PRINCIPLES OF HEALTH RISK ASSESSMENT

Paolo F. Ricci

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Edited by

Paolo F. Ricci

Electric Power Research Institute

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PREFACE

Health risk-benefit analysis and evaluation provide key information for a wide range of energy, safety, and environmental decisions that enable the user of that information to determine the effects of a variety of policy actions. The purpose of this analysis is to attribute risks and benefits to the appropriate sources. This book is aimed at those who seek to determine attribution and causality quantitatively. Both analyst and user will find the necessary theories, methods, and data to yield estimates of risks and benefits. The focus is on human health risks that may result from the generation of energy.

The scope of this work is limited to areas useful in providing quantitative information to a broad audience of policy analysts, decision-makers, risk assessors, and scientists. Because environmental and energy decisions rely increasingly on risk-benefit considerations to protect the environment and human health, students of public health, policy analysis, economics, environmental engineering, public administration, and the biological sciences will find this book particularly valuable.

Risk-benefit analysis and evaluation rely on economics, statistics, engineering, law, and biological sciences; this book integrates the contributions from these disciplines into a single source. The reader will not, however, find discussions of ecological effects or of damage to vegetation or materials; nor are ethical issues, geopolitics, or perception of technology examined.

The book is organized into nine chapters that address (1) the legal environment of risk and benefit assessment, (2) cost-benefit analysis, (3) air, surface, and groundwater transport models, (4) quantitative health risk analysis, and (5) concepts of technological risk assessment.

Chapters that deal with quantitative health risk analysis address the National Academy of Sciences principles:

> "Materials should be addressed in terms of human risk, rather than 'safe' or 'unsafe,'
>
> Methods do not now exist to establish a threshold for long-term effects of toxic agents,
>
> Effects in animals, properly qualified, can be applied to man,
>
> Exposure of experimental animals to high doses of toxic agents is a necessary, valid method to discover possible carcinogenic hazards in man."

Because the analyst or the user may be interested in particular chapter areas, each is designed to be as self-contained as possible. The figure that follows illustrates the relationships among the chapters. The sequence followed is the one normally used to analyze the risks associated with a technological system. The Introduction describes the context of each chapter.

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The following have given permission to reprint from their works:

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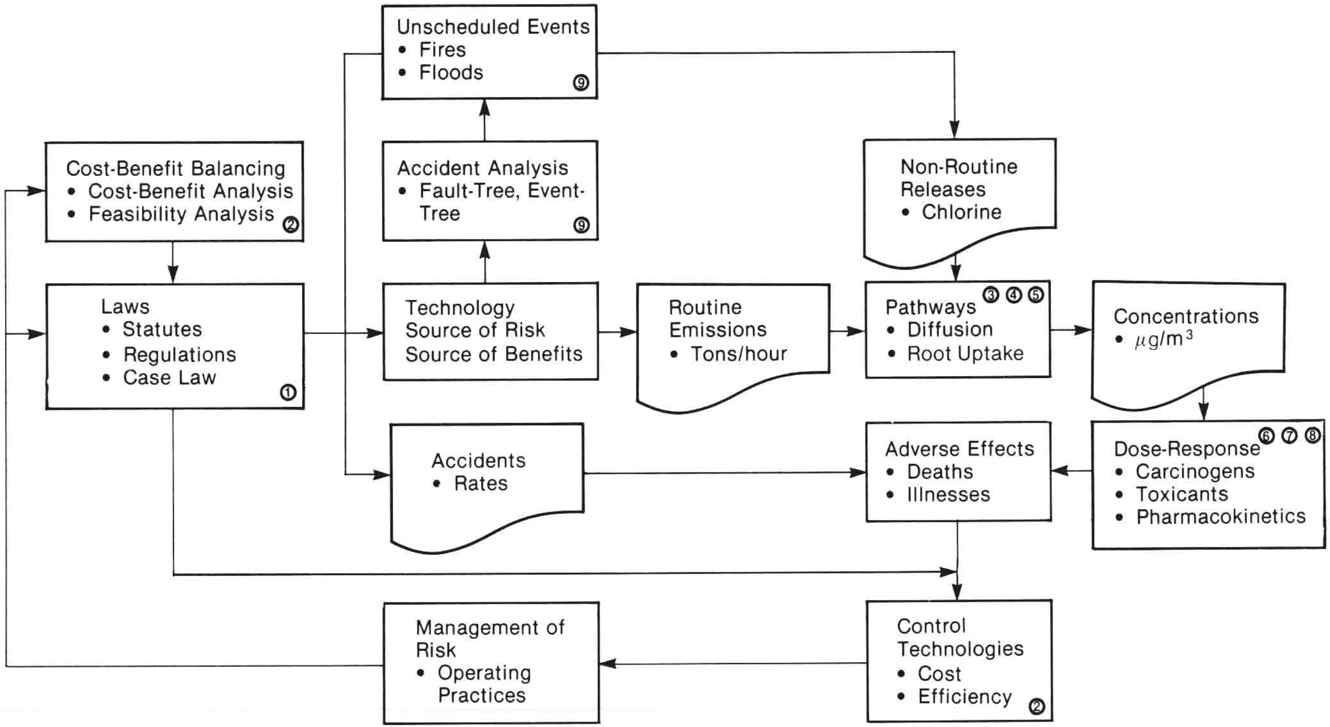
- Figures 6-9 and 6-10, Equations 6-28 through 6-35, and seven unnumbered equations listed on pg. 268 are taken from Gehring and Blau, Journal of Environmental Pathology and Toxicology, 1977, page numbers 173, 176, 177, and 175.

- Table 8-14 comes from Crouch E. and Wilson R. (1979). "Interspecies Comparisons of Carcinogenic Potency." Journal of Toxicology and Environmental Health, 5:1095-1118.



Linkages among key areas of quantitative health risk assessment. A square box indicates that one or more analytic steps are required; a box with a wavy line at the bottom indicates one or more results from the analytic steps. Chapters in this book are circled.

INTRODUCTION

CHAPTER 1

The assessment of public and occupational health risks is carried out by the federal regulatory agencies and the courts. The legal system plays a central role in setting risk policies, so an effective understanding of the structure of the federal government is essential to an examination of the policymaking process. The chapter explains the separation of powers, the federal court system, and the basic rules of administrative procedure. It describes the development of modern rulemaking, which enabled federal agencies to regulate in the increasingly technical and complex arena of health protection. There is an extensive discussion of judicial review and the standards by which courts evaluate agency action. Through the development of the "hard look" doctrine, the courts have closely scrutinized agency assumptions, reasoning, and thoroughness.

Science policy questions are actually a hybrid of factual and legal issues, making them difficult to resolve. Many of our most important regulatory decisions fit into this category, especially those dealing with cancer risk. The courts do not have an easy task evaluating these choices. Should action be taken immediately, or will delay produce a sounder policy? Should factual accuracy be the goal of a regulation, or should it strive to achieve a type of result, even if the evidence is weak?

The chapter then analyzes how the courts evaluate certain scientific issues, such as what is significant risk, what is the burden of proof, or what is adequate demonstration of adverse health effects? It then illustrates the frameworks used to balance costs and benefits under several major regulatory statutes, including the Occupational Safety and Health Act and the Clean Water Act. Such balancing is the law's method of resolving competing economic, medical, ethical, and scientific considerations.

CHAPTER 2

Cost and benefit analysis is a means to study the economic impacts of alternatives when given a single objective (e.g., the production of a certain amount of energy). Based on economic theory and decision analysis, it uses econometrics, probability theory, mathematical programming, and other techniques. The results of cost-benefit analysis are often summarized in the present discounted value (NPV) of the various alternatives under consideration to reach a specific objective, measured over all costs and benefits which are discounted at a certain rate, for a certain period of time. The simplicity of the formulation of the NPV approach belies several distinct difficulties: What are the costs and benefits? Can some of those costs and benefits be assigned monetary value? What discount rate, if any, can be used to discount future costs and benefits? What distributional impacts arise and how is compensation to take place? This chapter addresses these issues as well as uncertainty. Examples are drawn from cancer risks and from those adverse effects that may occur several generations hence.

Unlike disciplines where physical laws can be invoked, cost-benefit analysis utilizes ethical, behavioral, and economic constructs. Thus to presume that the simple formula which yields the net discounted benefits (negative or positive), or their ratio, is sufficient to decide among the alternatives available to reach a certain objective is naive. Nevertheless, cost-benefit analysis is a useful means for analyzing technological options. Certainly it is often used--and abused.

CHAPTERS 3, 4, AND 5

This section describes the modeling of transport and pathways of pollutants emitted into the air, water, and soil, with the key physical and chemical processes that govern their fate, until they eventually reach man.

The section contains three chapters: Chapter 3, Air Quality Models, deals with those models used to study systems that produce airborne effluents. In the analysis of risk, air quality models relate the concentration of pollutants to those who are at risk. Thus, the reader finds discussions of such phenomena as transport, diffusion, coagulation and absorption, dispersion, wet and dry removal, and chemical transformations, as these govern the phase in which pollutants reach man. The chapter also describes air quality models and their principal uses.

Chapter 4, Chemical Transport and Fate in Risk Analysis, addresses the physico-chemical phenomena that govern the path taken by pollutants in water. The material describes mechanisms, and their mathematical aspects, for transport; intermediate transfer; chemical and biological degradation; radioactive decay in surface water and groundwater; and overland transport. Hydrology, which plays an important role in determining the contribution from overland and subsurface flows, is viewed principally as a vehicle through which physico-chemical phenomena occur.

Chapter 5, Physico-Chemical Transport and Fate Models, reviews the models that describe the pathways taken by pollutants, from emissions to concentrations, in surface waters, groundwater, and on land. Some case studies are also presented. The models are applied to several areas. For surface water, the models are based on transport, transfer, degradation, decay, and transformation of the pollutants. For ground-water movement, the models describe saturated and unsaturated ground-water systems, solute transport, and methods to obtain numerical results. Finally, models based on hydrology, soil erosion, adsorption, removal, and degradation of toxicants are discussed for land surfaces.

Tabular summaries included throughout the section provide information on type of pollutants, mechanisms involved, dimensionality, time-dependency, and other information relevant to discriminating among models.

CHAPTERS 6, 7, and 8

This section is organized into three chapters: Chapter 6, Dose-Response Functions (with emphasis on carcinogens); Chapter 7, Methods for Estimating Dose-Response Functions; and Chapter 8, Interspecies Comparisons. Each of these chapters treats methods for obtaining quantitative estimates of health effects. The kernel of quantitative risk analysis is the dose-response function; the data from which those effects are calculated are derived from animal tests and epidemiology.

Yet there are pivotal issues. For instance, the processes through which most cancers evolve are often conjectural. In Chapter 6 the reader finds arguments for and against the threshold hypothesis for cancer as well as reasons for the linear, no threshold, dose-response relationship. Other functions, such as the multistage model, are also discussed.

There is a fundamental difference between determining cancer risk from chemicals and from ionizing radiation. For chemical carcinogens, animal data are often used to estimate the coefficients of dose-response functions. By contrast, epidemiological data from the atomic bomb survivors are used in radiation carcinogenesis. Lack of epidemiological data leads to the use of animal data (e.g., mice and rat studies) to establish the potency of carcinogens or other toxicants. These animal studies provide "strong and suggestive" evidence that a substance may be a carcinogen in humans; most environmental or safety regulations rely on such studies to limit exposure both in the work place and the general environment.

Chapter 7 compares the one-hit model with the multistage model, over different sets of data from different experiments. It also includes an initial discussion of methods commonly used in risk analysis to convert carcinogenic potencies from lower animals to man.

Chapter 8 covers methods for extrapolating toxic potency from animals to man. This chapter complements its immediate predecessors by reviewing recent methods for interspecies comparisons and how these developments are likely to influence the analysis of human health risks. Several examples show the variability arising from different interspecies formulas to estimate incremental risk levels.

CHAPTER 9

This chapter provides a comprehensive treatment of those issues that have arisen and that continue to arise in comparative risk analysis of energy systems. The definitions, measures, and methods discussed in this section are largely based on the techniques developed in the previous sections to estimate excess risk (e.g., prompt deaths) per unit of benefit generated (e.g., megawatts).

This chapter includes a formal definition of risk; measures through which risks are expressed (e.g., prompt fatalities per unit of energy output); criteria for aggregating risks (e.g., the expected value); definitions of routine and nonroutine events; and other issues related to measuring technological risk, with focus on systems that produce energy.

Chapter 9 also discusses cumulative distribution functions of the magnitude of consequences along with such methods as the process and input-output, which are commonly used in calculating and comparing technological risks. The process approach--which is separate from the input-output for simplicity--consists of a flow of information with logical interconnections. A simple process (for a given technology) might consist of linking these activities:

mining → transportation → conversion → disposal

to calculate the risks. The chapter explains how these risks may be calculated by combining the input-output and the process approaches. The reader will also find discussions of the fault-tree and event-tree methods, analogies, ad hoc approaches, and several other means through which quantitative estimates of technological risks can be developed. Previous sections of this book introduced methods to use in conjunction with either the process or input-output approach to estimate technology-specific risks. The input-output, particularly useful for aggregating occupational health risks at the regional or national level, yields not only direct risks but also less immediate ones. Typically, dose-response models are used to estimate public and occupational health effects for a specific agent or agents. Pathway models determine the concentrations of pollutants or other agents that are associated not only with power plants but also with components of the fuel cycle, such as refineries, storage depots, and so on. Once information provided by pathway models, dose-response functions, and data on the populations at risk is available, the data must be aggregated to calculate the risks associated with the system under analysis. This chapter provides the synthesis for those chapters that produce intermediate results, e.g., concentrations or the incidence of cause-specific occupational mortality, to yield those risks the analyst or the user seeks.

CONTENTS

Chapter 1

THE PROCESS OF RISK ASSESSMENT: ADMINISTRATIVE LAW AND ITS EFFECTS ON SCIENCE POLICY

Lawrence S. Molton and Paolo F. Ricci

GOVERNMENTAL STRUCTURE

The question of risk and how to deal with it arises again and again in the formulation of public policy. With the growth of federal regulation since the 1960s, Washington has become intimately involved in our determination of what risks exist, what can be done to alleviate them, what the costs of risk reduction are, and what risks are ultimately acceptable. The first step in analyzing policymaking about risk must be to scrutinize the structure and procedures of government.

The Three Branches

The Constitution of the United States establishes three independent branches of government: the legislative, executive, and judicial. The principle of separation of powers requires each branch to have certain powers and duties allocated to it that the other branches cannot usurp. These primary functions are enumerated in the Constitution: Congress shall "make all Laws which

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Sections of this chapter are based on Paolo F. Ricci and Lawrence S. Molton, "Risk and Benefit in Environmental Law," Science, Vol. 214, pp. 1096-1100, 4 December 1981.

shall be necessary and proper" for carrying out its powers; the President "shall take Care that the Laws be faithfully executed;" and the federal courts shall have power to decide "all Cases, in Law and Equity, arising under this Constitution, the laws of the United States . . ." (1). However, in reality, all three branches perform legislative, executive, and judicial functions. The legislature, through its committees, exercises oversight of many executive agencies. In a few cases it has passed a specific act to guarantee that an agency will enforce a law in the desired manner. A provision of the tax law requires the IRS to report all tax refunds over $200,000 to a Joint Committee of Congress and to delay payment for 30 days after submission of the report (2). A more specific example of Congress acting to execute the laws is the saccharin moratorium. Congress took from the executive branch the power to apply the law to a specific food additive (3). Congress has entered the judicial arena by creating special courts, such as the Tax Court and the Court of Military Appeals, to process certain classes of cases. These "Article I" courts are creatures of Congress and do not enjoy the privileges of the regular federal courts enumerated in Article III of the Constitution (4). Also, Congressional committees act as quasi-courts by holding hearings; they have subpoena and contempt powers, which are normal judicial powers.

The executive branch has vastly expanded its power during the last 80 years. The President has always had the power to act as legislator and judge as well as Chief Executive. All presidents have suggested or proposed legislation to Congress, and all have had the pardon power mentioned in Article II, Sec. 2, of the Constitution. But recent decades have seen the exponential growth of executive authority implemented in two ways:

- The White House staff and the policymaking groups that it oversees are one channel. The staff now carries out research, prepares legislation, and plans national policy on a scale equal to that of Congress. A supreme example is Budget Director David Stockman's line-by-line rewriting of the entire 1982 federal budget.

- Federal agencies, such as the Food and Drug Administration and the Federal Communications Commission that administer laws and programs, are the other channel.

These administrative agencies must perform legislative and judicial functions, which means that while acting as quasi-legislatures, they establish policies regulating every phase of industrial and commercial activity; while acting as quasi-courts, they adjudicate controversies between government and the regulated party. These vast agency powers have transformed the nature of wealth. Much of what constitutes property today is not land or money, but entitlements: the granting of a license or benefit by a government agency (5). Examples include welfare, tenure at a state university, permission to practice a profession, and Social Security. An individual recipient has a constitutional right to due process of law before an entitlement can be revoked (6).

The judicial branch has expanded its authority to make and administer the law through the institution of judicial review. Judicial review is the distinguishing feature of the U.S. system of government. The federal courts have the power to invalidate the constitutionality of acts of Congress, acts of the President, and state laws. Debate over the appropriateness of judicial review and whether the Founding Fathers intended the courts to have this power has continued for nearly two hundred years (7). The question is really academic: Since Chief Justice John Marshall's opinion in Marbury v. Madison (announced in 1803), which held that Congress may not restrict or enlarge the original jurisdiction of the Supreme Court, the Court has exercised this authority (8). It is clearly the final arbiter on constitutional issues. Despite long and vocal protest over many a court decision, the public generally accepts the Court's word as final and binding. In a 1958 case overturning a lower court's attempt to block the desegregation of schools in Little Rock, Arkansas, the Supreme Court cited Marshall's famous dictum, "It is emphatically the province and duty of the judicial department to say what the law is." The Court then added, "This decision declared the basic principle that the federal judiciary is supreme in the exposition of the law of the Constitution, and that principle has ever since been respected by this Court and the Country as a permanent and indispensable feature of our constitutional system" (9). The courts have not only made law through the use of judicial review, they have also become administrators. Judges have the authority to exercise continuing supervision over their decrees, which can require their ongoing involvement in the operation of a school district, prison system, or other large institutional system.

The Court System

There are three levels of federal courts: district courts, courts of appeal, and the Supreme Court. Most civil lawsuits and all criminal cases are tried at the district court, the lowest level. Each state has at least one district; California, the largest state, has four. The judges, like all federal judges, are appointed by the President and confirmed by the Senate; they have life tenure and may be removed only by impeachment. Appeals from the trial courts are heard in the circuit courts of appeal, of which there are twelve. Eleven are numbered and hear appeals from a different group of states; for example, Oregon cases are appealed to the ninth circuit. The twelfth court is the D.C. Circuit, which only hears D.C. cases. When a case reaches the court of appeals, three judges are assigned to hear it. On rare occasions the entire court will hear a case and all the judges will vote on it (a hearing en banc). Many, but not all, appellate decisions are published in the law reporters. These reporters are the source of the precedents used by other lawyers and courts to define the law in later cases. However, the environmental statutes usually provide for direct review of agency actions in the court of appeals, thereby bypassing the trial courts. Affected parties (such as polluters) may sue the Environmental Protection Agency (EPA) in the court of appeals to invalidate a standard. For example, under the Clean Air Act, the D.C. Circuit has exclusive jurisdiction over all challenges to EPA's national air policies. Challenges to a specific state's implementation plan are brought in the circuit for that state (10). So while all circuits hear environmental risk cases occasionally, the D.C. Circuit hears the bulk of them. It has developed great expertise in this area, and its judges include some of the finest legal scholars of the day.

The Supreme Court may hear appeals from all twelve circuits; however, it has complete control over its appellate docket. (It also may hear appeals from state supreme courts.) It hears only those appeals it considers of paramount importance. If four justices vote to hear a case, it is set for argument. If not, the decision of the lower court stands. There is no way to predict whether or not the Supreme Court will rule on any particular case.

The number of cases disposed of in one form or another by the Supreme Court has nearly tripled in the last 25 years (11). This is due to the creation of new federal laws in the civil rights and environmental areas and the explosion in the area of criminal defendants' rights. But most of the dispositions are refusals to hear a case. The number of cases that receive oral argument and a full opinion has remained fairly constant in recent years because the court has no more time to schedule additional arguments: its calendar is full.

It is critical to remember that the Supreme Court's denial of a request to hear a case (called a petition for *certiorari*) has no value as precedent. The court expresses no opinion on the merits of a case by denying *certiorari*; it "simply means that fewer than four members of the Court deemed it desirable to review a decision of the lower court as a matter 'of sound judicial discretion'" (12). This means that questions not ruled on by the High Court are not yet settled. Other courts may construe a statute differently. When conflict in the circuits arises on a specific point of law, the Supreme Court will usually resolve it by deciding a case in order to prevent federal law from varying sharply from state to state. Such a conflict existed on the issue of the use of cost-benefit balancing in formulating Occupational Safety and Health Administration (OSHA) toxicant standards. So the Court accepted the *American Textile Manufacturers Institute* case (see discussion later in this chapter) to resolve the conflict.

Agencies

The executive branch of government carries out the laws through the Cabinet departments and independent agencies. There are over 50 independent agencies today; among the most prominent are the Federal Communications Commission (FCC), the Securities and Exchange Commission (SEC), and the National Labor Relations Board (NLRB). The commissioners of some agencies are appointed by the President for a fixed term. For example, the NLRB has five board members who serve five-year terms. Other agencies, such as the Environmental Protection Agency (EPA), have a single administrator at the head with a deputy administrator and heads of "offices" at a lower level. These officials are appointed (and removed) by the President and confirmed by the Senate. Some Cabinet departments exercise regulatory functions through entities within them. The structure of an agency is not that crucial: the Postal Service was a Cabinet department for a long time and issued regulations controlling mail fraud, obscenity, and so on. Now that a quasi-independent company runs the mail service, regulation of these areas continues as before.

The set of requirements that controls the operation of these agencies is called administrative law. What an agency can and cannot do as it makes rules, adjudicates cases, publicizes, threatens, investigates, and advises private activity is the purview of administrative law (13). Four principal agencies regulate risk issues:

1. The EPA, an independent agency, administers air, water, and toxic substance legislation.

2. The OSHA, a part of the Department of Labor, sets exposure standards and safety rules for work places.

3. The Food and Drug Administration (FDA) regulates foods, drugs, and cosmetics; is housed in the Department of Health and Human Services; and reports to the Assistant Secretary for Health.

4. The Consumer Products Safety Commission (CPSC), an independent agency, controls the packaging, labeling, and distribution of a broad range of toys, clothes, electronics, and other products.

The agencies derive their authority from their organic legislation. For example, the FDA administers the Food and Drug Act of 1906; the Federal Food, Drug, and Cosmetic Act of 1938; and the Medical Device Amendments of 1976. The areas to be regulated, the general goals of an agency, and some of the procedures to be used are spelled out in these laws. In addition, all agencies must conform to the Constitutional provision guaranteeing that no individual shall be "deprived of life, liberty, or property without due process of law" (14). The agencies must also adhere to the Administrative Procedure Act (APA) of 1946, which formalized and defined the regulatory procedures that had