# INTRODUCTION AND OVERVIEW

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We are all more or less successful risk managers if we are still alive. Life is ntrinsically filled with dangers, real or perceived. Planes may explode and go down either because of terrorist activities or safety rules violations, nuclear power plant may blow-up (Chernobyl) or release radioactive cloud (Three Mile Island), a chemical plant may release toxic gas (Bhopal) or natural disaster (hurricane, flood, tornado, volcano, landslide) can strike the area in which we live. We may get acute food poisoning either from bacterial or chemical contamination, or we chronic diseases that are in part caused by the food choices we make. Whether we are crossing the street, making investments, deciding what to eat, how to get from one place to another, choosing our profession, or getting married, we are making our decision based on evaluating risks and benefits that a particular activity or avoidance would bring us. The subject of this book is to improve our analytical techniques in evaluating dangers and skills in confronting them.

### 1. Definition of Risk Analysis

We can define risk analysis as a body of knowledge (methodology) that evaluates and derives a probability of an adverse effect of an agent (chemical, physical or other), industrial process, technology or natural process. Definition of an "adverse effect" is a value judgment. It could be defined as death or disease (in most cases of human health risk analysis); it could be a failure of a nuclear power plant, or a chemical plant accident, or loss of invested money. In some recent cases of risk analysis even vaguely defined terms, such as "quality of life" or "sense of community", have been evaluated using risk analysis. Traditionally, most risk assessments (risk analysis applied in a particular situation), deal with health effects, or more recently with the ecological health or economic well being (in case of business risk analysis**)**. Although there are many types of risk analysis, some common elements are necessary to qualify the process as "risk analysis", particularly when dealing with the potential health effects of toxic chemicals. Those elements are (NAS 1983):

1. hazard (agent) identification
2. dose-response relationship (how is quantity, intensity or concentration of a hazard related to adverse effect)
3. exposure analysis (who is exposed? to what and how much? how long? other exposures?)
4. risk characterization (reviews all of the above and makes calculations based on data, with all the assumptions clearly stated. Often the conclusion is that more data and/or improvement in methodology is needed and that no numerical risk-number can be derived to express accurately the magnitude of risk.

Deciding WHAT is an adverse effect (and to some extent hazard identification) is a value judgment that can be made by well-informed citizens. Consideration of other components of risk analysis is a complex process, which in order to be properly conducted requires extensive training. Just as one would not want to have a surgery performed by an untrained layman, risk analysis may be a risky business if performed by untrained people. Because of its interdisciplinary nature and complexity, risk analysis requires an appropriate amount of time to evaluate all pertinent data, even when one deals with problems of lesser complexity. We are constantly performing risk analysis and risk management in everyday situations, such as observing traffic when planning to cross the street, or driving. However, in more complex situations where we maybe exposed to toxic substances, radiation or the possibility of a nuclear power plant disaster, formal risk analysis may be necessary in order to derive reasonable (and sometimes optimal) recommendations for most appropriate risk management.

**2. Purpose of this book**

This book provides a comprehensive overview of risk analysis and its applications to a broad range of human activities. The editor and co-authors seek to bridge the gap between theory and application, and to create a common basic language of risk analysis. They hope that the material in this book will provide a common knowledge base for risk analysts, which can be expanded according to their specific interests and fields of study, using the references provided in each chapter.

The intended readers are scientists, engineers, lawyers, sociologists, politicians and anyone interested in gaining an overview of risk analysis, and who wants to become proficient in speaking the basic language of risk analysis, and understanding its applications in difficult risk management decisions. The book can be used as a reference for undergraduate, graduate and other training courses in risk analysis. Also, the editor hopes that the book will be used by the legislators (local, state and federal) and their aids to devise better laws to protect the public and encourage responsible business development and increase profits, rather than using risk analysis to promote status quo or reduce environmental safeguards. Several chapters demonstrate that application of most enlightened environmental management increases profits (since pollution is equivalent to wasted resources) and thus fiscal conservatism and emphasis on private property rights also mean increased environmental protection***. Only in an unenlightened society are environmental safeguards mistakenly considered as opposed to business interests and free markets. Better business with cleaner environment is the paradigm for the 21st century*****.** The old paradigm "business vs. environment" needs to be retired.

The authors of the FUNDAMENTALS are practitioners in the field of risk analysis and risk management.

The book is divided in 4 sections:

**I. THEORETICAL BACKGROUND OF RISK ANALYSIS** consists of chapters demonstrating the scientific basis of risk analysis , types of risk analysis and basic concepts. Chapters in this section discuss human health toxic chemicals risk analysis, epidemiological risk analysis, uncertainty and variability of risk analysis, Monte Carlo risk modeling, probabilistic risk analysis of complex technological systems, ecological risk analysis and the basic economics of risk analysis.

**II. APPLICATIONS OF RISK ANALYSIS** demonstrates applications of risk analysis to real life situations. Examples come from agriculture (application of pesticides), indoors exposures, promoting pollution prevention, global climate change etc. A chapter on computer software programs and use of Internet in risk analysis is also added.

**III. RISK PERCEPTION, LAW, POLITICS AND RISK COMMUNICATION** deals with differences between public perception of risks, scientific risk analysis and its legal applications, and how to communicate risks to those who may be affected. This section also has two chapter dealing with setting environmental priorities and comparative risk analysis and environmental justice. The insurability of risk deals with societal response to various risks of living.

**IV. RISK MANAGEMENT** illustrates the use of risk analysis in devising better risk management in handling technologies (ex. nuclear power plants), or general everyday environmental problems. Also, chapters deal with the management of natural risks such as earthquakes and floods, and with the clean-up of radioactive hazardous waste sites on Indian reservation. The final chapter integrates a world view as seen by a risk analyst (the editor).

The conclusion summarizes the topics elaborated in the chapters and suggests how the practice of risk analysis affects social management of environmental problems in view or the recent controversies in risk-benefit analysis applications in legislative proposals and regulations.

**3. Historical Overview of Risk Analysis**

Historical perspective on risk analysis applications in society was given by Covello and Mumpower (1985):

Around 3200 BC in Tigris-Euphrates valley, a group called Asipu served as risk analysis consultants to people for making risky, uncertain or difficult decisions. Greeks and Romans observed causal relationships between exposure and disease: Hippocrates (4th century BC); Vitruvious (1st century BC) noticed lead toxicity, Agricola noticed the correlation between occupational exposure to mining and health.

Modern risk analysis has roots in probability theory and development of scientific methods for identifying causal links between adverse health effects and different types of hazardous activities: Pascal introduced probability theory 1657; Halley proposed life expectancy tables 1693 and in 1792, LaPlace developed a true prototype of modern quantitative risk analysis, with his calculations of the probability of death with and without smallpox vaccination. With the rise of capitalism, money use and interest rates, there was an increased use of mathematical methods dealing with probabilities and risks. For example, the risk of dying was calculated for insurance purposes (life expectancy tables). Physicians in the middle ages also observed correlation between exposures to chemicals or agents and health: Evelyn noticed that smoke in London caused respiratory problems. Correlation of scrotal cancer was made with occupational exposures to soot by chimney sweeps.

**4. Risk Management**

Insurance, which started 3900 years ago in Mesopotamia, is one of the oldest strategies for dealing with risks. In 1950 BC the Code of Hamurabi formalized bottomry contracts containing risk premium for the chance of loss of ships and cargo. By 750 BC Greeks also practiced bottomry. In 1583, first life insurance policy was issued in England. In contemporary society, insurance has developed to deal with a wide variety of phenomena associated with adverse effects, from health insurance to mortgage insurance. Actuaries (people who calculate insurance premiums based on historical losses and estimates of the future income from premiums, and losses) are probably the best risk assessors, since the failure in making accurate predictions about losses and premia income can result in the loss of the business. Companies with bad actuaries go bankrupt (see a chapter by Kunreuther).

Government interventions to deal with natural or man-made hazards are recorded in all great civilizations . In order to manage air pollution from burning coal in London, King Edward (1285) issued an order forbidding the use of soft coal in kilns, ***after an unsuccessful trial to voluntary decrease its use.*** Perhaps we can learn from this historical example that "voluntary" reduction in risks from pollution and technological risks in general is best achieved by designing and enforcing intelligent environmental and occupational laws. Carrots and sticks may be more effective in dealing with environmental and occupational risks (accidents or pollution) than either sticks or carrots alone! Thus, while we may chose to believe that industries and individuals sincerely have the public good in their minds when dealing with industrial production and/or pollution and waste management, it is helpful to have laws and regulations to insure responsible behavior in cases where the promises are not kept because the budgetary constrains have pushed the environmental considerations out of the picture. ***The irony is that in most cases improvement in environmental management would improve also the bottom line in a long-run and often in a short-run, thus budgetary constrains should encourage environmental protection and pollution prevention since they save money for the company!*** However, as a great physicist, Max Plank, said: "The new ideas do not win by the strength of their logic, but because their opponents eventually die!" Hopefully, the idea of pollution prevention and safe environmental management, as one of the most obvious ways to improve profits, will prevail before all of its opponents die!

Water and garbage sanitation in the 19th and 20th centuries were extremely successful in decreasing our risks of mortality and morbidity. So were building and fire codes, boiler testing and inspection and safety engineering on steamboats railroads and cars. A whole field of risk management was developed based on common sense risk analysis, which increased the longevity and generally improved the quality of life for most citizens in the developed world.

**5. Modern Risk Analysis**

Conceptual development of risk analysis in the USA and other industrially developed countries (referred by the UN as North) started from two directions: 1. with the development of nuclear power plants and concerns about their safety; This problem led to the development of the clasical probablilistic risk analysis. 2. with the establishment of US EPA, OSHA, NIOSH and equivalent governmental agencies in developed countries in response to a rapid environmental degradation caused by indiscriminate use of pesticides, and industrial pollution, and the public outcry and environmental movement triggered by the publishing of Rachel Carson's Silent Spring.

Modern industrial society underwent changes that must be factored into risk analysis and risk management associated with industrial development. However, one should keep in mind that in the under-developed countries (referred to as South by the UN), one still deals with infectious disease, malnutrition and other diseases of pre-industrial society, in addition to environmental degradation due to either overpopulation or imposed industrial development. In the North, the following applies for modern risks:

1. A shift in the nature of risks from infectious diseases to degenerative diseases.

2. New risks such as from nuclear plant accidents, radioactive waste, pesticides and other chemicals release, oil spills, chemical plant accidents, ozone depletion, acid rain generation, global warming.

3. Increased ability of scientists to measure contamination.

5. Increased number of formal risk analysis procedures capable of predicting a priori risks.

6. Increased role of governments in assessing and managing risks.

7. Increased participation of special interest groups in societal risk management (industry, workers, environmentalists, scientific organizations), which increases necessity for public information.

8. Increased citizen concern and demand for protection.

Risk analysis can help manage technology in a more rational way to promote sustainability of desirable conditions for societies and eliminate conditions detrimental to the well-being of humans and ecosystems. However, in each particular case of risk assessment, the assumptions and uncertainties have to be clearly spelled out. All the models used in performing risk analysis have to indicate assumptions and uncertainties in conclusions.

Formal risk analysis can be organized into (Figure 0.1):

1. Non-cancer chemicals risk analysis

2. Carcinogen risk analysis

3. Epidemiological risk analysis (which could include both cancer and non cancer chemicals, or other non-chemical hazards, such as accidents, electromagnetic radiation, nutrition etc.).

4. Probabilistic risk analysis associated with nuclear power plants safety and chemical plants safety

5. *A posteriori* risk analysis, which is applied in actuary science to predict future losses, either from natural phenomena, investments or technology.

6. Non-quantitative risk analysis, or "common sense" risk analysis, which can give only vague patterns of possible risks.

Chapters in Part I of the book will deal with these types of risk analyses and their limitations.

For non-carcinogenic chemicals, it is assumed that an adverse effect occurs only if exposure to the chemical exceeds a threshold. Risk analysis is used both for establishing criteria and standards for chemicals in the environmental media and for evaluating risk in particular cases of exposures to toxic chemicals (such as to contaminated water, soil or air in the vicinity of a pollution source or evaluations of Superfund sites). It is assumed that there is no probability of harm if the exposure is below such a threshold. Criteria are based mostly on animal studies, and risk analysis methods deal with extrapolations from animal to human, from short-range to long range exposures and with similar scientific issues, which require expert judgments and cannot be neatly put into a formula. Uncertainty in the derived criteria and standards is usually one to two orders of magnitude.

Risk analysis for establishing criteria for toxic substances is probabilistic only in the case of carcinogens. The probability of developing cancer or a cancer potency slope as a result of exposure to a particular level or concentration of a chemical is derived by modeling from animal data. Depending on the model applied, a variety of results may be obtained .

Probabilities of developing cancer or other diseases can be also obtained from epidemiological research correlating exposures to toxic substances with development of cancer or other type of disease. Epidemiological risk analysis deals with establishing correlations or causal relationships between exposure to a chemical and disease. Most frequently retrospective, cohort, mortality studies of occupational groups are used for assessing cancer risk. Standard morbidity or mortality ratios can be regarded as increase in probability of a health risk with exposure. However, because of the large uncertainty in estimating exposure the results of the epidemiological studies are combined with studies in animals in order to confirm the causal relationship between exposures to an agent (carcinogen) and cancer.

Probabilistic risk analysis is applied to industrial process safety and nuclear plant safety (fault-tree and failure-tree analysis). The probability of an adverse outcome (failure of a component or a system) of a series of interconnected events is obtained by evaluating probabilities of failures of individual components. These probabilities are obtained either based on historical data or on assumptions of failure. Once a probability of failure of a chemical process is established, one can apply chemical risk analysis to establish severity of consequences of a release of a particular toxic substance. This type of probabilistic risk analysis was a the beginning of the modern discipline of risk analysis, when atomic energy promised a new way of tapping into an almost limitless energy resource. Until Chernobyl, the risk analysis numbers were very clear indicator of its safety. Chernobyl and the problems with disposing of radioactive waste from nuclear reactors demonstated again that the technology that initially promised to be a panacea may not be all that was promised. Thus, it may be wise to be cautious when promoting technological "fixes".

Based on historical data, one can establish probabilities of adverse effects from natural phenomena (earthquakes, floods, etc.), or types of human activities (transportation accident rates etc.). This type of risk analysis is used extensively by insurance industries to establish insurance rates. Economic risk analysis could be also regarded as belonging to this category, because adverse economic effects are obtained from known prices of wasted chemicals and other costs associated with pollution (cost of cleanup of hazardous waste sites, legal costs, medical costs to society etc.).

Some recent phenomena are not yet quantifiable. For example, risks from acid rain generation are not yet easily amenable to numerical analysis or are the risks from global warming. Therefore, one can only establish qualitative risks, until more data is obtained to perform quantitative risk analysis. However, one should keep in mind that perhaps in study of such complex phenomena we will never have sufficient data for accurate predictions and base our risk management decisions on prudence in the particular case.

### 5. Limitations of Risk Analysis

Each chapter elaborates on topics, in which the definition of risk analysis may vary depending on the application. The reader will notice the wide diversity of definitions and controversy, which indicate that, unlike with the physical sciences, there is much uncertainty associated with any risk analysis (assessment). While risk analysis maybe a useful tool to evaluate relatively simple risks (such as health risks from toxic substances in a particular exposure scenario) and compare them with alternative risks if different human actions were taken (ex. replacement of particular chemicals or industrial processes and technology), it maybe dangerous to apply it to more complex phenomena in order to derive definitive risk ranking or risk management plans. Thus, risk analysis should be applied with caution to the real-life problems, keeping in mind its limitations. The caution may be even more critical in risk-benefit analysis, where calculations of benefits maybe even more uncertain, dependent on various underlying assumptions (see Chapter on Economic Risk Analysis).

A Nobel Laureate economist, Dr. Friedrich Hayek, expressed the dangers of applying science that deal with "essentially complex phenomena" (such as risk analysis or economics) for sweeping policy decisions (Hayek 1991). His assessment of economics could be translated to a cautionary note on risk analysis: "There is as much reason to be apprehensive about long-run dangers created in a much wider field, by the uncritical acceptance of assertions which have the appearance of being scientific. There are definite limits to what we can expect science to achieve. This means that to entrust the science - or to deliberate control according to scientific principles - more than scientific method can achieve may have deplorable effects. This insight will be especially resisted by all who have hoped that our increasing power of prediction and control, generally regarded as the characteristic result of scientific advance, applied to the process of society, would soon enable us to mold it entirely to our liking. Yet the confidence in the unlimited power of science is only too often based on a false belief that the scientific method consists in the application of a ready-made technique, or in imitating the form rather than the substance of scientific procedure, as if one needed only to follow some cooking recipes to solve all social problems".

The current controversy between industry, government and environmentalists about the use of risk analysis follows the above reasoning. Many environmentalists regard risk analysis as a devious tool used by the industry to maintain status quo ("proving" that something is NOT dangerous), and totally deny its usefulness, while industry and governmental agencies in increasing numbers want to base all decisions on results of risk analysis. While it is true that risk analysis may be used by both sides in an issue to justify their actions, often based on some rather questionable numerical values, risk analysis could be useful to point out the dangers of pursuing one or another course of action. The most important thing is to always make risk assessment transparent to the public, with all the assumptions and parameters clearly stated***. The thought process that is going into evaluating a particular hazard is more important than application of some sophisticated mathematical technique, or formula, which often may be based on erroneous assumptions or models of the world***. The controversy about the requirement for risk/benefit analysis **before** any law is enacted may lead the legislators into total regulatory deadlock, which may leave the public unprotected even in obvious cases of environmental abuse.

Risk analysis can, under certain circumstances, make general predictions of outcome of our decisions; sometimes, we can only obtain a very rough feeling about the possible outcomes. While in physical sciences the predictions are usually very accurate, in risk analysis our predictions could have a range of several orders of magnitudes. If we were to build a bridge based on an assumption of the average value obtained for a weight put on this bridge, and in reality the weight may vary for 1-2 orders of magnitude, we would soon experience collapse if we did not allow ample space for uncertainty and caution.

The best we can hope for in applying risk analysis to the complex problems that we face today (such as environmental exposures to chemicals and radiation, ozone hole, resource depletion, soil loss, global warming etc.) is to ascertain patterns that could be useful for risk management. The numbers derived by risk analysis are at best crude and often misleading, if the uncertainty associated with them is not clearly spelled out. We could compare risks of different cleaning methods at the hazardous waste sites, or risks of use of different types of energy or different types of transportation with more certainty than predict the global warming phenomena. Risk analysis could help us predict the economic and human health impact of certain decisions (ex. either to use public transport modes or personal cars, nuclear energy, coal-powered plants, or conservation) (see Chapter IV.6), which could help develop more livable and equitable sustainable societies.

Compared with the accurate predictions we can get in the physical sciences, this sort of mere pattern prediction is not satisfying**. *However, to act on the belief that we posses the knowledge and the power to enable us to shape the processes of society entirely to our liking, knowledge which in the real world we do NOT posses, is likely to make us do much harm.***

As Dr. Hayek pointed out: "The recognition of the insuperable limits to his knowledge ought indeed to teach the student of society a lesson in humility which should guard him against becoming as accomplice in man's fatal striving to control society -a striving which makes him not only a tyrant over his fellows, but may will make him destroy a civilization which no brain has designed but which has grown from the FREE efforts of millions of individuals. "

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