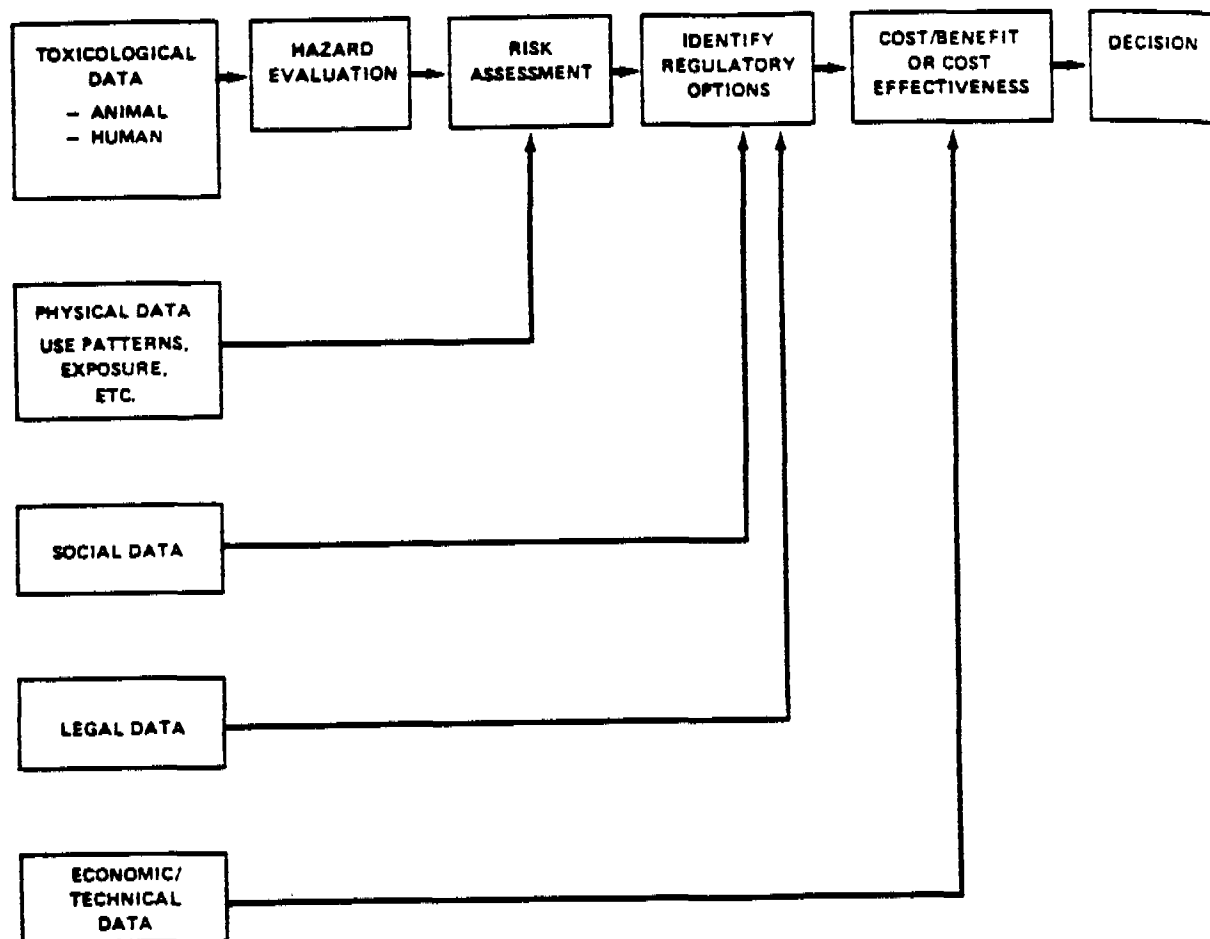
The first steps, i. e., the estimation of exposure required to produce a biological effect and an estimate of the exposure the population will experience, are basically scientific. Many techniques (listed below and more fully described in Appendix IV) have been devised to improve the quality of risk 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.

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



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 pre-sumption 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".

-
- 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.

FEMA DECISION TREE

(Figure 1)

Decision tree prediction of toxic risk

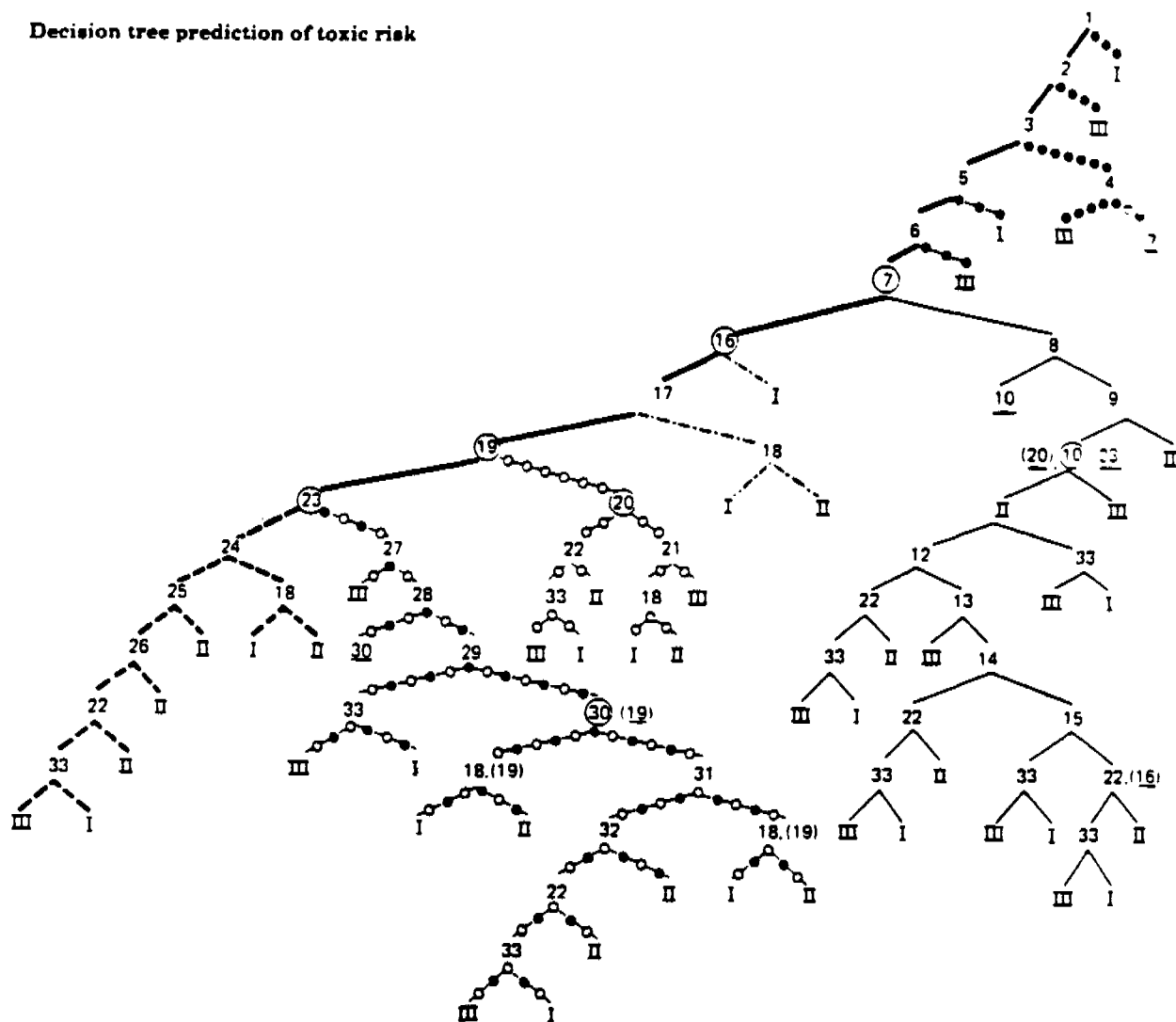


Fig. 1. A schematic diagram of a decision tree for the estimation of probable toxicity. Assessor should (a) start with question 1. (b) proceed by 'no' / or 'yes' \, (c) move from any underscored number encountered to same circled number and (d) proceed to final classes I, II or III. Working downwards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

FSC Revised Quantitative Risk Assessment³⁾

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
- Bischloromethyl urea
- Sodium Saccharin
- Ethylenethiourea

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.

- 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-dose 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 P0 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.

- 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 be psychological and emotional as well as material.

The application of measure, especially dollars for comparative purposes, in the second activity is heavily value-laden. Quoting B. R. Putna 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 reducing 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 acceptance of the philosophy underlying the process."

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?

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.

I. Washington Governmental Activities*,^o

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 ^o 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 ^o 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.

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

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

Subcommittees 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 Fischhoff
 ° 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)

- 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.

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.

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 FFDC. 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.

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.

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):60038-60045

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.

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.	Weyerhaeuser
A. Karim Ahmed	National Research Defense Council
David Cohen	Common Cause

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

III. Academia

Clark University
UCLA
Harvard University

MIT (Center for Policy Alternatives)
University of Maryland
Georgetown University
UC, Davis
Bryn Mawr College
Carnegie Mellon
Stanford University
American University
UCLA
Yale University
Duke University
UC, Berkeley
Washington University
Harvard University

New York University

°*R. W. Kates and R. Kasperson
*David Okent
°Richard E. Wilson

°Nicholas Ashford
°Martin J. Bailey
Edward J. Burger
M. Goldman
Jane C. Kronick
°Lester Lave
°William D. Lowrance
William D. Rowe
Rakesh Sarin
Peter Schuck
°James W. Vaupel
°Aaron Wildavsky
°Murray L. Weidenbaum
Richard Zeckhauser

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
Food Safety Council
Brookings Institution

The Conservation Foundation
Decision Research
(Perceptronic)

Franklin Institute
Resources for the Future
American Enterprise Institute(AEI)

Electric Power Research Institute

American Health Foundation

General Motors Research Laboratory-
Dept. of Societal Analysis

New York Academy of Sciences

Daniel Callahan
J. B. Cordaro
°Robert Crandall
°Lester Lave
Terry Davies
°Baruch Fischhoff
Sarah Lichtenstein
°Paul Slovic
Gio B. Gori
Allen Kneese
°James C. Miller
°Martin J. Bailey
°Murray L. Weidenbaum
Chauncey Starr
Chris Whipple
E. L. Wynder

Walter A. Albers, Jr.

V. Contractors

Clement Associates, Inc.
Decision Research
Engineering Science, Inc.
Arthur D. Little, Inc.

Warner North
C. R. Barden
R. E. Wechsler

Mitre Corporation
Rand Corporation

John Van Ryzin
K. Rai
Kenny S. Crump
M. Merkhoffer

Science Research Systems
SRI International
Tracor Jitco, Inc.

VI. Law

Franklin Pierce Law Center
U.S. Court of Appeals
Harvard Law School
U. S. Court of Customs and
Patent Appeals
(Washington law firm; formerly FDA)
Covington and Burling

M. S. Baram
°Hon. David L. Bazelon
J. P. Leape

°Hon. Howard T. Markey
Richard M. Cooper
Peter Barton Hutt

VII. Public Interest Groups

Congress Watch
Corporate Accountability
Research Group
Environmental Defense Fund
Environmental Law Institute
Public Interest Economics Center

°Mark Green
Norman Waitzman
Robert Rousch
R. C. Anderson
Allen F. Ferguson

VIII. Trade Associations

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