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A COMPARISON OF THE RISK DECISION-MAKING PROCESS FOR PROTECTION OF HUMAN HEALTH FROM AIR POLLUTION IN THE UNITED STATES AND THE REPUBLIC OF KOREA

By

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ABSTRACT

A COMPARISON OF THE RISK DECISION-MAKING PROCESS FOR PROTECTION OF HUMAN HEALTH FROM AIR POLLUTION IN THE UNITED STATES AND THE REPUBLIC OF KOREA

By

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Over the past several decades, the world-wide industrial nations have been intensively concerned over increasing human health risks from various chemicals in the air. Many countries in the world have already made some plausible regulatory policies to reduce the unreasonable risks. However, the risk management policies have varied considerably from country to country due to the national and cultural attitudes relative to the characterization and control of risks.

This dissertation investigates the fundamental risk decision-making process including the risk management policy for protecting the human health from air pollution in the United States and the Republic of Korea. The two government organizations, U.S. Environmental Protection Agency (USEPA) and Korea Ministry of Environment (KMOE), are selected for the comparative analysis of a cross-national research. Analytical approach is used to compare and contrast the risk decision-making process including methods and techniques of each country.

Two case studies, including the criteria and standards, are presented to examine similarities and differences between the two countries relative to the regulatory decision

process. Sulfur dioxide and total suspended particulate in ambient air are used as non-carcinogenic examples and benzene in the air as the carcinogenic example. The following criteria are used to make evaluation: a) regulatory framework, b) principles used for the standard-setting, and c) factors affecting risk decision-making.

Specifically, the USEPA's risk decision-making system is basically an open system based on explicit procedures and principles of law. The court decisions, public participation, and peer review process have significantly affected the USEPA's risk management policy. The USEPA's approach for risk management decision is largely based on scientific calculation such as risk quantification and risk probability.

Conversely, the KMOE's risk decision-making system is essentially a closed system based on personal contracts within the Ministry and principles of confidentiality. The legal system, public participation, and peer review process play relatively a minor role in terms of health risk management decision. The KMOE's approach for risk management decision is largely based socio-economic consideration rather than scientific findings through toxicological research and risk assessment technique.

For My Family

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LIST OF ACRONYMS

ACGIH	American Council of Government Industrial Hygienist
AQPD	Korean Air Quality Planning Division
AQPL	Korean Air Quality Preservation Law
BACT	Best Available Control Technology
BEPL	Korean Basic Environmental Policy Law
CAA	U.S. Clean Air Act
CEPAC	Korean Central Environmental Preservation Advisory Committee
CERCLA	U.S. Comprehensive Environmental Response, Compensation, and Liability Act
CPSP	Consumer Product Safety Commission
CWA	U.S. Clean Water Act
EDSL	Korean Environmental Dispute Settlement Law
EPL	Korean Environmental Preservation Law
FDA	U.S. Food and Drug Administration
FIFRA	U.S. Federal Insecticide, Fungicide and Rodenticide Act
HCSCL	Korean Hazardous Chemical Substance Control Law
HEW	U.S. Department of Health, Education, and Welfare
IARC	International Agency for Research on Cancer
ISCST	Industrial Source Complex Short Term
ISPL	Korean Industrial Safety Preservation Law
KMOE	Korean Ministry of Environment
LOAEL	Lowest Observed Adverse Effect Level
LOEL	Lowest Observed Effect Level
MACT	Maximum Available Control Technology
MOHSA	Korean Ministry of Health and Social Affairs
MOTI	Korean Ministry of Trade and Industry
NAAQSs	National Ambient Air Quality Standards
NIER	U.S. National Institute of Occupational Safety and Health
NOAEL	No Observed Adverse Effect Level
NRC	U.S. National Research Council
NSPS	New Source Performance Standards
NVCL	Korean Noise and Vibration Control Law
OEHR	U.S. Office of Environmental Health Research
OSHA	U.S. Occupational Safety and Health Administration
PPL	Korean Pollution Prevention Law

PSD	Prevention of Significant Deterioration
RCRA	U.S. Resource Conservation Recovery Act
SAC	U.S. Scientific Advisory Committee
SDWA	U.S. Safe Drink Water Act
SLWTL	Korean Sewage and Livestock Waste Treatment Law
TLV	Threshold Limit Values
TSCA	U.S. Toxic Substances Control Act
TSP	Total Suspended Particulates
UNEP	United Nations Environment Program
USEPA	U.S. Environmental Protection Agency
WQPL	Korean Water Quality Preservation Law

CHAPTER I

INTRODUCTION

Statement of the Problem

Since the beginning of the early 18th century, worldwide contamination resulting from the effects of the Industrial Revolution have resulted in successive impacts on human history and the world envirionment (McCord, 1937; Lanier, 1985; Worster, 1988). This can be summarized by: rapid population growth; urbanization; industrialization; and the continuous technological boom. It is no doubt that the quality of human life has been improved continuously due to such change.

As the result of changing world system, however, it is commonly accepted that these activities have altered the earth's chemistry in ways that may cause serious ecological damage resulting in economic consequences not only for our generation but also for the succeeding generations. Among these, the three that stand out as particularly threatening and costly to the society are risks to: forests; food security; and human health (Portney, 1990; Postel, 1986). The origin of these risks comes from the intrinsic toxic nature or hazard potential of some anthropogenic generated chemicals, and the probability of biota being exposed to it.

The rising concern over increasing human health risks related to hazarouds chemicals has led to the realization that there is an urgent need for the scientific

community to develop sound methods for assessing the wide range of human health effects resulting from exposure to toxic chemicals in drinking water, ambient air, and foods inclucing occupational envirionment. In response, industries and governments throughout the world already began to invest unprecedented sums of money into the identification, evaluation, and the control of various toxic chemicals (KMOE, 1989; NRC, 1983; USEPA, 1987a; UNEP, 1987). Scientists throughout the world began to recognize that dramatically new and different approaches needed to be developed regarding risk assessment and management of toxic chemicals which might not only adversely affect human health but also the environment (Heiberg and Tronnes, 1988; Jasanoff, 1986; Paustenbach, 1989; Santos, 1987).

Among the various risks, human health risks resulting from exposure to various air pollutants from fossil-fueled power plants, metal smelters, and automobiles are still of strong concern throughout the world (UNEP, 1987; World Bank, 1992). For example, the World Bank (1992) has estimated that worldwide excessive urban particulate matter is responsible for 300,000 - 700,000 premature deaths annually. In the case of the United States, the U.S. Office of Technical Assessment (1984) reported that fossil fuel pollutants alone might cause as many as 50,000 premature deaths each year. In the Republic of Korea, respiratory diseases resulting from air pollution show increasing trend every year (KMOE, 1990).

Although human beings cannot live in a risk free society, it is obvious that unreasonable risks must be minimized by whatever means possible. Threfore, the main object of ny risk assessment effort is to determine the probability and the magnitude of the harm to public health, welfare, or to the envirionment caused by the release of toxic

chemicals (Santos, 1987). The process of risk assemssment is usually composed of two main components; toxicity assessment and exposure assessment. Each component, therefore, must be evaluated to determine the level of overall or total risk posed by a given pollutant. Generally, for each contaminated situation the following questions must be answered: 1. What are the nature and extent of the risks posed to human health and the envirionment? 2. What methodology is appropriate for assessing the magnitude of these risks? 3. How can these problems and risks be mitigated or prevented?

Study Objectives

The primary objective of the dissertation is to investigate the fundamental rish decision-making process including techniques and criteria for protecting human health from air pollution in the United States and the Republic of Korea. Because the U.S. Envirionmental Protection Agency (USEPA) and the Republic of Korea Ministry of Envirionment (KMOE) have been the given primary authority to regulate air pollution each country, the respective agencies are selected for the comparative analysis of a cross-national research.

Study across these two countries may offer special insight into the problems of using science in risk assessment and management with respect toair pollution control policy. The main thursts of this work involve (1) considering the adequacy of current regulatory procedures and attitudes in terms of the decision-making process for resolving similar envirionmental and/or human health problems in each country and (2) a briefly examining the methods for public policy-making in health risk management.

This study will include (1) a generic overview of toxicological risk analysis (2) an examination of generic differences and similarities between the united States and Republic of Korea regarding their approaches to air pollution control and risk management decision and (3) an analysis and comparison of two specific case studies of toxicological risk assessment and management involving (a) sulfur oxides (SOx) and total suspended particulate (TSP) in ambient air as non-carcinogenic examples and (b) benzene in the air as a carcinogenic example.

Research Approach

While this disseration focuses almost exclusively on the current risk management decision process used by both the USEPA and the KMOE, the general process of toxicological risk analysis will also be discussed because understanding the toxicology is a critical element of the overall risk management process. The information for this study has been extracted from relevant books, journlas, newspaper articles and statutes from the United States and the Republic of Korea. The central theories will be risk, probability, and toxicological theory. An analytical process will be used to compare and contrast the decision-making process, methods and the techniques for protection of human health from air pollution used by the USEPA and the KMOE.

The specific procedure to be followed includes these major steps:

1. Review the literature on basic principles of toxicological risk ahalysis.
2. Examine the evolution of air pollution regulations including criteria and standards used in the United States and the Republic of Korea.

3. Observe current risk analysis culture and techniques, and analyze the decision-making process for the health risk management used by the USEPA and the KMOE.
4. Evaluate two case studies of the air pollution regulations used in the United States and the Republic of korea. The first case study will consider sulfur oxides and suspended particulates in the ambient air as a non-carcinogenic chemical example, while the second case study will focus on benzene in the air as an example of a carcinogenic chemical.
5. Compare and contrast the policies for assessing and managing human health risk in the United States and the Republic of Korea using the selected case studies. The following criteria will be used to make these evaluations: a) regulatory frameworks, b) principles used for the standard-setting, c) factors affecting risk decision-making in each country.
6. Formulate conclusions and recommendations.

This dissertation is organized as shown in Figure 1.1. Following the introduction, Chapter II will review the general process used for Toxicological risk assessment, and provide a historical overview of health risk assessment and mnagement used in various parts of the world. The general process of toxicological risk analysis is summarized in four major steps: hazard identification; dose-response assessment; exposure assessment; and risk characterization. Chapter III will present the growth of the air pollution control policies in the United States and the Republic of Korea. The history and organization of both the USEPA and the KMOE will also be addresed. Chapter IV will focus on the

risk decision process for protection of the human health and envirionment used by the USEPA and the KMOE currently. Relevant statues and regulations including risk assessment techniques and criteria will be evaluated. The two case studies, first SOx and TSP in the ambient air and second, benzene in the air will be discussed in Chapter V. This evaluation is then followed by comparisons and contrasts of the approaches to environmental health risk management between the United States and the Republic of Korea in Chapter VI. Finally, the conclusions relative to the risk decision-making process and the risk assessment techniques and criteria used for protection of human health from air pollution are made as well as the recommendations for further research are described. These conclusions and recommendations may apply not only to the developed countries, but also to the developing countries, which have the enviable opportunity to learn from both the lessons and the mistakes of others. Figure 1.1 presents the general scheme of this dissertation.

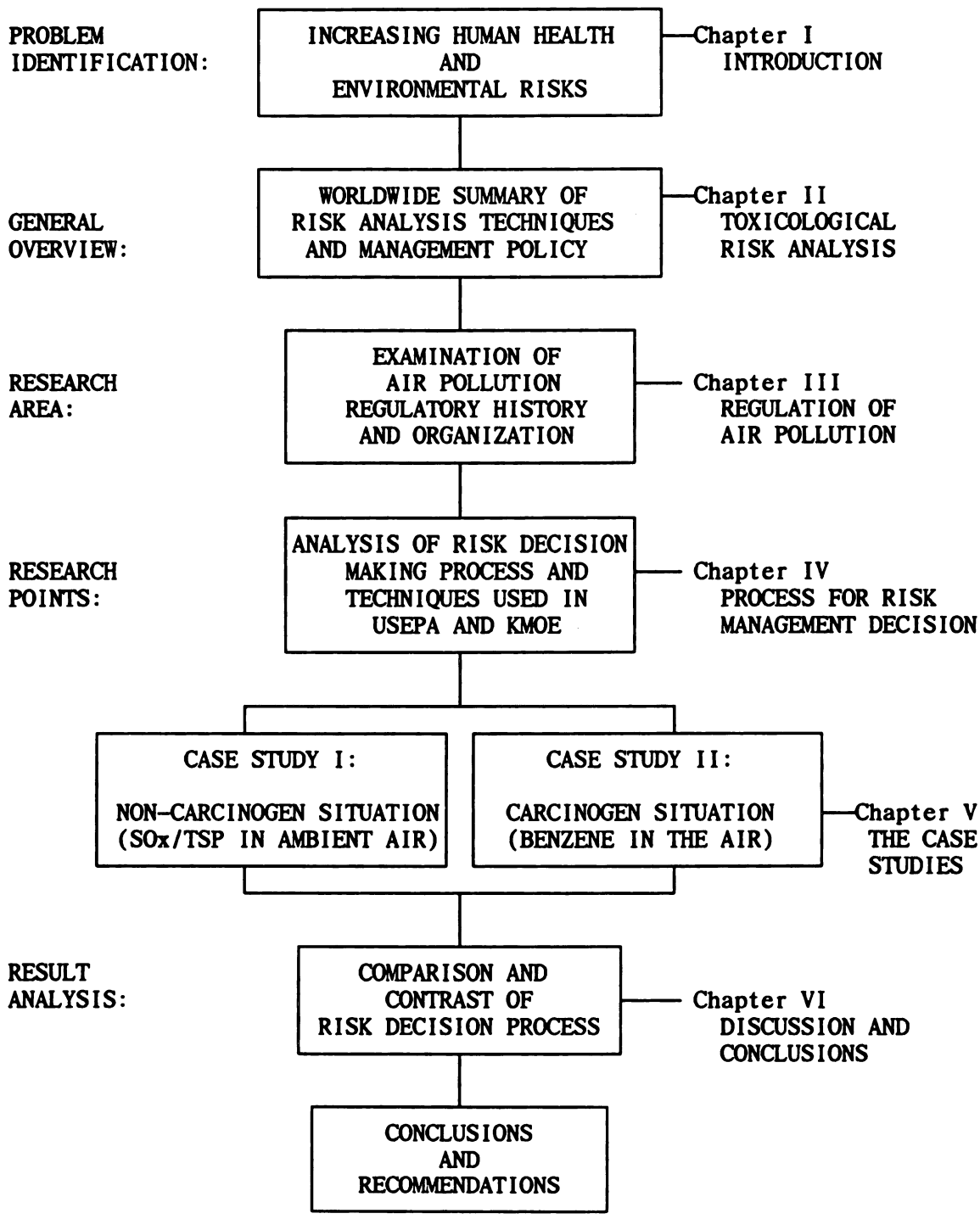

Figure 1.1 The General Scheme of the Dissertation

CHAPTER II

TOXICOLOGICAL RISK ANALYSIS

Terminology

Although the term "risk assessment" has been extensively discussed in recent years, and as the National Research Council (1983) pointed out, no standard definition has evolved, resulting in the same concepts being used under different names. To minimize any confusion regarding to the terminology, in this dissertation, the following terms will be defined: risk, risk assessment, risk assessment process, risk management, toxicological risk assessment, criteria and standards.

Risk

The term "risk" is a statistical concept, defined as the expected frequency or probability of undesirable effects, direct or indirect, on human health and welfare resulting from human exposures to known or potential environmental concentrations of hazard materials (NRC, 1983; Wentz, 1989; WHO, 1978). Hence risk (R) can be calculated as a product of the probability (P) of the event times the severity of the harm (H), or $R = P \times H$. In practice, risk is expressed in terms of time or unit activity, e.g., worker days lost per year from illness due to drinking contaminated water, or lung cancer cases per pack of cigarettes smoked for some specified time period, etc.

A material is considered safe if the risks associated with its exposure are judged by risk assessors and managers to be acceptable. Rand and Petrocelli (1985) classified risk in either absolute or relative terms. Absolute risk is the excess risk to an individual or population due to exposure, while relative risk is the ratio of the risk in the exposed population to the risk in the unexposed population. As Douglas (1985) points out, however, the idea that risk means only absolute risk is very widespread, even where "risk-benefit" is a method deliberately compared with cost-benefit analysis.

Risk Assessment

The term "risk assessment" refers to the characterization of the potential risk either to human health or to the environment as the result of chemical releases into the environment from some specific sources (NAS, 1983; Paustenbach, 1989; USEPA, 1986a). The National Research Council (1983) described some elements of risk assessment as follows:

1) description of the potential adverse health effects based on an evaluation of results of epidemiologic, clinical, toxicologic, and environmental research;

2) extrapolation from those results to predict the type of health effects and estimate the extent of health effects in humans under given conditions of exposure;

3) judgements as to the number and characteristics of persons exposed at various intensities and durations;

4) summary judgements on the existence and overall magnitude of the public-health problem.

Assessment of risk also includes characterization of the uncertainties which is inherent in the process of inferring risk. In this dissertation, risk assessment will be used synonymously with the term "quantitative risk assessment," which emphasizes reliance on numerical results. In addition, the process or procedure used to estimate the likelihood that humans will be affected adversely by a chemical or a physical agent under a specific set of conditions is referred to the term "health risk assessment."

Risk assessment is a tool for arriving at decisions that will result in gaining the best benefits from the use of chemicals while avoiding their hazards (Wentz, 1989). The following techniques are included: environmental impact assessment, system analysis, cost-benefit analysis, and probability analysis. Therefore, the assessment of risk must take into account the cumulative effects of all instances of exposure. For example, in assessing the risk that a person will suffer an adverse effect from air pollution, exposure to both indoor and outdoor pollution should be taken into account. Because of its complexity, risk assessment generally requires the interaction and cooperation of scientists from a variety of disciplines, including geology, hydrology, meteorology, ecology, biochemistry, chemistry and toxicology.

Risk Assessment Process

Risk assessment is not a one-time activity but a process. Therefore, the risk assessment process is defined as the steps utilized to assess the probability of adverse effects on human health from various pollutants (Paustenbach, 1989). Conway (1982) and Deilser (1988) reported that this process may involve collecting, analyzing, and

communicating scientific and economic information for use in policy formulation, decision-making, and risk management.

There are several steps in the risk assessment process. First, the system boundaries are established and all assumptions are explicitly stated. Second, the uncertainty is calculated, explained, preserved in sequential analysis, and communicated in the final report. Third, risks are quantified and compared. The National Research Council (1983) established a four-step procedure for risk assessment that is widely used. The four steps are as follows: hazard identification; dose-response assessment; exposure assessment; and risk characterization. These processes for risk assessment will be described thoroughly in the last two sections of this chapter.

After assessing risks, alternative management actions, including no action, for mitigation of each risk are identified and ranked using parameters such as lives saved, morbidity and ecological damage avoided, cost effectiveness, degree of uncertainty, and acceptability. This is generally called risk management step. During the risk management process, as Wilkinson (1987) pointed out, decisions about whether additional research and monitoring are necessary should be made in terms of potential improvement in decision-making procedures and reduction of uncertainty.

Toxicological Risk Assessment

The term "toxicological risk assessment" refers to assessing the risks of the adverse effects of chemicals on living organisms, and the probability of their occurrence (USEPA, 1987a). In many cases, this term is interchangeable with the term "health risk assessment" which emphasizes human health (Paustenbach, 1989; USEPA, 1987a).

To make it clear, it is necessary to understand the meaning of toxicology. Generally, toxicology is defined as the science that studies the adverse effects of chemicals on living organisms (Timbrell, 1987). Toxicologists, are involved in both risk assessment and risk prediction. Therefore, it is often said that toxicology is part science and part art: the science of toxicology is the observation and study of the toxic effects occurring, while the art of toxicology is how we can use the results observed under one set of conditions (e.g., rats exposed for a lifetime to high doses in the laboratory) to predict effects that are likely to occur in another (e.g., humans exposed intermittently to very low doses).

"Toxicology testing" is also important to the risk assessment process. Acute tests include those to determine oral and dermal toxicity, eye and skin irritation, etc., whereas chronic studies focus on endpoints such as carcinogenicity, teratogenicity, etc.

Risk Management

This dissertation will use the term "risk management" to describe the process of evaluating alternative regulatory actions and of selecting among them. Risk management, which is carried out by regulatory agencies under various legislative mandates, is defined as an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related data (NRC, 1983). Hence, it can include education and communication of risks.

Its purpose is to develop, analyze, and compare regulatory options and to select the appropriate regulation in response to a potential health hazard (NRC, 1983; Wilkinson, 1987). Covello (1983) and Krewski (1987) indicated that the selection

procedure inherently requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control.

Criteria and Standards

"Criteria" are defined as "descriptive factors" taken into account in setting standards, while "standards" are "prescriptive norms" established by some authority to govern action (Lowrance, 1976). As Lowrance (1976) pointed out, standards are established in the perspective of criteria. Therefore, it is often said that criteria are measuring sticks by which hazards are gauged when standards are established. Lowrance (1976) shows a good example in his book, "Of Acceptable Risk."

> The Health, Education, and Welfare Department's document, Air Quality Criteria for Sulfur Oxides, establishes criteria for the states to take into account in developing their standards governing these common pollutants from combustion of fossil fuels. Stating that " Air quality criteria are an expression of the scientific knowledge of the relationship between various concentrations of pollutants in the air and their adverse effects on man and his environment," the report describes the physical and chemical properties of the sulfur oxides and method for measuring them; it surveys concentrations of sulfur oxides in the national environment; it reviews the effects of these substances on materials, vegetation, animals, and man (including synergistic effects with particulate matter); and it summarizes the epidemiological record. In other words, the report describes the factors that are judged to be most important. This is principally a scientific documents, although some subjective, social value judgments are implicit in it. It does not set any standards.

Many types of standards are currently used for protecting or reducing various risks. Some examples of these are: personal exposure standards; ambient composition standards; producer design standards; product composition standards; product performance standards; work practice standards; promotional claims standards; packaging

standards; and national emission standards. Almost all of these standards are expressed in numerical values.

Historical Overview

Risk assessment is not an invention of the 1970s, but has been with us since Adam assessed the risk and chose to bite into the apple in the Garden of Eden. A thoughtful review of the history of risk analysis has been developed by Covello and Mumpower (1985). According to their research, the Asipu, a group of ancient Babylonian who lived in the Tigris-Euphrates valley about 3200 B.C., practiced risk analysis within a religious form. The Asipu served as consultants for risky, uncertain, or difficult decisions such as profit or loss, success or failure. In contrast to today's risk analysts, who usually express their results in terms of statistical probabilities and confidence intervals, the Asipu expressed their results with certainty, confidence, and authority (Covello and Mumpower, 1985). It seems that the practices of the Asipu mark the first recorded instance of a simplified form of risk analysis. As it is implied by Grier (1981), religious beliefs played a significant role in the evolution of probability theory and risk analysis.

According to Paustenbach's report (1989), contamination of the air, water, and land has long been understood as a potential health problem, but the need to control pollution was not recognized for a rather long period. Concerning the history of air pollution, Covello and Mumpower (1985) reported the following story:

> Air pollution (due to dust and smoke from wood and coal fires) has been a ubiquitous problem in congested urban areas since ancient times. The

> first act of government intervention did not occur until 1285 when King Edward I of England responded to a petition from members of the nobility and others concerning the offensive coal smoke in London. Smoke arising form the burning of soft coal had long been a problem in London. Edward's response to the petition was one that is now commonly practiced by government risk managers - he established a commission in 1285 to study the problem. In response to the commission's report, several private sector actions were taken, including a voluntary decision by a group of London smiths in 1298 not to ...work at night on account of the unhealthiness of coal and damage to their neighbors. These voluntary efforts were not sufficient, however, and in 1307 Edward issued a royal proclamation prohibiting the use of soft coal in kilns. Shortly after this, Edward was forced to establish a second commission, the main function of which was to determine why the royal proclamation was not being observed.

In 1107, King SokJong in Koryo Dynasty [one of the old Korean Dynasties] prevented peasants from making forest-fires for agricultural purposes because it was thought that fires may break down the harmony between heaven and earth (Kim, 1988a). It seems that this action originated not to control air pollution, but from the oriental philosophy of Lien and Yen.[1] According to Covello and Mumpower (1985), an attempt was made to set forth a causal relation between disease and the environment in 'Airs, Water, and Lands,' probably written by Hippocrates in the 4th or 5th Century B.C. Giffillan (1965) and Nriagu (1983) noted that the Greeks and Romans observed the adverse effects of exposure to lead as early as the 1st Century B.C. Nevertheless, it wasn't until the 18th Century that the basis for current techniques of health risk assessment was established. Covello and Mumpower (1985) reported that among the many advancements were the following studies by:

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[1] The philosophy of Lien and Yen stands for the dual principle of the negative and positive such as the male vs. female, shade vs. light, and the sun vs. moon. It was emphasized that the harmony of Lien and Yen is essential for sound life on the earth.

Agricola in 1556 linking adverse health effects to various mining and metallurgical practices.

Evelyn in 1661 linking smoke in London to various types of acute and chronic respiratory problems.

Ramazzini in 1700 indicating that nuns living in Appennine monasteries appeared to have higher frequencies of breast cancer.[2]
Hill in 1781 linking the use of tobacco snuff with cancer of the nasal passage.

Sir Percival Pott in 1775 indicating that juvenile chimney sweeps in England were especially susceptible to scrotal cancer at puberty.

Ayrton-Paris in 1822 and Hutchinson in 1887 indicating that occupational and medicinal exposures to arsenic can lead to cancer.

Chadwick in 1842 linking nutrition and sanitary conditions in English slums to various types of ailments.

Snow in 1885 linking cholera outbreaks to contaminated water pumps.

Unna in 1894 and Dubreuilh in 1896 linking sunlight exposure with skin cancer.

Rehn in 1895 linking aromatic amine with bladder cancer.

Because of two major obstacles, however, Covello and Mumpower (1985) indicated that progress in risk analysis did not develop rapidly until the early 20th Century. The first obstacle was the paucity of scientific models of biological, chemical, and physical processes at this time. This was related to the lack of instrumentation and experimental techniques for collecting data and testing hypotheses. The second was the

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[2] Ramazzini suggested that this might be due to their celibacy, an observation that is in accord with recent observations that nulliparous women may develop breast cancer more frequently than women who have had children.

belief, rooted in ancient tradition, that most illnesses, injuries, misfortunes, and disasters could best be explained in social, religious, or magical terms.[3]

During the early 20th Century, the Industrial Revolution was an important turning point for introducing health hazards that were adversely affecting a large number of workers (McCord, 1937; Lanier, 1985). Many scientific research projects have been conducted on the various sectors relative to human health risks since then. For example, the need to protect human health from the adverse effects of chemicals in the workplace, the marketplace, and the environment was recognized as a common goal in the United States and Europe since the beginning of the 1930s. Around this time, setting permissible limits for the workplace introduced the concept of acceptable levels of exposure to toxic chemicals (Paustenbach and Langner, 1986). It is generally accepted that present concept of risk assessment began roughly during the 1930s (Friess, 1987).

Until the early 1940s, society's concern for health risks focused generally on those factors that could increase the risk of infectious disease.[4] However, in the late 1940s, after having eliminated many of the serious infectious threats to human health, society's attention began to divert to more subtle and insidious factors, and began to focus on the hazards posed by chemical agents found in our environment (Eisenbud,

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[3] For example, in 1721, White (1967) reported that an influential critic of medical experimentation in Boston insisted that smallpox is "a judgment of God on the sins of the people" and that "to avert it is ...an encroachment on the prerogatives of Jehovah, whose right it is to wound and smite." In Korean society, many rural communities still show a practice of an exorciser by a shaman, traditionally called MuDang, when they face a specific disaster such as an infectious disease.

[4] Historically the risk of infectious disease was considered as the greatest hazard. As one of notable examples, the epidemic of the Black Death (bubonic plague, 1348-1349) killed an estimated 25 million people in Europe.

1978; Jasanoff, 1986; Paustenbach, 1989). In 1962, Rachel Carson's "Silent Spring" alerted the world to the dangers posed by the proliferation of many synthetic chemical compounds which were applied to croplands. Around this time, the United States Food and Drug Administration (FDA) started to research and identify those chemicals that could safely be added to foods and drugs (Paustenbach, 1989).

During the 1950s, two important studies were conducted by Barnes and Denz (1954), and by Lehmann and Vorhes (1959) at the U.S.FDA. These studies established the rationale for safety factors (later called an uncertainty factor) to be used in the animal-human No Observed Effect Level (NOEL)[5] extrapolation. For example, for a chemical, which has a well known toxic action at a target tissue, a safety factor of 100 was applied.

Since the NOEL concept for carcinogens was first challenged by Mantel and Bryan in 1961, for the regulatory purposes, however, most human exposure to carcinogens was assumed to present a finite incremental cancer risk, irrespective of whether repair processes were operable after the chemical interacted with genetic material-deoxyribonucleic acid (Crump et al., 1976). From this regulatory philosophy, many mathematical models have been developed in order to estimate the excess lifetime cancer risk for humans based on the dose-response curve obtained in animal bioassay.

Many U.S regulatory agencies including the USEPA have had experience with regulating carcinogens such as saccharin, EDB, dioxin, formaldehyde, and methylene chloride since the early 1970s. The 1980s were difficult years for regulatory agencies that

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[5] According to these studies, the NOEL is defined as the highest level [concentration] of a material in a toxicity test that has no statistically significant adverse effect on the exposed population of test organisms as compared with the controls.

had been mandated to protect the public health, partly because the human hazard posed by typical levels of exposure in the environment was probably much lower than that predicted from exposure assessments and low-dose extrapolation models (Paustenbach, 1989).

Friess (1987) indicated that the years between the late 1980s and the early 1990s may be considered a time when public health officials, toxicologists, statisticians, and risk assessors began to question the appropriateness of using dose-response models to estimate the incidence of tumors in exposed human populations. In the United States, the acceptance of the potential upper-bound excess cancer risk models was an important turning point in the history of environmental regulation, and risk management. Recently biologically based dispositon models coupled with the biologically based cancer models have been used to estimate risks at low doses which are believed more realistic than the past cancer models. In addition, risk communication issue has also become an important part of health risk management.

Examining the historical progress of risk analysis and risk management, it is clear that there are some generic differences between the past and the present. The nine important changes between the past and the present were summarized by Covello and Mumpower (1985) as follows:

(1) There has been a significant shift in the nature of the risks to which human beings are subject.

(2) There has been a significant increase in average life expectancies.

(3) There has been an increase in new risks fundamentally different in both character and magnitude from those encountered in the past.

(4) There has been a significant increase in the ability of scientists to identify and measure risks.

(5) There has been a significant increase in the number of scientists and analysts whose work is specifically focused on health, safety and environmental risks.

(6) There has been an increase in the number of formal quantitative risk analyses that are produced and used.

(7) There has been an increase in the role of the federal government in assessing and managing risks.

(8) There has been an increase in the participation of special interest groups in the societal risk management process.

(9) There has been an increase in public interest, concern, and demands for protection.

General Process for Toxicological Risk Assessment

The process of collecting and interpreting the information needed to perform a toxicological risk assessment consists of two main branches: toxicity assessment and exposure assessment. The U.S. National Research Council (NRC, 1983)[6] divided these two branches into four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. At present most of the scientific community accepts this process as a general procedure for toxicological risk assessment

[6] The NRC was established by the National Academy of Sciences in 1916 to associate the broad community of science and technology with the Academy's purposes of furthering knowledge and of advising the federal government.

(Falco and Moraski, 1989; Chung, 1988; Paustenbach, 1989; Preuss, 1988; Wilkinson, 1987).

For some perceived hazards, however, the risk assessment might stop with the first step - hazard identification, if no adverse effect is identified, or if an agency elects to take regulatory action without further analysis. With respect to the toxicological risk assessment process, the ultimate goal usually is to derive a reliable estimate of the amount of chemical exposure which is considered acceptable for humans or other organisms. As the USEPA's risk assessment workgroup (1986a) pointed out, however, for many chemicals present knowledge of toxicological effects on humans is still insufficient to answer this question with assurance.

The following discussion will describe NRC's four steps as general process of toxicological risk assessment. Figure 2.1 is a generalized scheme that provides an overview of the risk assessment and risk management process.

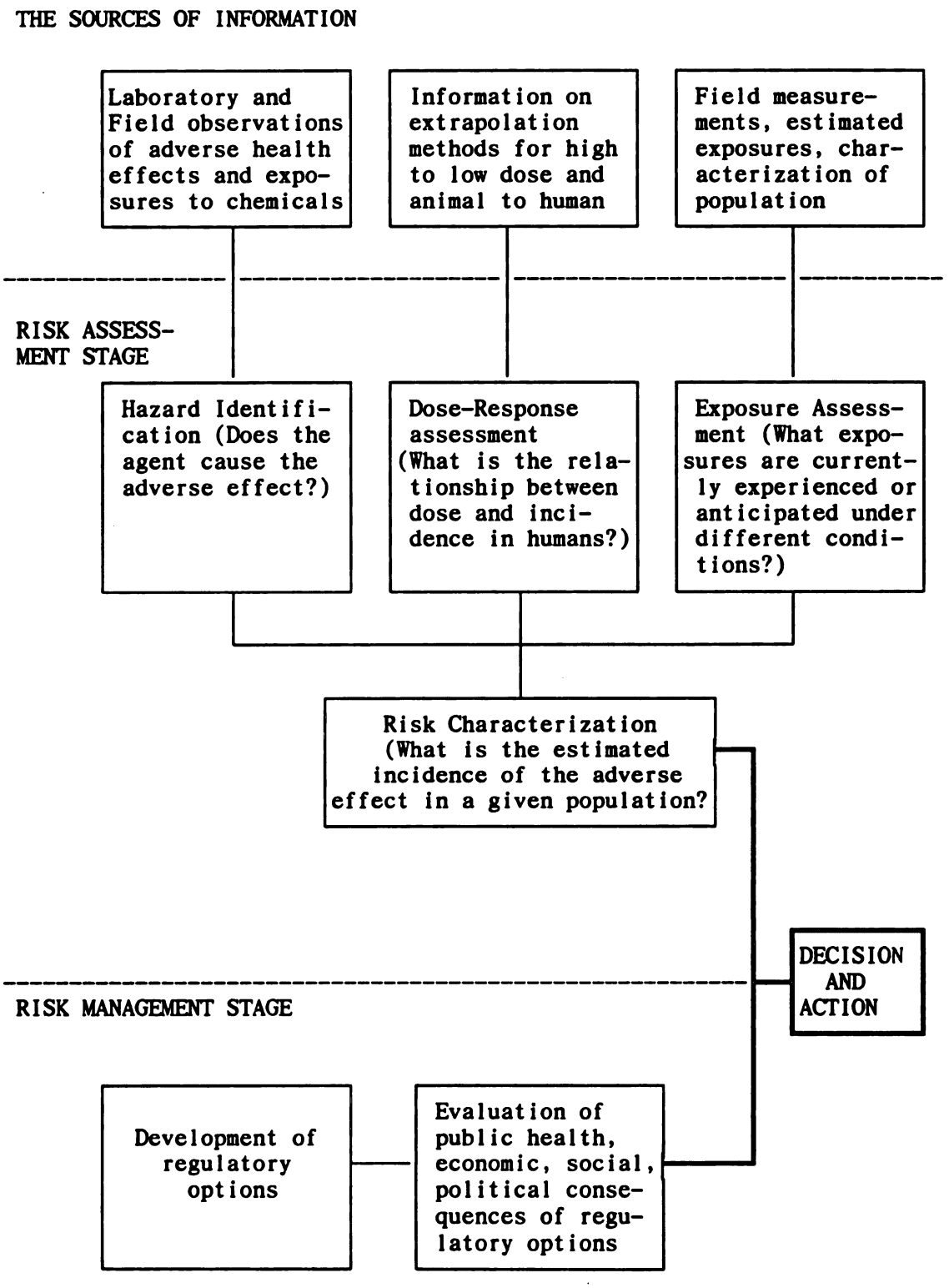

Figure 2.1 General Process of the Risk Assessment and Risk Management (Adopted from NRC with slight modification, 1983. p.21)

Table 2.1 General Classification of Chemical Toxicity.

TOXICITY RATING	DOSAGE[a]		EXAMPLES
Practically Non-toxic	> 15	g/kg	Sucrose
Slightly toxic	5 - 15	g/kg	Alcohol
Moderately Toxic	0.5 - 5	g/kg	Sodium Chloride
Very Toxic	50 - 500	mg/kg	Aspirin, DDT
Extremely Toxic	5 - 50	mg/k	Nicotine, LSD
Supertoxic	< 5	mg/kg	Botulin, TCDD

[a] Probable lethal oral dose per body weight for humans.
Adopted from Klaassen (1986) p.13

Hazard Identification

The hazard identification step is the most easily recognized action of regulatory agencies. The National Research Council (NRC, 1983) defined this step as the process of determining whether a particular chemical is or is not causally linked to particular health effects like cancer, birth defects, etc. Therefore it may contain a description of a particular chemical or physical agent's capacity to adversely affect the health of biota such as fish, wildlife, or human beings at certain dose level. Table 2.1 shows a typical classification of toxic agents based on their potential for acute effects.

The National Research Council (NRC, 1983) noted the four methods of collecting the information which are commonly used in attempting to identify the hazard: epidemiologic data, animal-bioassay data, data on in vitro effects, and comparisons of molecular structure and activities. Bronstein and Engelberg (1984) clearly summarized

these classes of tests especially relative to determining carcinogenicity. Table 2.2. shows general methods of carcinogenic tests.

Table 2.2 General Classification of Tests Available to Determine Carcinogenicity.

Method (Time required)	System	Basis For Test	Results	Conclusion, If Positive
Epidemiology (Months to lifetimes)	Humans	Chemicals that cause cancer can be found by studying human population	Chemical is associated or not associated with higher cancer rates	Chemical recognized as a human carcinogens
Bioassay (2-5 years)	Laboratory animals	Chemicals that cause tumors in animals may also cause them in human	Chemical does or does not increase incidence of tumors	Chemical is carcinogen in animals and may be in man
Short-term in vitro test (Weeks)	Petri dish test tube	Interaction with DNA can be measured in laboratory systems	Chemical does or does not cause a response similar to that of a carcinogen	Chemical is a suspected carcinogen
Molecular structure analysis (Days)	Paper or computer	Chemical with like structures interact similar with DNA	Does or does not resemble a known carcinogen	Chemical may be a carcinogen

Adopted from Bronstein and Engelberg (1984) p. 21.

Epidemiologic studies,[6] if well conducted, can show whether there is a positive relationship between the chemical agent and the adverse health effect. Epidemiological

[6] Two types of epidemiological study are currently available: the cohort study and the case-control study. The cohort study follows a particular population and looks for differences in disease rates between groups exposed differently to the suspected substance. In the case-control study, one picks out a diseased individual case and matches him or her with one or more disease-free persons to serve as control in order to identify differences due to environmental conditions. Sometimes, a hybrid method called the "case-cohort study," is also used in the particular cases (Heiberg and Tronnes, 1988).

data can be analyzed by means of various statistical methods, including analysis of categorical data, logistic regression, and survival analysis (Heiberg and Tronnes, 1988). One clear advantage of this method is that it does not require extrapolating to human beings. Because the test situation is identical or quite similar to the actual one, it includes potentially significant synergism and antagonism[7] which might be overlooked in the laboratory.

Although the evidence gathered in epidemiologic studies would be the most convincing evidence about the adverse effects of chemical and biological agents to human beings, the difficulty of obtaining statistically meaningful data at the time of release of the agent into the environment poses limitations on the use of such data and requires the use of less direct evidence that a health risk exists (Layard and Silvers, 1989). Another limitation is that epidemiology is weak in detecting and in identifying the causes of small degrees of excess risk. It is apparent that a potentially significant degree of absolute risk could exist and be undetected if the exposed population were large enough (Dybing, 1986). Consequently, as a tool in risk management, Heiberg and Tronnes (1988) indicated that epidemiology is unsatisfactory in that it only provides evidence of adverse health effects after years of exposure to a chemical, when damage is already a fact.

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[7] Synergism is a phenomenon in which the toxicity of a mixture of chemicals is greater than that which would be expected from a simple summation of the toxicities of the individual chemicals present in the mixture. Antagonism, on the other hand, is a phenomenon in which the toxicity of a mixture of chemicals is less than that which would be expected from a simple summation of the toxicities of the individual chemicals present in the mixture (i.e., algebraic subtraction of effects).

Animal bioassay[8] data are the most commonly available data used in hazard identification (NRC, 1983; Falco and Moraski, 1989; Heiberg and Tronnes, 1988). The bioassay is defined as a laboratory procedure in which scientists administer the test substance at one or more dose-levels to one or more groups of animals and compare their adverse effects with that of a control group that has not been exposed to the substance (Heiberg and Tronnes, 1988; USEPA, 1987a).

The fundamental inferences resulting from animal experiments is applicable to human beings only if considered accepted and valid. In some cases interpretation of such data has been difficult, but depending on chemicals and mechanism of action, these tests generally have proven to be reliable indicators of carcinogenic properties, as well as other properties such as those adversely affecting reproductive capacity (See Table 2.2). With regard to detecting carcinogenicity, it is recommended that consistent positive results in two sexes of tested animals and in several strains and species and higher incidence at higher doses constitute the best evidence of carcinogenicity (NRC, 1983).

Short-term tests on microorganisms or cell cultures for detecting mutagenicity of a chemical are also available. Because a considerable amount of evidence supports the fact that many carcinogens are also mutagen, and many mutagen are carcinogens, the rationale for short-term tests is related to receiving a positive response in a mutagenicity assay as supportive evidence that the chemical or agent tested is likely to be carcinogenic (USEPA, 1987a).

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[8] There are two types of bioassay: long-term or short-term tests on animals such as mice, rats, and rabbits, and short-term tests on microorganisms or cell cultures.

Because short-term tests have clear benefits such as rapidity and low cost,[9] they are widely used for screening chemicals for potential carcinogenic activity and lending additional support to observations from animal and epidemiologic investigations (NRC, 1983). The best known short-term test is the Ames test[10] (Turk and Turk, 1984; Williams and Weisburger, 1986). In addition to the Ames test, there are several other short-term mutagenicity tests, and some of them use cultures of animal or human cells.

Other supportive evidence comes from comparing an agent's physical-chemical properties and structure and chemical reactivity with that of known carcinogens (NRC, 1983). If the comparisons indicate possibility of a human health effect, further investigation may be needed before identifying the chemical as health hazard. These studies may be useful in priority-setting for carcinogenicity testing.

Dose-Response Assessment

This step is the process of characterizing the relationship between the dose of an agent, either administered or received, and the incidence of the health effect (NRC, 1983; Falco and Moraski, 1989; Paustenbach, 1989). It takes into account such variables

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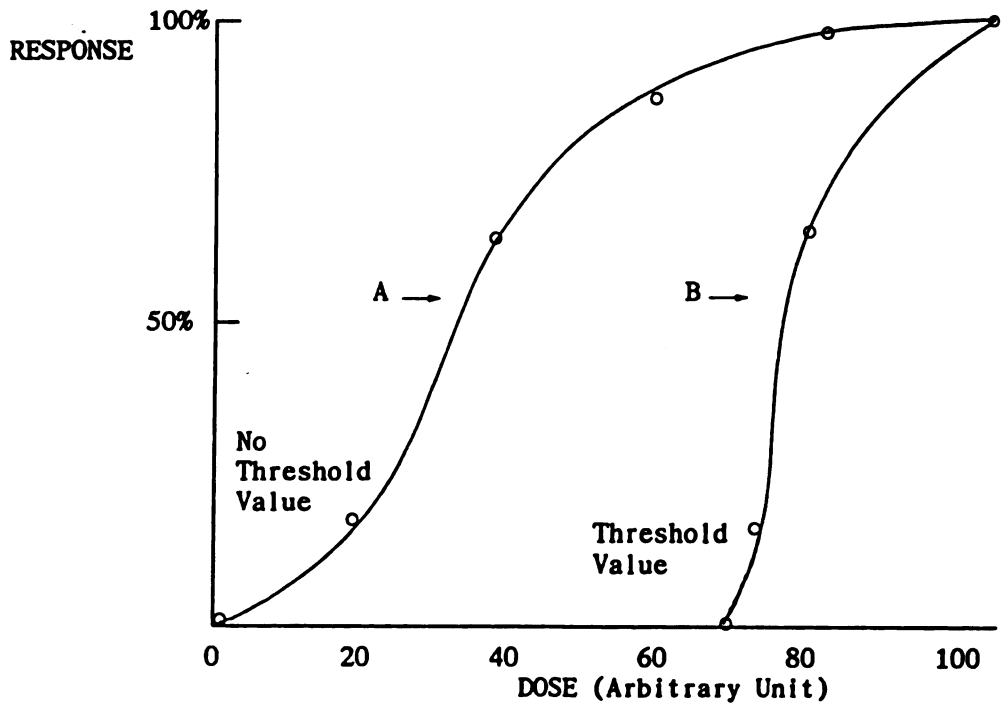
[9] In the case of animal-bioassay, the laboratory tests to establish the possible carcinogenicity of a substance using mice or rats, currently takes about three years and costs over $500,000.

[10] The Ames test, developed in the 1970s by Bruce Ames and his coworkers at the University of California at Berkeley, can be completed in three days for a very modest cost. This test measures back-mutation to histidine independence of histidine mutants of Salmonella typhimiurium and can be conducted with strains that are also repair-deficient, possess abnormalities in the cell wall to make them permeable to carcinogens, and carry an R factor enhancing mutagenesis. A chemical that is shown by the Ames test to be mutagenic may be classified as a suspected carcinogen .

as intensity of exposure, age and/or activity patterns of the persons exposed, and some other factors such as sex and lifestyle (Paustenbach, 1989; Timbrell, 1987).

The goal of a dose-response assessment is to obtain a quantitative relationship between duration and level of exposure and the probability of producing a certain adverse health effect. For this purpose, the dose-response curve for a chemical is commonly used. As Heiberg and Tronnes (1988) pointed out, two main approaches are available to achieving this goal: epidemiological studies and laboratory testing on living organisms. However, both approaches have strengths and weaknesses, and neither one alone is usually sufficient to establish a reliable dose-response relationship.

There are several basic assumptions underlying the dose-response relationship. Klaassen (1986) and Rand and Petrocelli (1985) clarified these as follows: (1) the response is a function of the concentration at a site, (2) the dose is a function of the concentration at the site, and (3) response and dose are causally related. When the chemicals enter into the mammalian body, they may exist in either metabolized or unmetabolized forms. In general, a consensus has been reached that the more dose absorbed or ingested, the more serious effects are expected above any possible threshold (Kamrin, 1988; Turk and Turk, 1984).



Note: The curve "A" illustrates a no threshold effect; there is a response at all doses greater than zero. The curve "B" illustrates a threshold effect; no response occurs until some minimum dose is exceeded.

Figure 2.2 Hypothetical Dose-Response Curves.

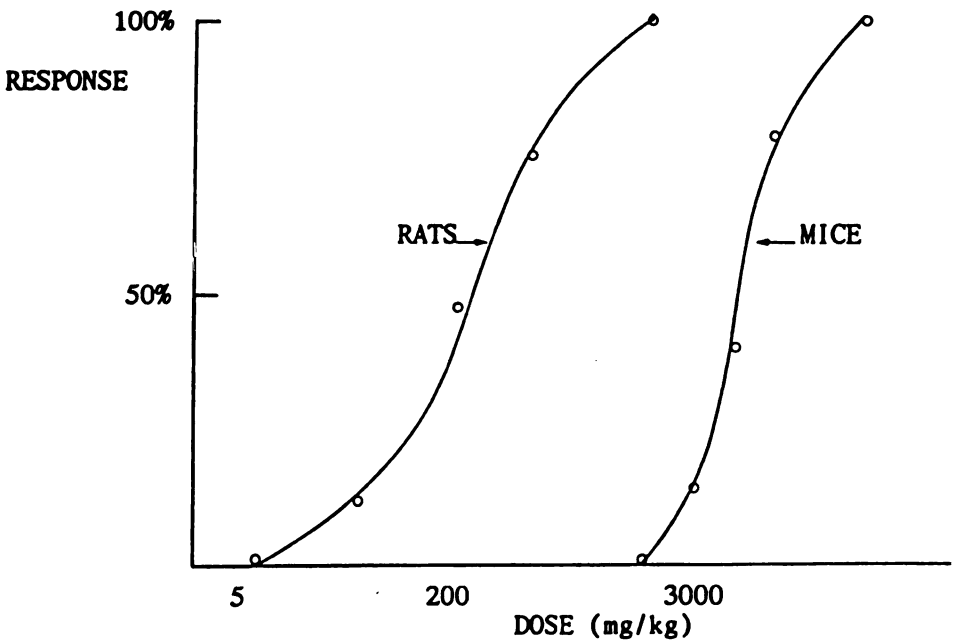


Figure 2.3 Variation of Dose-Response for the Same Chemical in Two Different Species.

The dose-response curve shows the relationship that exists between degree of exposure to a chemical (dose) and the magnitude of the effect (response) in the exposed organism. By definition, no response is seen in the absence of chemical. In most cases, the adverse effect begins to increase gradually as the dose increase. Depending on the mechanism by which chemical acts, the dose-response curve may rise with or without a threshold. In any case, the response finally reaches at a plateau where the effect no longer increases with the dose (Kamrin, 1988). Figure 2.2 shows a typical dose-response curve. It illustrates examples of both the no threshold effect and threshold effect. Although all dose-response curves may have the same general shape, a different curve exists for each chemical and each type of living organisms tested. Figure 2.3 shows the two different dose-response curves for the same chemical in two different species.

Because, in most cases, data related to human beings are not available, usually animal test data are used to evaluate a dose-response relationship of a certain chemical. As a result, the process requires extrapolation from animal data to human beings and this process introduces important sources of uncertainty in the risk assessment process. In case of carcinogenicity test, the NRC (1983) described three of the major uncertainties: 1) high to low dose extrapolation; 2) interspecies conversion of dose; and 3) decision on whether to combine tumor types in determining tumor incidence.

Regarding high to low dose extrapolation for quantifying carcinogenic response, many mathematical dose-response models have been developed. These include: Probit model, one-hit model, multihit model, and multistage model. Currently most of regulatory agencies use at least one of these mathematical models. For example, the USEPA employs the "linearized multistage model" for quantitative carcinogen risk

assessment (USEPA, 1986a). However, in practice different extrapolation methods may produce different results by several orders of magnitude.

Regarding interspecies conversion of the dose-response relationship, it is widely accepted that the toxicity of a foreign compound either from chemical or biological agent and its mode of expression are dependent on many variables. According to Timbrell (1987), large variations in susceptibility between species, even within the same species, due to many factors such as sex, age, genetic variations, and stress may be involved.

Table 2.3 Comparison of Dosage by Weight and Surface Area

Species	Weight (g)	Dosage (mg/kg)	Dose (mg/animal)	Surface Area(cm^2)	Dosage (mg/cm^2)
Mouse	20	100	2	46	0.043
Rat	200	100	20	325	0.061
Guinea pig	400	100	40	565	0.071
Rabbit	1500	100	150	1270	0.118
Cat	2000	100	200	1380	0.145
Monkey	4000	100	400	2980	0.134
Dog	12000	100	1200	5770	0.207
Human	70000	100	7000	18000	0.388

Adopted from Klaassen (1986) p. 22.

This problem is that the results of animal data must be adjusted to reflect the differences of metabolism and size between human beings and laboratory animals. It means that interspecies extrapolation requires calculation of equivalent does. If a certain dose causes a specific disease incidence among the test animals, one has to find out what

dose will cause the same incidence in human beings. Different scientists and agencies advocate different approaches to this problem.

Currently the most commonly applied procedure is based on the assumption that the equivalent dose is proportional to the species' relative body weights or to body surface areas (Klaassen, 1986). The choice of assumptions varies among the regulatory agencies.[11] Table 2.3 introduces some selected values including human to compare the differences in dosage by these two alternatives. Because the dose-response curve is frequently generated from the use of limited numbers of test animals, there also exists an additional uncertainty relative to data interpretation due to the limitation of statistical power.

Exposure Assessment

This is the process for describing, measuring and estimating the intensity, frequency, and duration of human or animal exposure to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment (NRC, 1983). It is considered an explicit and central component of the quantitative risk assessment procedures that are routinely used to formulate chemical regulatory decisions.

Paustenbach (1989) suggested that this process should contain at least the following components: the magnitude, duration, schedule, and route of exposure; the size, nature, and classes of the populations exposed; and the uncertainties in all the

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[11] Currently, the USEPA tends to favor using surface area, whereas the FDA tends to calculate based on body weight.

estimates. Therefore, quantitative measures used to describe the hazards of a chemical require similar quantitative estimates of exposure (See Figure 2.1).

According to the Guidelines for Exposure Assessment used by the USEPA (1986c), the main objective of this step is to provide reliable data and/or estimates for a risk assessment. Therefore, the exposure assessment may generally be used to identify feasible prospective control options and to predict the effects of available control technologies for controlling or limiting exposure. In fact, various statutes and regulatory programs are currently used in many countries based on exposure control and reduction of chemicals in environment (United Nations Economic Commission for Europe, 1987b). Many control approaches such as banning the use of a chemical, setting standards for occupational conditions, selecting remedial actions, as well as training and labeling to control use have been employed by various regulatory offices in the world (Severn, 1987).

While exposure assessments based on actual data are preferred, generally such exposure data are very limited, and the assessor may have to rely on models for estimating past, present or future exposure. With new chemicals, reliance on data for similar chemicals may be necessary.

Currently there are two fundamental approaches to determine the extent of human exposure to chemicals: measurement and prediction.[12] Measurement is a direct approach to measure both the concentration of a substance in various environmental media or in living organisms and behavior of exposed populations or individuals. On the other hand,

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[12] The USEPA uses these terms, as "passive dosimetry and biological measurements." (The USEPA's Guidelines for Exposure Assessment, Fed. Reg. 34049)

the prediction method is used to indirectly estimate the past, present or future exposure of human beings to some chemicals in environment. For example, the past human exposure to chemicals can be extrapolated from measured concentrations of chemicals in human tissue, hair, blood, and /or urine samples. Sometimes biological markers, e.g. enzyme levels, can also be used to identify and to quantify the past human exposure. However both approaches have strengths and weaknesses. If chemicals are concentrated enough in biological samples to allow direct measurement, it is relatively easy to determine concentrations of chemicals in specific environments such as workplace, and to provide precise information about present and future exposure. However, if background concentrations are too low to detect, or direct measurement is costly or impractical, this technique is not feasible and it cannot provide information about the past exposures.

On the other hand, one clear strength of the prediction method is that past human exposure both quantitatively and qualitatively can be estimated through the extrapolation from measured concentrations of chemicals in organ. This process is usually best accomplished by the use of computer transport models. However, there exists a large uncertainty because data are limited and the model does not represent the real world.[13] This is mainly due to lack of knowledge about the behavior of individuals and populations as well as chemicals.

In practice, exposure assessment is often complicated by the necessity to consider multimedia effects. The assessor has several options available to estimate the exposure

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[13] A model is defined "a representation of an object, system, or idea in some form other than that of the entity itself" (Shannon, 1975, p. 4).

in a specific medium, which will yield more or less conservative estimates. The same process is then applied to the other media of concern, and the exposures are added together. Still the problem is how to determine the concentration of chemicals in each medium, and how to determine chemical variations over time.

Risk Characterization

This step is the process of estimating the incidence, including nature and magnitude of a health effect under the condition of human exposure described in the exposure assessment (NRC, 1983). However, it needs to contain not only a risk estimate for a specific exposure, but a summary of the biological information, the assumptions used as well as their limitations, and a discussion of uncertainties, both qualitatively and quantitatively, in the risk assessment (Preuss, 1988; Falco and Moraski, 1989).

The risk characterization step is generally performed by combining the exposure assessment and the dose-response assessments, including the analysis of the uncertainties underlying the assessments. In cases of carcinogenicity, mutagenicity, and chemical mixtures (USEPA, 1986a; 1986b; 1986d; 1986e), it consists of the dose-response extrapolation as well as the associated weight-of-evidence determination (See Chapter 3). For the chemical mixtures case, especially the weight-of-evidence covers three areas such as health effect information, toxic interactions, and exposure estimates (USEPA, 1986e). Also USEPA (1986b) has developed a specific mathematical technique for assessing uncertainty related to the use of the exposure assessment guidelines. In this case, the probability distributions estimated for the uncertainty around each of the components in the calculation are entered into a computer program, and the probability distribution of

the results of the exposure assessment then can be calculated or estimated. Falco and Moraski (1989) summarized overall processes of risk assessment steps as follows:

> Data and assumptions contain varying degrees of uncertainty. In the dose-response assessment, statistical and biological uncertainties need to be characterized. The accuracy of the exposure assessment is dependent on the quality and quantity of the data and the type and complexity of the mathematical models used. For each exposure pathway assessed, a discussion of the strengths and weaknesses of the methodologies used to generate the exposure estimates should be presented. A thorough discussion of these attendant uncertainties is an important part of the overall risk assessment process.

Risk Management

As it was defined earlier in the terminology definition section, risk management is a process of deciding on the appropriate action choice which is performed by various regulatory agencies. Such choices are the central role of a regulatory agency.

With respect to the relationship between risk assessment and risk management, the National Research Council (1983) emphasized that risk assessment and risk management should clearly be functionally separated. Many observers also feel that it is important to make a distinction between risk assessment and risk management (Lave, 1987; Wentz, 1989). As Russell and Gruber (1987) pointed out, however, there is no natural "bright line" between the policy considerations inherent in risk management and those inherent in risk assessment. Practically there is often a very fuzzy dividing line between the risk assessment process and the risk management process.

Relating to the goal of risk management and risk assessment, the former is the process to select the option that balances the benefits of an action against the real or perceived risks. On the other hand, the latter is the process to estimate the potential adverse health effect either on an individual or population of a given agent or condition. As Lave (1987) pointed out, risk assessment is one small aspect of the entire process of risk management. A model developed by Krewski (1987) clearly illustrates the relationship between risk assessment and risk management for the general case of risks posed by toxic chemicals present in the environment. This model includes various factors which risk assessors and risk managers have to take into account in each step. Figure 2.4 introduces the model for risk assessment and risk management.

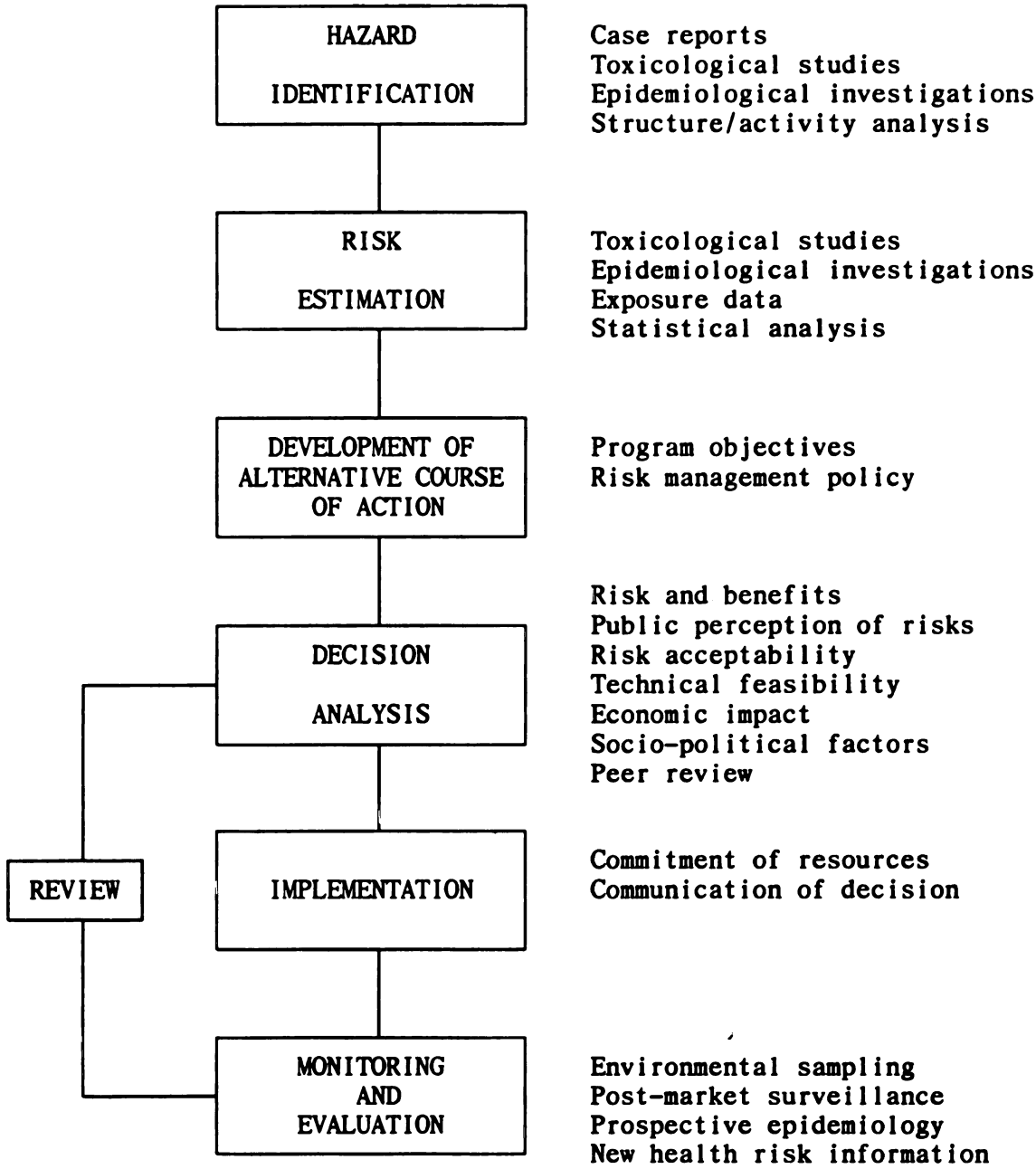

Figure 2.4 Krewski's Model for Risk Assessment and Risk Management. Adopted from Krewski, 1987. p. 32.

Risk managers have a number of choices available to them when presented with the need to make a decision regarding human exposure to a chemical. In practice, the basic ones are banning, limiting use, and no restrictions. In order to select one of these options, for example, Munro and Krewski (1981) recommended that the risk manager consider the following factors which need to be balanced against the perceived risk. The examples in case of pesticides are as follows:

- Consumer expectations.
- Education to permit informed choice by consumers.
- Cost to industry and ultimately to consumers.
- Ability to control exposure monitoring program
- Availability of less hazardous substitutes.
- Ability to enforce regulations.
- Impact on future regulatory policy.

Although the scientific community has given much attention to the best methods for developing more comprehensive and objective risk assessments since the 1970s, these assessments may not serve the intended purpose if a poor decision is ultimately reached by the risk manager.

During the 1980s, scientific attention was focused on the technical intricacies of hazard identification, low-dose extrapolation, and risk characterization (Paustenbach, 1989). However, the public must be assured that high-quality and responsive management decisions are being reached or they may choose to take matters into their own hands. Eventually risk communication became an important part of risk management process.

Whipple (1987) suggested one possible answer for these problems. He indicated that if properly applied, the de minimis[14] risk concept can help set the priorities for bringing regulatory attention to risk in a socially beneficial way. Concerning this, Comar (1987) suggested some guidelines which can be used to make decisions for risk managers in terms of numerical value:

1. Eliminate any risk that carries no benefit or is easily avoided.
2. Eliminate any large risk (about 1 in 10,000 per year or greater) that dose not carry clearly overriding benefits.
3. Ignore for the time being any small risk (about 1 in 100,000 per year or less) that does not fall into category 1.
4. Actively study risks falling between these limits, with the view that the risk of taking any proposed action should be weighed against the risk of not taking the action.

Even though Comar's guidelines are clearly a gross over-simplification, it is clear that the guidelines will help the risk managers to make the decision whether the risk should be reduced or eliminated entirely. In the case of the cancer risk decision-making, most regulatory agencies including USEPA have used one excess cancer in a population of 1 million as the limit for acceptable risk (Blumberg and Gottlieb, 1989; Curlee, 1987).

By the early 1990s, however, a number of agencies are considering raising the acceptable risk number to one in 100,000 as the general rule of thumb for acceptable risk because of such factors as the cost of the pollution control technology in the eventual risk

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[14] From the Common Law maxim, de minimis non curat lex: the law does not concern itself with trifles. De minimis risks are those judged to be too small to be of social concern, or too small to justify the use of risk management resources for control.

management decision. Consequently, the numerical values of risk estimation will be continuously reevaluated depending on the goal of society as well as on the change of risk perception.

CHAPTER III

REGULATION OF AIR POLLUTION

The U.S. Environmental Protection Agency Approach

In the United States, traditionally four federal agencies, the Environmental Protection Agency (USEPA), the Food and Drug Administration (FDA),[1] the Occupational Safety and Health Administration (OSHA),[2] and the Consumer Product Safety Commission (CPSC)[3] have been given primary authority to regulate activities and substances that pose human health risk (Merrill, 1985; NRC, 1983). During the last decades, the approach to risk analysis as a decision-making tool has varied considerably among the four agencies. These differences stem primarily from not only the variations

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[1] The FDA was established in 1927 as the Food, Drug, and Insecticide Administration to enforce the Food and Drugs Act of 1906 and other protective laws. Currently FDA regulates food and food additives, color additives, human and animal drugs, medical devices, and cosmetics under the Federal Food, Drug, and Cosmetic Act.

[2] The OSHA was established in 1971 as a part of the Department of Labor, under the Occupational Safety and Health Act (Public Law 91-596). The OSHA is comprehensive nationwide attempt to insure occupational safety and health for America's workers. As of 1981, 18 potential carcinogens had been acted on by OSHA.

[3] The Consumer Product Safety Commission is an independent federal regulatory agency established by the Consumer Product Safety Act (15 U.S.C. 2051). The CPSC protects the public against unreasonable risks of injury from consumer products.

in agency structure but also from the differences in statutory mandates and their interpretation (NRC, 1983; Portney, 1990).

In this section, the discussion will focus on the United States Environmental Protection Agency (USEPA) relating to its 1) brief history and organization, and 2) evolution of air pollution regulation including criteria and standards in the United States.

History and Organization

In 1887, the United States Congress created the Interstate Commerce Commission to regulate surface transportation industries and since the 1930s, many other federal regulatory agencies had been created.[4] Basically, most of these regulatory agencies were created to remedy a perceived failure of the free market to allocate resources efficiently (Grad, 1985; Portney, 1990).

Through 1960s, growing public awareness of problems associated with both environmental quality and human health risk from various chemical and biological agents presented the second major burst of federal regulatory agencies which started in the 1970s.[5] These agencies have a somewhat different rationale in terms of social regulations such as environmental protection, and the safety and health of workers and consumers.

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[4] These were the Federal Power Commission, Food and Drug Administration, Federal Home Loan Bank Board, Federal Deposit Insurance Corporation, Securities and Exchange Commission, Federal Communications Commission, Federal Maritime Commission, and the Civil Aeronautics Board.

[5] These are the Environmental Protection Agency, the National Highway Traffic Safety Administration, the Consumer Product Safety Commission, the Occupational Safety and Health Administration, the Mining Safety and Health Administration, the Nuclear Regulatory Commission, the Commodity Futures Trading Commission, and the Office of Surface Mining Reclamation and Enforcement.

The USEPA was created at this time to permit coordinated and effective governmental action on behalf of the environment (USEPA,1971).

The USEPA was founded on December 2, 1970 as an independent agency pursuant to Reorganization Plan No. 3 of 1970 (5 U.S.C. 84 Stat. Sec.1).[6] Since its creation as one of the new social regulatory agencies, the USEPA has endeavored to abate and control pollution systematically, by proper integration of a variety of research, monitoring, standard setting, and enforcement activities (U.S National Achives and Records Administration, 1989/90).

According to the relevant statutes,[7] the USEPA's primary mission is to control and abate pollution in the areas of air, water, solid waste, pesticides, radiation, and toxic substances. As a complement to its activities, the USEPA also coordinates and supports research and anti-pollution activities by state and local governments, private and public groups, individuals, and educational institutions (USEPA, 1972).

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[6] President Nixon submitted the Reorganization Plan No. 3 to Congress on July 9, 1970 for approval. The reorganization plan proposed to consolidate under the EPA, various functions performed at that time by various sections of the Departments of Interior, Health, Education and Welfare, and Agriculture, as well as by the Atomic Energy Commission, the Federal Radiation Council, and the Council on Environmental Quality. By December, 1970, the plan had been approved by Congress and the USEPA was in action.

[7] Major laws administered by USEPA are: Clean Air Act (CAA); Clean Water Act (CWA); Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); Toxic Substances Control Act (TSCA); Safe Drinking Water Act (SDWA); Resource Conservation and Recovery Act (RCRA); and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA); and Emergency Planning and Community Right-to-Know Act.

The USEPA is composed of six staff offices, eleven program offices and ten regional offices currently (See Appendix A). Although the fundamental organizational frame of the USEPA has not been changed since its creation of 1970, certain offices have been functionally separated or integrated. For example, the duties of the former Assistant Administrator for Air and Water Programs were separated into two divisions: the Assistant Administrator for Air and Radiation, and the Assistant Administrator for Water. And the Division of Research and Monitoring was renamed as the Division of Research and Development, and reshaped from three program offices to seven program offices.

One important characteristic of the USEPA's structure is that the Agency's research, policy evaluation, and enforcement efforts, are separated organizationally from the program offices that write regulations. For instances, the Office of the Assistant Administrator for Policy, Planning and Evaluation is responsible for the overall activities concerning policy, planning and evaluation, and standard setting efforts. On the other hand, the Office of the Assistant Administrator for Air and Radiation[8] is responsible for the development of national programs, technical policies and regulations for air pollution and radiation protection programs (USEPA, 1990).

The Office of the Assistant Administrator for Research and Development is responsible for the development, direction, and conduct of the national USEPA's research and development program. It initiates demonstration programs in pollution sources, fate,

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[8] The Division of Air and Radiation is composed of three working offices: Office of Air Quality Planning and Standards; Office of Mobile Sources; and Office of Radiation Programs.

health and welfare effects, pollution prevention and control, and environmental sciences and monitoring systems. Thus the Assistant Administrator for Research and Development serves as principal science advisor to the Administrator and coordinator for the Agency's policies and programs concerning health and environmental related problems.

With respect to health risk assessment, the Office of Health and Environmental Assessment under the Research and Development Division is the unit which is most responsible for human health risk assessment. Figure 3.1 shows the offices responsible for health risk analysis under Division of Research and Development.

The primary responsibility of the ten regional administrators is to carry out the national program objectives. The regional administrator and his staff serve as the Agency's principal representatives in that region in contacts and relationships with federal, state, and local agencies; industry; academic institutions; and other public and private groups (USEPA, 1990).

As Portney (1990) indicated, the USEPA was never a very small agency since it was created out of existing programs. During its first full year of existence in 1971, it had about 6,000 employees acquired from fifteen governmental programs located in three department (Health, Education and Welfare, Agriculture, and Interior) and a budget of $3.3 billion; $512 million of which went to operate the agency, with the remainder being passed through the USEPA in grants to state and local governments (Marcus, 1983).

By 1980, the agency had grown to more than 12,000 employees with around $5 billion budget. For fiscal year 1989, however, only $4.8 billion was requested for the USEPA's budget including $1.6 billions for the Superfund (USEPA, 1990).

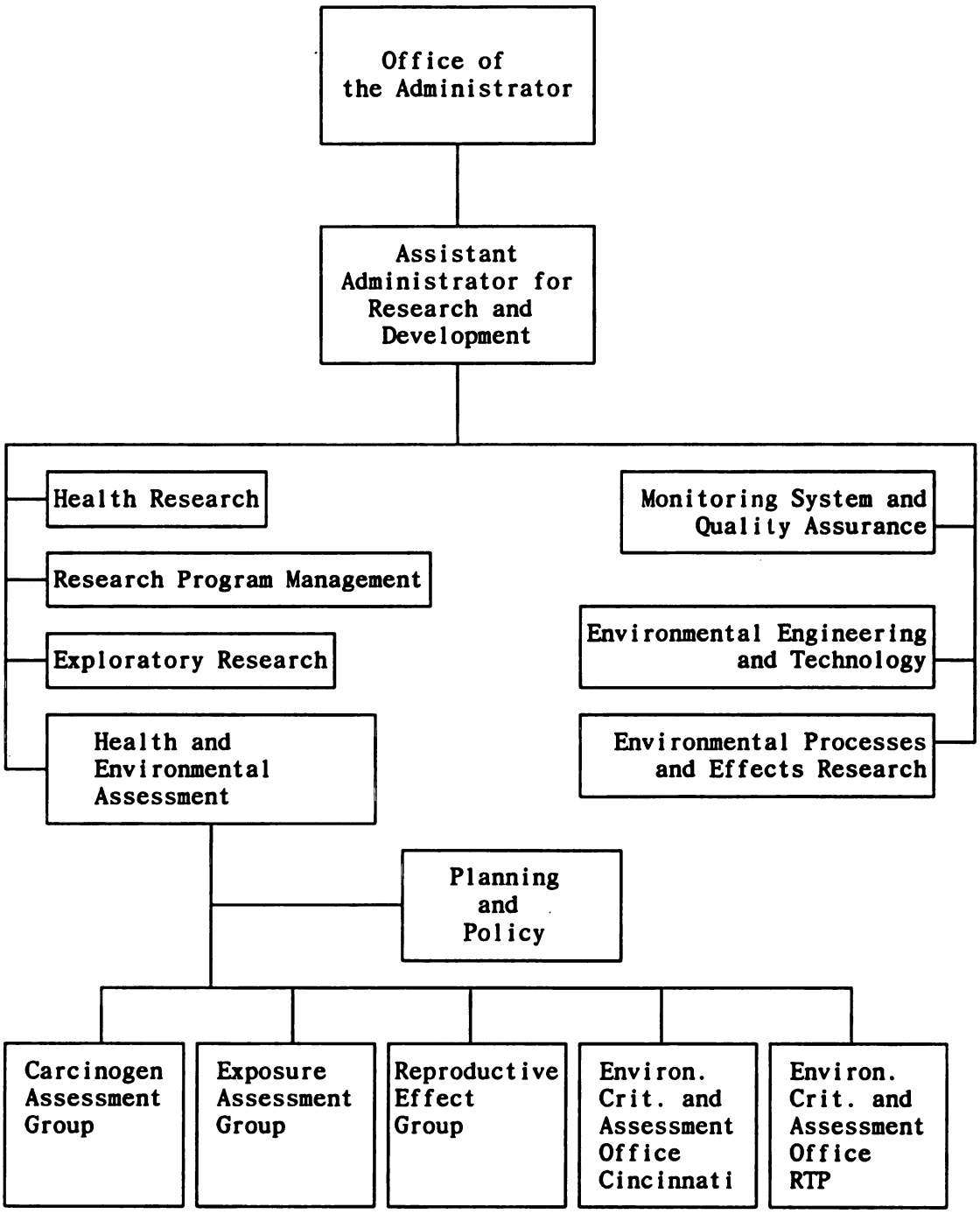

Figure 3.1 Organization Chart of USEPA Related to Human Health Risk Assessment. Adopted from the NRC, 1983. p.106

Evolution of Air Pollution Regulation

In the United States, the control of air pollution was long considered as the responsibility of municipal governments, not a state or federal function. Although the first municipal regulations for air pollution control were passed in the 1880s,[9] it was not until the late 1950s that air pollution was recognized as a national problem. At the early stages, most of the local ordinances were designed to limit factory fumes and reduce smoke from the burning of coal and to control such smelly operations as glue factories and rendering plants (USEPA, 1979). Despite scattered successes in smoke and soot cleanup, however, air pollution continued to increase and became much more serious in the United States like many other industrial nations (Miller et al.,1989; Portney, 1990). Eventually its nature began to change.

With a growing awareness of the air pollution problem, large-scale surveys were made of pollution in some cities like New York as a first step toward finding a solution. The first National Air Pollution Symposium was held in Pasadena, California, in 1949, and the first U.S. Technical Conference on Air Pollution was held in Washington, D.C., in 1950 (Miller et al., 1989). Prior to the 1950s, however, no significant air pollution control legislation or regulation was enacted. After World War II, some major air pollution incidents such as that in Donora, Pennsylvania, had accelerated the need for the development of new legislation. The passage of the Air Pollution Control Act in 1955

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[9] In 1881 the cities of Chicago and Cincinnati passed the first air pollution statutes. Until the 1950s air pollution in the U.S. was perceived to be of local origin, affecting isolated regions, and as result, local governments were held responsible for providing remedies.

was followed by the original Clean Air Act in 1963.[10] In 1965 the U.S. Congress passed the Motor Vehicle Air Pollution Control Act which permitted the federal Secretary of Health, Education, and Welfare (HEW) to establish emissions standards for new motor vehicles. It is generally recognized that the Motor Vehicle Air Pollution Control Act marked the real beginnings of an active federal role in controlling air pollution from mobile sources (Portney, 1990).[11]

In 1967 the U.S. Congress passed the Air Quality Act which was the temporal and philosophical precursor of the 1970 changes. It required states to establish air quality control regions and also directed the HEW to investigate and publish information about the adverse health effects associated with a number of common air pollutant so that the states could set the air quality standards for them. The HEW, however, was slow in developing the guidance documents detailing the adverse health effects associated with the common air pollutants (Rosenbaum, 1977). Even where these had been prepared, the states had either failed to set the air quality standards or were slow in developing implementation plans showing how they would meet the standards.

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[10] Under this Act, the federal government could support air pollution research and assist the states where cross-boundary air pollution problem took place. The laws that began in 1955 are considered simple grants-in-aid to state and local governments, and those recipients were being given very specific responsibilities by the federal government to combat air pollution problems.

[11] It stopped short of imposing actual vehicle emissions standards, something only the state of California had done by that time. Congress also amended the Clean Air Act for first time, requesting HEW to set the first federal emissions standards for motor vehicles.

Finally the Clean Air Act Amendments of 1970 (hereafter CAA) were passed as the first comprehensive attempt to provide air standards for the nation.[12] It was amended twice, once in 1977 and again in November, 1990. Under the CAA, the Administrator of the USEPA was required to establish the preeminent environmental goals of federal air quality policy, the National Ambient Air Quality Standards (NAAQSs). The NAAQSs are defined as the levels of the principal types of pollution that should not be exceeded for the protection of public health and welfare (USEPA, 1971). The USEPA formally adopted the first ambient air quality standards[13] in the summer of 1971. These ambient air standards became the most important part of the Clean Air Act as revised in 1970. Table 3.1 presents the current NAAQSs for the six common pollutants covered.

Primary standards were to protect the human health and secondary standards were to be established if the health-based standards were insufficient to protect exposed materials, agricultural products, forests, or other non-health values (USEPA, 1971). These standards, which were to be set by the states under the old approach, represent the maximum permissible concentrations of the common air pollutants which the HEW had been studying at the time the 1970 amendments were made. Hence, each of the air quality control regions that had been established under the earlier legislation had to reduce the ambient or outdoor air pollution concentrations at least to the level of the

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[12] The CAA only affects air to which the public has access. Thus the USEPA regulates air quality beyond the factory fence line. Air quality on privately owned property is covered by regulations of the OSHA and the accidental release of toxic substances is included in the 1986 amendments to a solid waste law.

[13] The first national air quality standards involved six major pollutants as follows: sulfur oxides; nitrogen oxides; particulate matter; carbon monoxide; photochemical oxidants; and hydrocarbons (USEPA, 1971).

NAAQSs within a specific time limitation. The states could elect to impose stricter standards if they wished; however, no area could elect to have dirtier air than that called for in the NAAQSs (USEPA, 1979).

Table 3.1 The U.S. National Ambient Air Quality Standards in Effect in 1989

Pollutant	Primary Standard Average time	Concentration	Secondary Standard Average-time	Concentration
Particulate Matter (PM10)	Annual Arithmetic Mean	50 $\mu g/m^3$	Same as primary	
	24-Hour	150 $\mu g/m^3$	Same as primary	
Sulfur Dioxide	Annual Arithmetic Mean	80 $\mu g/m^3$ (0.03 ppm)	3-Hour	1300 $\mu g/m^3$ (0.50 ppm)
	24-Hour	365 $\mu g/m^3$ (0.14 ppm)		
Carbon Monoxide	8-Hour	10 $\mu g/m^3$ (9 ppm)	No Secondary Standard	
	1-Hour	40 $\mu g/m^3$ (35 ppm)	No Secondary Standard	
Nitrogen Oxide	Annual Arithmetic Mean	0.053 ppm (100 $\mu g/m^3$)	Same as Primary	
Ozone	Maximum Daily 1-hour Average	0.12 ppm (235 $\mu g/m^3$)	Same as Primary	
Lead[a]	Maximum Quarterly Average	1.5 $\mu g/m^3$	Same as Primary	

[a] An ambient air standard for lead was adopted by EPA in 1978. Source: Office of Planning and Standards, USEPA (1989).

With respect to setting the ambient air standards, Congress directed the USEPA to set the primary and secondary standards at levels that would "provide **an adequate margin of safety**...to protect the public ...from any known or anticipated adverse effects associated with such air pollutants in the ambient air." (CAA Section 109). Inevitably the margin-of-safety provision has become controversial because it embraces what is known as the **"threshold model"** of air pollution-related illness. Because the Congress definitely signaled its belief that "safe" levels existed and could be identified for the common air pollutants, a problem occurs if no safe levels exist for any air pollutants for which the NAAQSs must be set. Therefore the possible disparity between the apparent mandate of the law and the realities of science became a major consideration of the USEPA administrator. As another problem, because national standards apply to whether control costs are high or not, less stringent air quality standards cannot be adjusted to account for the situation.

With respect to the means of attainment, the CAA of 1970 allowed all existing sources to continue their operations, but stringent regulations were applied to all new sources. In 1971 the USEPA established a uniform system based on New Source Performance Standards (NSPS), which stipulated standards for fossil-fuel-fired utility boilers. Table 3.2 illustrates the NSPS for utility boilers.

In addition, all major new facilities must apply Best Available Control Technology (BACT). This is determined on a case-by-case basis by identifying the best controlled facility of the type in the world, either permitted or in operation, and then justifying through economic, environmental or energy arguments why the degree of control is or is not achievable at the specific site (Schulze, 1991). Hence, no construction is allowed

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to begin until the control agency has granted a permit. In many cases today, the BACT is used to achieve an emission limit that is 20 to 50 percent of the NSPS (Schulze, 1991).

Table 3.2 The New Source Performance Standards for Fossil-Fuel-Fired Utility Boilers

Pollutants	New Source Performance Standards
Sulfur Dioxide	1.2 lb./mill. Btu heat input emission limit and a 3-hour stack test to show compliance
Particulate	0.10 lb./mill. Btu heat input with a normal stack test for compliance
Nitric oxide	0.7 lb./mill. Btu emission limit on coal burned

Source: Miller, et al., 1989.

Because there was no requirement to permit old sources, under the 1970 CAA, inspectors often had a difficult time determining whether the facility was in operation at production rates and with emissions no greater than was the case in 1970 (USEPA, 1979). In some cases, as Schulze (1991) pointed out, sharply differing emission limits apply to similar, adjacent facilities simply because one facility is a few years newer. Therefore, the CAA amendments of 1990 makes a start at correcting the indulgent treatment of older sources by requiring the reduction in emissions of sulfur dioxide by over 10 million tons per year and nitrogen oxides by 2 million tons per year by the year of 2000 from steam electric generation facilities (Schulze, 1991).

The CAA Section 112 also required the USEPA to protect the public health from exposure to toxic and hazardous air pollutants. Hence the USEPA administrator was directed to set National Emissions Standards so that the concentrations remaining in the

air would be as low enough to provide "an ample margin of safety" against adverse health effects. In essence, a similar environmental goal was established not only for the common air pollutants [criteria pollutants] but hazardous and toxic air pollutants as well [non-criteria pollutants].[14]

Relating to the emission inventories of air pollutants, the 1977 amendments of the CAA required each state to draw up specific plans for bringing each non-attainment region up to the standards and for maintaining the purity of the air in regions that already met the standards. The law indicated that each plan should contain an "inventory of pollution sources" such as power plants, factories, and mobile sources, with a careful estimation of how much of each kind of pollutant is emitted each year.

Since the passage of the 1970 and 1977 amendments to the Clean Air Act, the USEPA's strategies for reducing air pollution and improving air quality have been developed in considerable detail. Schulze (1991) summarized these as follows: 1) develop regulations; 2) institute a permit system; 3) inspect polluting facilities and vehicles; and 4) take enforcement actions when violations are found. Although there is not much room for discretion or choice for USEPA in carrying out the Congressional mandates, it seems that the USEPA could maintain a degree of uniformity in the application of its programs nationwide mainly through both annual audit systems and the threat to withhold funds.

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[14] Since 1970 seven hazardous substances have been listed, or targeted for regulation under Section 112 of CAA. These are as follows: arsenic, mercury, beryllium, asbestos, vinyl chloride, radionuclides, and benzene. However, some sources of these pollutants still remain unregulated.

The Korea Ministry of Environment Approach

In the Republic of Korea, currently five government ministries, Ministry of Environment (KMOE), Ministry of Health and Social Affairs (MOHSA),[15] Ministry of Labor (MOL),[16] Ministry of Agriculture and Fisheries (MAF),[17] and Ministry of Trade and Industry (MOTI)[18] have been given primary authority to regulate activities and substances that pose a human health risk (KMOE, 1990). Like many other developing countries, however, none of above agencies has effectively applied this authority to protect both the human health and the environment until recently (Han, 1991; Chung, 1988). Koo (1985) pointed out the reasons as follows:

1) the government priority has been given to economic development,

2) technology in risk analysis and pollution control have not been developed,

3) administrative capabilities, whether in manpower or resources, are not adequate for the protection of human health and the environment,

4) fiscal budget on the government's part is not sufficient for pollution control and environmental protection,

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[15] The MOHSA was established in 1955 to administer generic public health programs such as epidemic disease control, and food and drug safety. Until 1979, the MOHSA was responsible for overall national environmental protection.

[16] The MOL was established in 1981. The MOL is to insure occupational safety and health for workers. Before its creation, MOTI had taken care of workers' safety and health since 1948.

[17] In 1973, the MAF which was established in 1948 was renamed from Ministry of Agriculture and Forestry. It deals with various agricultural activities and programs as well as the fisheries industry. With respect to public health issues, the MAF has authority to control various chemicals used in the agricultural sector.

[18] The MOTI was established in 1948. It deals with national trade and industrial development. The MOTI protects the public against unreasonable risks of injury from consumer products.

5) entrepreneurs do not voluntarily invest their money in environmental protection,

6) environmental legislation is not adequate to effect human health and environmental protection, and

7) environmental awareness of citizens is not high.

In this section, the discussion will focus on the Korea Ministry of Environment (KMOE) regarding its history and organization, and will provide an overview of air pollution regulation including criteria and standards in the Republic of Korea.

History and Organization

On December, 1989, the former Korea Environment Administration (KEA) was upgraded and renamed the Korea Ministry of (KMOE) and became the first independent government executive branch dealing with various environmental pollution problems (Han, 1991; KMOE, 1990). Before discussing the KMOE, it is noteworthy to discuss the history of KEA because it was the origin of the current KMOE and served as the first quasi-independent executive branch agency to manage and control various environmental problems under the MOHSA during the past ten years.

The KEA was established in 1980 incorporating the Environmental Management Bureau of the MOHSA to take charge of national environmental protection under the Presidential Decree No. 9707 [19] (Koo, 1985). It was created to alleviate various environmental pollution problems which tended to be more serious starting in the late

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[19] On May 17, 1979, the former President Park ordered the Prime Minister to create an authoritative agency for environmental preservation under the Environment Preservation Law which was promulgated on December 31, 1977. About six month later, the Korea Environment Administration (KEA) was created.

1970s. The six regional environment offices which were located throughout the nation, were later organized under the KEA (KMOE, 1986; Lee, 1988). With this institutional setup, the Korean government started to take active measures to protect the national environment.

The KEA's primary mission was to control and abate pollution in the areas of air, water, soil, and solid waste (KMOE, 1986).[20] As a complement to its primary activities, the KEA also established various new social regulations such as the national air quality standards, emission standards, and the industrial effluent discharge permit standards (KMOE, 1988). These various standards will be discussed in the following section.

With respect to regulation of chemicals, most of the KEA's control efforts had been concentrated on the agricultural chemicals such as pesticides, insecticides, and herbicides including chemical fertilizers (Koo, 1985). This was because the KEA had the authority to prevent soil pollution under the Environmental Preservation Law. By the early 1980s, it had set up a permissible concentration level in agricultural products for 21 agricultural chemicals (Koo, 1985). For example, in 1983 and 1984, toxaphene and nitrofen [21] were banned for agricultural purposes because these two chemicals were thought to be carcinogens (KMOE, 1986).

With its ten-year experience in pollution control, however, it became clear that the KEA was not the proper organization in terms of its size and authority to achieve the

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[20] Although the KMOE was created in 1990, to avoid confusion, all of references both from KMOE and KEA will be expressed as "KMOE".

[21] Toxaphene is classified as "suspected carcinogen" by the USEPA. Nitrofen is not a known carcinogen but can cause prenatal damage (Simonian, 1988).

national environmental goal for preventing various types of environmental pollution (KMOE, 1990). At the end of 1980s, many social scientists including the KEA's officials asserted that a new upgraded agency should be established at an independent ministerial level (Hong, 1988). Finally the KMOE was established in December, 1989, followed by the fifth amendment of Environmental Preservation Law on September, 1989, which became effective on January 1, 1990 (KMOE, 1990).

Table 3.3 Chronological Events Associated With the Evolution of Major Environmental Organizations in Korea

Date	Major Events
March 1973	The first Pollution Control Division was organized into the Bureau of Sanitation, Ministry of Health and Social Affairs (MOHSA)
March 1977	The Environmental Management Bureau with three divisions in areas for environmental planning, air, and water was organized into MOHSA
July 1978	The National Institute of Environmental Research was established under MOHSA
January 1980	The Korea Environment Administration headed by a vice minister level Administrator was established as an independent central government agency under MOHSA
July 1980	Six Regional Environmental Monitoring Offices were set up under the Korea Environment Administration (KEA)
October 1986	Regional Environmental Monitoring Offices were enlarged and reorganized as Regional Environment Offices
January 1990	The KEA was upgraded to the Korea Ministry of Environment (KMOE) headed by a cabinet minister

Source: KMOE (1990) with slight modification.

The KMOE, headed by a cabinet minister, was expected to develop strong policies and programs to ensure a clean and healthy environment throughout the nation.

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Also the government attempted to improve the legal system of environmental administration, by enacting six new laws replacing the former Environmental Preservation Law which was thought to cover too broad range of the environmental issues to handle within one law.[22] Table 3.3 summarizes the chronological events associated with the history of the KMOE.

The fundamental organizational structure of the KMOE is not that much different from the former KEA. In order to provide more authority to control national environmental problems, certain bureaus in the KMOE have been functionally separated or newly created (KMOE, 1990). For example, the former Bureau of Water Quality Preservation was separated into two bureaus: the Bureau of Water Quality Management, and the Bureau of Solid Waste Management. And the Bureau of Engineering and Technology was newly created to develop various environmental pollution control technology.

The KMOE is currently composed of three staff offices, four program bureaus, and six regional offices (See Appendix B). The three staff offices include the following: the Office of Planning and Management, the Office of Policy Coordination, and the Office of Emergency Planning. The four program bureaus are: the Bureau of Air Quality Management, the Bureau of Water Quality Management, the Bureau of Solid Waste Management, and the Bureau of Engineering and Technology.

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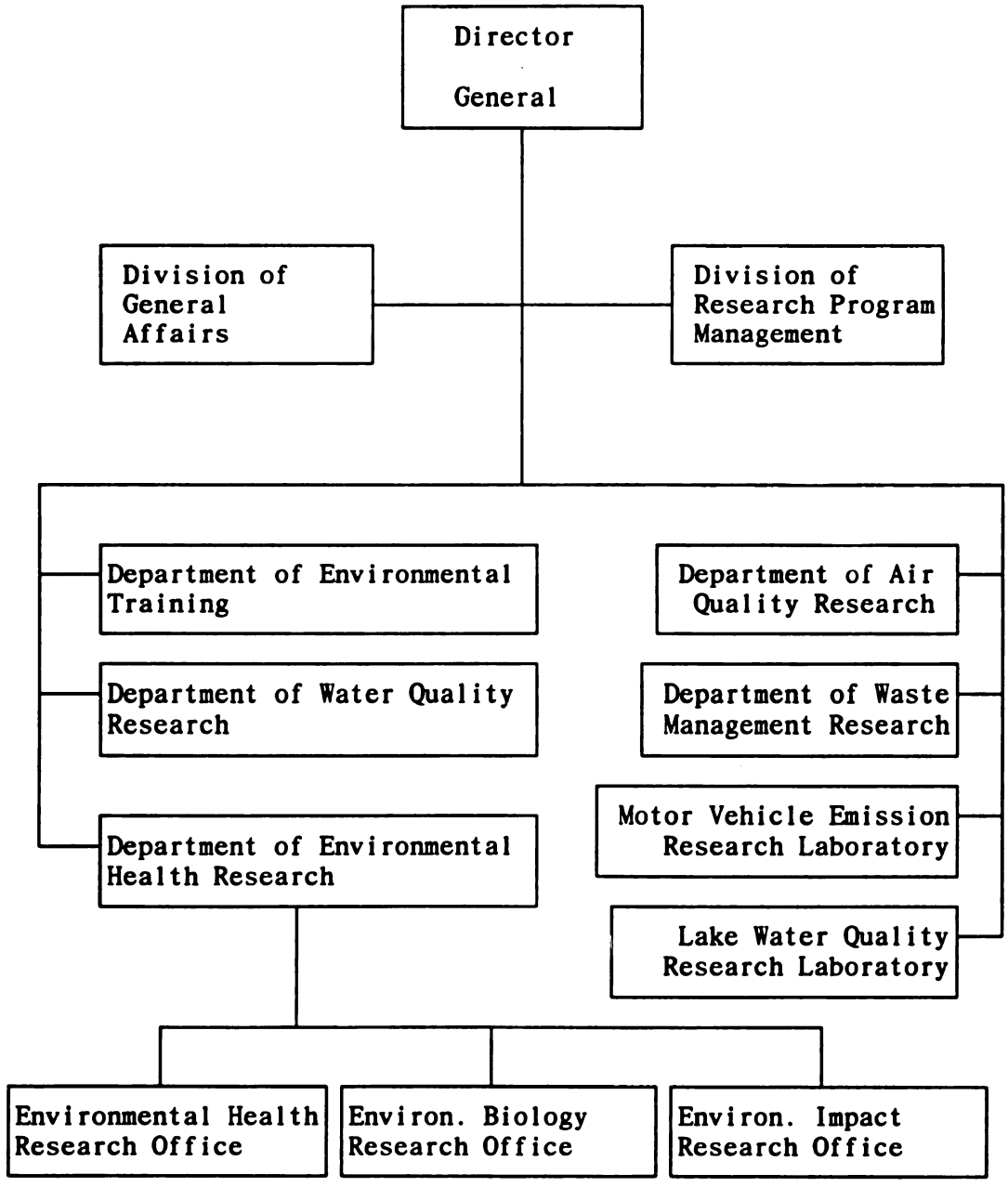
[22] The six new laws administered by KMOE are: Basic Law for National Environmental Policy; Air Quality Preservation Law; Noise and Vibration Control Law; Water Quality Preservation Law; Hazardous Chemical Substance Control Law; and Environmental Dispute Settlement Law.

The three staff offices are generally responsible for the overall policy and management activities such as personnel management, policy coordination, wartime planning, budget control, and international affairs (KMOE, 1991). The Bureau of Air Quality Management is responsible for setting the national air quality standards, automotive pollution controls including automobile emission standards, and noise and vibration control. The Bureau of Water Quality Management is responsible for setting water quality standards, effluent discharge permits, industrial and domestic wastewater control, and marine environmental protection. The Bureau of Solid Waste Management is responsible for toxic substances management, industrial waste management and household waste management, and soil contamination control.

With regard to the KMOE's scientific research, the National Institute of Environmental Research (NIER), which was established under the MOHSA in 1978, was incorporated into the KMOE (See Figure 3.2). The NIER performs wide range of the KMOE's research and education relative to environmental science and technology (KMOE, 1990). The Environmental Health Research Department under the NIER is the unit which is most responsible for human health risk assessment. Figure 3.2 shows the offices involved in health risk research under the Department of Environmental Health Research in the NIER.

The basic responsibility of the six regional administrators is to carry out regional inspection, environmental monitoring, and data collection. They also provide various information about environmental pollution to both public and the local governments.



Note: Total Number of Staff: 184 (Dec. 1991) (Research Scientists: 52, Research Technician: 47)

Figure 3.2 The Organization Chart of the NIER Related to Environmental Health Research (Adapted from the KMOE, 1991. p.668).

Since the first quasi-independent government executive branch, KEA, was created in 1980, the total budget and number of employees have been increasing continuously. For example, during its first year of existence in 1980, it was reported that the KEA's total budget was only about $15 million or about 0.18 percent of total national budget (KMOE, 1984).

Ten years later, the total budget increased to approximately $120 million or about 0.33 percent of total national budget (KMOE, 1991). In 1985, only 369 employees served in the KEA and NIER, and 363 in the six regional offices (KMOE, 1986). By 1990, the KMOE had grown to more than 1,200 employees including the staffs in the six regional offices (KMOE, 1991).

Evolution of Air Pollution Regulation

Since World War II, the Korean peninsula has been divided into the North and South because of various political reasons. North Korea was built under the communist system and South Korea under the democratic system. Therefore, the ideological differences between the North and South caused a tense military confrontation. As a result, the Korean War (1950-1953)[23] broke out and massive destruction on the agricultural and industrial sectors followed during the War. According to Cole and Lyman (1971), the overall physical destruction attributable to the War was estimated to be equivalent to $2 billion, which was roughly equal to the value of one year's Gross National Product (GNP) at that time.

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[23] The Korean War started in June 25, 1950 and ended in July 27, 1953. The War was initiated by the massive attack of North Korean troops across the 38th parallel.

After the Korean War, rehabilitation and reconstruction of war damage was the primary concern of the Korean Government (Kwon, 1987). Thus, the Korean Government was focused on two major national tasks: 1) rebuilding the nation through rapid economic growth, and 2) establishing a military balance between the North and South (Koo, 1985). The latter goal has been achieved partially through the Mutual Defence Treaty between the U.S. and Korea in effect since 1953. It was thought that industrialization was the only way for performing economic growth to support such an urgent national task. Hence, 5-year economic development plans were developed to rebuild the whole nation in the early 1960s (Han, 1991; Kwon, 1987).

Since the first national industrialization program was launched in 1962, the "5-Year Economic Development Plan" was repeated six times until 1991. The seventh plan (1992-1996) is now under process. As a result, a remarkable economic growth has been achieved during the last 30 years. For example, in 1990, the GNP increased to as much as 69 times more than that of 1961 with average annual economic growth rate of 7.6 percent, and Korea's per capita GNP increased from $82 in 1961 to $5,569 in 1990 (Economic Planning Board, 1991). Table 3.4 summarizes some major socioeconomic changes between 1961 and 1990.

Since the late 1970s, however, rapid economic growth coupled with industrialization, urbanization and population growth has started to cause serious environmental problems (KMOE, 1990; Kwon, 1990). Particularly, air and water pollution has been threatening the ecosystem as well as public health throughout the nation (Koo, 1985). Although the first Pollution Prevention Law (PPL) was passed in

1963,[24] environmental pollution control including the air pollution was not actively implemented until the late 1970s. For example, air pollution regulation under the PPL was mainly focused on the control of factory fumes (Koo, 1985). For reducing the factory fumes, the major control strategy only limited to the facilities which were located in specific air preservation zones such as residential areas.

Table 3.4 Socioeconomic Developmental Indicators of Korea.

Indicator	1961	1990	Increase
GNP per Capita (US$)	82	5,569	69 times
Motor Vehicle Registered (Thousand Vehicles)	29	3,000	113 times
Energy consumption (Thousand TOE)[a]	8,759	81,660	9.3 times
Total Population (Thousand Persons)	25,441	42,869	1.7 times
Urban Population Rate (Percentage)	27.5	71.4	2.6 times

[a] TOE refers to ton of oil equivalent. Source: Korea Economic Planning Board, Statistical Yearbook (1991).

In the late 1970s, with a growing awareness of environmental problems especially in the industrial complex areas,[25] the first comprehensive Environmental Preservation Law (EPL) was passed in September, 1977 (KMOE, 1986). The MOHSA had the primary responsibility for administering and enforcing the EPL of 1977, while the

[24] The PPL was designed primarily to control air pollution, water pollution, and noise and vibration (KMOE, 1986).

[25] In 1979, for example, the annual average concentration of SO_2 was estimated 0.093 ppm. However, in 1984 one industrial complex area near the city of Seoul recorded 0.317 ppm (Koo, 1985).

authorities for implementing various programs for environmental quality control belonged to many other ministries.[26] Until 1980, no centralized government agency existed to deal with the various environmental problems (Koo, 1985).

In 1980, as mentioned earlier, the Korea Environment Administration (KEA) was established as the first quasi-independent government agency and had the authority to control various environmental problems until 1989 (Koo, 1985). In 1991, after the KEA was upgraded to the Korea Ministry of Environment (KMOE), the Government adopted the pluralistic approach in terms of environmental legislation (Han, 1991). Six new laws replaced former EPL: the Basic Environmental Policy Law (BEPL), the Air Quality Preservation Law (AQPL), the Water Quality Preservation Law (WQPL), the Noise and Vibration Control Law (NVCL), the Hazardous Chemical Control Law (HCCL), and the Environmental Dispute Settlement Law (EDSL).[27]

According to Article 1 of the BEPL, the Law was intended "to prevent public health risk from environmental pollution, and to preserve and manage the natural environment and living environment properly." To implement the goals described in Article 1, the Law strengthened methods and techniques for pollution control, invested the central government with more power, and enlarged the categories of pollution to be controlled

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[26] At that time, the authority for implementing environmental protection was distributed as follows: Natural protection by the Ministry of Internal Affairs; management of air and water quality by MOHSA; radioactive pollution control by the Ministry of Science and Technology, etc. At present the KMOE has authority over most of these environmental protection issues.

[27] Upon submission by the government's bill Assembly group, the bill was passed by the National Assembly in July, 1990 and the government promulgated it on August 1, 1990 and the Laws became effective on February 2, 1991 (KMOE, 1991). Since then, the former EPL was repealed.

in the following areas: air pollution, water pollution, noise and vibration, and hazardous chemicals (KMOE, 1991).

With respect to the air pollution control, a brief summary of the AQPL is as follows: chapter one contains general provisions; chapter two, emission control for the industrial facility; chapter three, emission control for the living environment; chapter four, motor vehicle emission control; chapter five, business for air pollution prevention; chapter six, supplementary provisions; chapter seven, punitive provisions.

Under the EPL Amendment of 1979, the Administrator of the KEA was required to establish national environmental quality standards (EPL, Article 4). Since the KEA adopted the first national ambient air quality standard for sulfur dioxide in 1979, the following five additional pollutants; carbon monoxide, nitrogen oxide, oxidants, total suspended particulates (TSP), and hydrocarbons were added in August, 1983 (KMOE, 1986). In February, 1991, the ambient air quality standard for lead was also added under the Implementing Decree of the BEPL. Table 3.5 shows the current criteria and standards for national ambient air quality control in Korea.

According to the BEPL [Para.1 Article 10], the Law provides: "the government shall establish environmental quality standards in order to preserve the **pleasant environment** and to protect the **human health**, and shall maintain proper levels of environmental quality." For determining the standards of the environmental quality, two criteria should be considered: one is the degree of protecting human health, and the other is the level of preserving a pleasant environment. However, the Law did not provide any explicit statement associated with the degree of protection and the meaning of a pleasant environment.

As a result, environmental quality standards prescribed in Article 10 of the BEPL, served as the primary objectives of the Korean environmental administration. As Han (1991) points out, these standards are just a goal which is desirable to achieve and maintain so as to protect the human health and conserve the atmospheric environment. Furthermore, the BEPL of 1991 has no explicit provision which defines the maintenance and enforcement of environmental quality standards as a responsibility of the government, while in the case of the U.S., state governments and/or local governments are responsible for maintaining the NAAQSs under the Clean Air Act [Section 110].

Table 3.5 The Korea National Ambient Air Quality Standards in Effect in 1991.

Pollutants	Averaging time	Standards	
Total Suspended Particulates (TSP)	Annual	150	$\mu g/m^3$
	24-Hours[a]	300	$\mu g/m^3$
Sulfur Dioxide	Annual	0.05	ppm
	24-Hours[a]	0.15	ppm
Carbon Monoxide	1-Month	8	ppm
	8-Hours[a]	20	ppm
Nitrogen Oxide	Annual	0.05	ppm
	1-Hour	0.15	ppm
Oxidants as O_3	Annual	0.02	ppm
	1-Hour[a]	10	ppm
Hydrocarbons (HC)	Annual	3	ppm
	1-Hour[a]	10	ppm
Lead (Pb)[b]	3-Months	1.5	$\mu g/m^3$

[a] Should not be exceeded more than 3 times per year.
[b] Ambient standard for lead was added in February, 1991.
Source: The Korea Environmental Yearbook, KMOE (1991). p.551

The first motor vehicle emission standards for production line passenger cars were promulgated and became effective in 1980 under the EPL of 1977, and emission standards for both the gasoline and the diesel fueled motor vehicles were enforced in July, 1984 (KMOE, 1986). Under the EPL Amendment of 1986, new models of gasoline passenger cars were required to be equipped with catalytic converters for exhaust systems, and to use unleaded gasoline by 1987 (KMOE, 1991).

In the late 1980s, the KEA also has started to expand the clean fuels policy by substituting liquefied natural gas (LNG) for high sulfur coal and oil. Since September, 1988, in fact, the KEA designated fourteen large cities and towns as LNG using areas (KMOE, 1991). In these cities and towns, LNG should be used for all heating facilities in business and public buildings with capacities of more than 2 ton per day. Among the air pollutants discharged from the various emission sources, currently, 26 air pollutants such as ammonia, carbon monoxide, and sulfur dioxide, have been included as the permissible air discharge standards under the Implementing Decree of AQPL of 1991 [Article 9].

In summary, air pollutants have been regulated by the EPL from 1978 to 1990 and by the AQPL since 1991. The KMOE has set various standards to protect human health from the air pollution. It also has set permissible limits for industrial emission measured both from the sources and at the boundary of the plant involved.

Although overall national ambient air quality has been improved by the KMOE's various efforts, the maximum acceptable levels of the air pollution in urban areas have been exceeded continuously (Chung, et al., 1991; Kwon, 1990; Song and Shin, 1991). According to recent research, for example, the annual average standard of sulfur dioxide

[0.05 ppm] in Seoul, has been violated at 80 percent of the total monitoring stations and the 24-hour average standard [0.15 ppm] has been exceeded at 95 percent of the stations respectively (Song and Shin, 1991). During the winter season of 1989, it was also reported that the level of sulfur dioxide in Seoul and Inchon was as high as 0.358 ppm. This level of sulfur dioxide is even higher than that of London disaster case in 1952.[28] What all these stories indicate is that the KMOE's pollution control policies including the implementing techniques still need to be improved and/or changed to become more effective.

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[28] It was estimated that between 3500 and 4000 excess deaths occurred during the month of December, 1952. At that time, the recorded level of sulfur dioxide was as high as 0.3 ppm (Turk and Turk, 1984. p. 466.).

CHAPTER IV

PROCESS FOR RISK MANAGEMENT DECISION

The U.S. Environmental Protection Agency Approach

Since its creation in 1970, the USEPA's human health risk assessment and the management approach has played an important role in the regulatory process (Beardsley, 1988; Berry, 1986; Preuss, 1988; Trinh, 1991; Yosie, 1987). In this section, the discussion will focus on the USEPA's risk analysis policy, risk assessment techniques, and risk management decision process for regulation of environmental pollutants.

Risk Analysis Policy

The USEPA's fundamental policies for health risk assessment and management have been based on the interpretation of statutes and/or scientific judgements, mainly toxicological findings (Preuss, 1988). Currently the Agency has the authority to control the human health risk in the environment under the seven major pieces of legislation, which are listed in Table 4.1.

Lave (1981) divided this legislation into two types based on their approach to risk control: (1) requirement to lower risks for a substance to zero or negligible levels without concern for the resulting costs [technological feasibility is the only constraint]; and (2) requirements to balance some measure of the benefits from lowering the risk against the

cost of control. Table 4.1 illustrates the present public laws which provide the bases of risk management under USEPA's authority. In fact, each statute accords different weights to such criteria as risk, costs of control, and technical feasibility.

Table 4.1 Risk Management Approaches Under Major Environmental Statutes in the United States.

Statute	Management Approaches
Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)	Ban; label; train
Toxic Substances Control Act (TSCA)	Ban; set PCB spill cleanup standards
Safe Drink Water Act (SDWA)	Set standards
Clean Water Act (CWA)	Set standards
Clean Air Act (CAA)	Set standards
Resource Conservation Recovery Act (RCRA)	Prevent environmental release
Comprehensive Environmental Response Compensation, and Liability Act (CERCLA)[a]	Remediate environmental release

[a] CERCLA is also called as "Superfund" because it provides a huge amount of funds for cleanup of contaminated sites throughout the nation.
Adapted from Severn (1987), p. 1160

In the late 1970s and the early 1980s, two important steps concerning the risk assessment and the risk management took place almost simultaneously: one was the recommendation from the National Academy of Sciences (NRC, 1983) for organizational arrangements that separate risk assessment from risk management; another was the USEPA's effort to establish some generic risk assessment guidelines through the

publication of various policy documents on human health risk assessment.[1] These documents contain a number of important guidelines to help achieve quality and consistency in its risk assessments. Hence, the USEPA's risk assessment culture has been depended largely on these various guidelines.

While the first guideline for assessing cancer risk was developed in 1976, the systemic toxicant and mutagenicity guidelines were promulgated in 1980, and exposure assessment was issued in 1983. Later, these guidelines were endorsed by the NAS committees as the most appropriate processes for making informed public policy decisions to protect human health from toxic chemical exposures (NRC, 1983).

In 1986, after a two-year public review process, the USEPA finally published the generic risk assessment guidelines for carcinogens (USEPA, 1986a), developmental toxicants (1986b), exposure assessment (1986c), mixtures (1986d), and mutagenicity (1986e). Later, the guideline for municipal waste combustors (1986f) was also published. In addition, the USEPA issued a handbook for conducting endangerment assessments (USEPA, 1987b) and risk assessment of Superfund sites (USEPA, 1986g). In 1988, systemic toxicants (1988a) as well as female (1988b) and male reproductive toxicants (1988c) guidelines were published.

Among these various guidelines, the two important documents relative to carcinogenic risk assessment and exposure assessment, had great difficulty dealing with the question of uncertainty in data and laying out the ground rules for presenting

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[1] General agreement on the need for risk assessment guidelines does not exist. Some scientists argue that articulation of guidelines is inappropriate, and that every situation should be evaluated on a case-by-case basis. However, others prefer detailed guidelines that take risk assessors through each step of the process and spell out specific approaches or scientific conclusions.

information in a way that allows the decision-makers to take ranges of uncertainty into account (Dowd, 1986). In fact, throughout all five sets of the 1986 guidelines, the USEPA emphasizes the need to include variability and to assess uncertainties in evaluating results (USEPA, 1988a).

According to the guidelines for carcinogen risk assessment (USEPA, 1986a), the use of upper and lower bound estimates is encouraged. However, Wilkinson (1987) points out that the values generated by the Agency are all upper bound estimates of risk, usually the upper 95 percent confidence limits, which are obtained from the so-called "linearized multistage model." This extrapolation process is based on the assumption that the effects at low doses can in fact be estimated from the effects observed at high doses by using mathematical models. As a result, the practical consequence is that this model may exaggerate the real cancer incidence. At a recent American Chemical Society meeting, the linear multistage model was criticized because it cannot take into account the effects of increasing cell division on cancer causation. Therefore, it is suggested that a new model that allows incorporation of such new data should be developed.

Regarding the implications of the USEPA's guidelines, Preuss (1988) indicated that "the guidelines are not regulations; in fact, they are intentionally flexible to encourage the use of all data and the appropriate scientific methods and judgments." Therefore, the guidelines are nonbinding policy statements and have no direct effect on the regulated community. As Dowd (1986) pointed out, however, these guidelines incorporate important decisions that USEPA has made about important issues regarding the human health risk assessment process. Although they only officially affect the USEPA's actions, there is no doubt that these guidelines will affect the world-wide risk

assessors and managers as well as Americans who have a stake in the regulation of chemicals in the environment.

Risk Assessment Techniques

As discussed in Chapter II, the USEPA currently uses the following four-step standard procedure for the risk assessment process as a general method: (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization. Thus, the Agency's health risk analysis is a multi-step process which describes the increased possibility of adverse health effects, using the scientific information available (USEPA, 1986a,b,c).

With regard to air regulation, the health risk assessment provides a safe level and/or the probability that exposure to an air toxic will result in adverse health conditions, ranging from mild, temporary conditions, such as eye and throat irritation and shortness of breath, to permanent serious conditions, such as cancer and birth defects as well as damage to kidney, liver, and other organs (Trinh, 1991). It also includes estimation of the chance that adverse health effect will occur.

The hazard identification step in air pollution regulation involves determining the potential health effects which may be associated with emitted pollutants. This is to identify qualitatively whether a pollutant is a potential human carcinogen or can provide other type of adverse health effects including mutagenicity and developmental toxicity (USEPA, 1986b,e). For identification of chemical carcinogenesis,[2] the USEPA has

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[2] In the United States, the majority of experience with health risk assessment and management approaches has been in the areas of radiation and chemical carcinogenesis.

adopted a technique called "weight-of-evidence," designed to permit judgments about the importance of various experiments performed to determine carcinogenicity (USEPA, 1986a). Various information such as physical and chemical properties, metabolic and pharmacokinetic data, short-term tests and long-term animal studies, and human studies have been included for the qualitative evidence (USEPA, 1986a).

Table 4.2 The USEPA's Carcinogenicity Categorization Based on Animal and Human Data.

Human Evidence	Animal Evidence				
	Sufficient	Limited	Inadequate	No Data	No Evidence
Sufficient	A	A	A	A	A
Limited	B1	B1	B1	B1	B1
Inadequate	B2	C	D	D	D
No Data	B2	C	D	D	E
No Evidence	B2	C	D	D	E

Source: Federal Register, Vol. 51, No. 185, page 34000.

After the available information and data are reviewed concerning the evidence of carcinogenicity, the USEPA (1986a) divided the animal and human data into five groups: (1) sufficient evidence of carcinogenicity, (2) limited evidence of carcinogenicity, (3) inadequate evidence, (4) no data available, and (5) no evidence of carcinogenicity. Hence, these degree of evidence assessments are combined into a weight-of-evidence classification scheme to make a decision whether a chemical agent is carcinogen or not (See Table 4.2). More importantly, this scheme gives more weight to human evidence

when it is available. The following shows the USEPA's weight-of-evidence classification scheme into which chemical agents are categorized (USEPA, 1986a):

Group A: Human Carcinogen.

Group B: Probable Human Carcinogen.

B1; Usually Limited Human Data,

B2; Sufficient Animal Evidence.

Group C: Possible Human Carcinogen.

Group D: Not Classifiable as to Human Carcinogenicity.

Group E: Evidence of Non-carcinogenicity towards Humans.

Table 4.2 illustrates how the human studies and long-term animal studies are combined through the matrix to derive the first approximation of the overall weight-of-evidence classifications. For example, if a chemical agent has sufficient evidence of carcinogenicity based on the human studies, without any further information from animal studies, the chemical will be classified as a "Group A" agent: i.e. a known human carcinogen. Whenever other types of evidence are available, however, the first approximation may go upwards or downwards through the adjustment of appropriate new information and data (USEPA, 1986a).

In the case of chemical mixtures, the USEPA also conducts its hazard identification by considering the weight-of-evidence for the mixture's component chemicals (USEPA, 1986d). For complex mixtures, the evidence for a health hazard may come from the studies on the mixture itself. Information on the mixture itself,

however, must be carefully reviewed for evidence of masking of one toxic end point by another (Preuss, 1988). For example, when one of the component chemicals is a suspected carcinogen, but the data show distinct toxicity in major organs and no indication of cancer, there is the possibility that other toxic effects may conceal the evidence of carcinogenicity. The hazard identification then would suggest no cancer risk at any dose, when in fact, at doses below the threshold for systemic toxicity, there could be significant risk of cancer (Preuss, 1988).

In the case of hazard identification for developmental toxicity, four types of information on a series of end points may include: death, structural abnormalities, growth alterations, and functional deficits (USEPA, 1986b). In order to identify maternal toxicity, the following criteria are used as an evaluation of the individual end points of maternal toxicity: fertility, body weight change, clinical signs of toxicity, and specific target organ pathology and histopathology (USEPA, 1988b). For most species, however, body weight and the change in body weight are viewed collectively as indicators of maternal toxicity.

The next step after hazard identification is a dose-response or toxicity assessment. This step is the process for characterization of the relationship between the exposure to a chemical substance and the incidence of an adverse health effect in exposed populations. Data for assessing toxicity are mainly derived from experiments on animals, which are administered increasing doses of a certain chemical until some effects or responses are observed (USEPA, 1986a, 1987a).[3] Besides animal experiments, toxicity

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[3] To calculate human equivalent dose from experimental animal dose, the USEPA (1987a) has suggested following formula for generic application: $Dh = (Da)(Wa/Wh)^{1/3}$, where: Dh = the human equivalent dose (mg/kg), Da = the animal dose

data are also derived from the occupational, clinical, and the epidemiological studies (USEPA, 1987a).

Responses can vary from no observable effect to temporary or reversible effects, to chronic impairment, and to permanent injury to organs. Dose is expressed in milligrams of substances inhaled, ingested, or absorbed through the skin per kilogram of body weight per day (mg/kg/day).

In the case of quantitative carcinogen risk assessment, dose is translated to risk as a potency slope [compiled from the potency values] which is used to calculate the probability or risk of cancer associated with a given exposure level. These potency values, or cancer slope factors, give the probability of a person contracting cancer from a unit intake of a toxic chemical over a lifetime of 70 years. Potency values or unit risk factors due to inhalation exposure are expressed as the reciprocal of micrograms per cubic meter (USEPA, 1987a). Ingestion potency values are expressed as the reciprocal of milligrams per kilogram of body weight per day.

In the case of systemic toxicity, the USEPA's approach is different from its approach to expressing the carcinogenic risk because the different mechanisms of action are thought to be involved in each case (Barnes and Dourson, 1988). As mentioned earlier, because the USEPA assumes that there is theoretically no level of exposure for any carcinogen that does not pose a small probability of generating a carcinogenic response, the Agency adopted the assumption that carcinogens work by a **"nonthreshold"** mechanism. However, in the case of systemic toxicity, the USEPA adopted the **"threshold"** assumption because body mechanisms such as organic homeostasis,

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(mg/kg), Wh = human body weight (kg), Wa = animal body weight (kg)

compensation, and adaptation exist to overcome effects before a toxic end point is manifested (Barnes and Dourson, 1988). Hence, dose-response data obtained from studies of human populations (epidemiologic investigations) and/or studies using laboratory animals are used to develop non-carcinogen acceptable exposure levels for either acute or chronic exposure.

Table 4.3 USEPA's Guidelines for Uncertainty/Modifying Factors and Criteria for Application.

Uncertainty Factors (UFs)	Criteria for Application
10	Individual difference within the human population
10	Additional 10x factor when extrapolating from chronic animal studies to humans.
10	Additional 10x factor when extrapolating from less-then-chronic animal studies.
10	Additional 10x factor when deriving a RfD from a LOAEL[a] instead of a NOAEL.
Modifying Factor (MF)	Scientific judgement is used to establish any additional safety factor to account for uncertainties not addressed
$0 < MF < 10$	previously. The default value for MF = 1.

[a] LOAEL = lowest observed adverse effect level.
Adapted from Barnes and Dourson (1988) with slight modification.

In 1987, USEPA's Reference Dose Work Group[4] introduced the concept of **Reference Dose** (RfD),[5] which means an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive sub-groups) that is likely to be without appreciable risk of deleterious effects during a lifetime. Table 4.3 presents the USEPA's guidelines deriving a RfD using uncertainty factors and modifying factors.

In addition to the development of reference doses, the USEPA is also pursuing other ways of assessing systemic toxicity (Barnes and Dourson, 1988). In the case of criteria pollutants, for example, the Office of Air Quality Planning and Standards is using probabilistic risk assessment procedures. In this procedure, the population at risk is characterized, and the likelihood of the occurrence of various effects is predicted through the use of available scientific literature and of scientific experts' rendering their judgements concerning dose-response relationships. This dose-response information is then combined with the results of the exposure analysis to generate population risk estimates for alternative standards (Barnes and Dourson, 1988).

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[4] This work group is composed of two co-chairpersons from the Office of Research and Development in addition to other nineteen members from various offices within the USEPA. The Group has introduced the following less value-laden terminology to clarify and distinguish between aspects of risk assessment and risk management: reference dose (RfD), Uncertainty factor (UF), margin of exposure (MOE), and regulatory dose (RgD). Currently these concepts are in general use in many parts of the USEPA (Barnes and Dourson, 1988).

[5] The RfD can be calculated from the following formula: RfD= NOAEL/(UF x MF), where NOAEL = no observed adverse effect level, UF = uncertainty factor, and MF = Modifying factor. For more detail information, see the Barnes and Dourson (1988) Reference Dose.

The third step, the exposure assessment, is the determination or the estimation of the magnitude, frequency, duration and route of public exposure to each substance for which cancer risk or non-cancer effects is possible (USEPA, 1986c). In the case of air pollutants, it involves detailed emission quantification, modeling of environmental transport, evaluation of environmental fate, identification of exposure routes and populations, and estimation of short and long-term exposure levels. Currently the USEPA (1986c) divides the process of exposure assessment into two major phases: (1) the preliminary assessment; and (2) the in-depth assessment.

During the preliminary assessment phase, the potential risk is estimated. This is based on the data derived from the environmental measurements, the simulation model results, and the assumptions about parameters used in approximating actual exposure conditions. The data from this preliminary assessment are then coupled with toxicity information to perform a preliminary risk analysis (USEPA, 1986c). As a result of this analysis, a decision will be made that either an in-depth exposure assessment is necessary or there is no need for further exposure information.

Table 4.4 Standard Exposure Factors of Human Health Risk Assessment.

	ADULT	CHILD
Body Weight (Kg)	70	10 - 16
Body Surface Area (m^3)	1.9	1.4
Water Ingested (1/day)	2	1
Air Inhaled (m^3/day)	20	5
Soil Ingested (mg/day)	100 (70 yr)	200 (5 yr)
Fish Consumption (g/day	6.5	-
Food Consumption (g/day)	1500	
Lifetime Exposure (yr)	70	-

Source: Adapted from Trinh, 1991.

The in-depth assessment contains the following five major components: sources, exposure pathways, measured or estimated concentrations and duration, exposed populations, and integrated exposure analysis (USEPA, 1986c). Generally, this phase results in exposure estimates which are expressed as the magnitude and duration of an individual event of exposure or as potential lifetime exposure (Preuss, 1988). In the case of acute or subacute effects, the estimate is expressed as the magnitude of exposure per event or several events over a short period of time. On the other hand, exposure estimates for chronic effects like carcinogenic risk often consider the average daily exposure calculated over a lifetime.[6] Table 4.4 presents the standard exposure factors for humans which are currently used in USEPA.

The Federal Community Emergency Preparedness and Right-to-Know Act requires industry to provide information to the public about emissions of toxic air contaminants and their impacts on public health.[7] Therefore, facility owners have to submit comprehensive air toxic emission inventory reports to local air pollution control districts and perform a multi-pathway exposure assessment based on the emissions data reported (Trinh, 1991).

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[6] For an example, exposure (mg/kg/day) is calculated as a dose averaged over the body weight (kg) and lifetime (days) as follow:

$$\text{Average Daily Lifetime Exposure} = \frac{\text{Total Dose}}{\text{Body Weight} \times \text{Lifetime}}$$

[7] Title III of the Superfund Amendments and Reauthorization Act of 1986, PL 99-499.

Generally facility owners conduct an air dispersion modeling analysis to estimate the ambient air concentrations resulting from the air toxic released. The modeling analysis also requires site-specific meteorological data over a period of three to five years, and ensures that the worst-case meteorological conditions are represented adequately in the models.[8] The results from the modeling analysis provide the ambient ground level concentrations of each toxic substance, expressed in micrograms per cubic meter (USEPA, 1986c). Annual average concentrations and one-hour maximum concentrations are usually used in assessing both acute and chronic health effects.

Finally, risk characterization is the last step of a health risk assessment, integrating the health effects and public exposure information developed for emitted pollutants (Barnes and Dourson, 1988). The purpose of risk characterization is to present the risk manager with a summary and synthesis of all the data that could contribute to a conclusion with respect to the nature and the extent of the risk.

This step is composed of two parts: a presentation of numerical estimates of the risk; and a framework to help judge the significance of the risk (USEPA, 1986a). Depending on the needs of the various program offices, numerical estimates of risk are presented in one or more of the following ways: unit risk, dose corresponding to a given level of risk, and individual and population risks. The exposure units are expressed as ppm or ppb in water, mg/kg/day by ingestion, or ppm or $\mu g/m^3$ in air.

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[8] The following two models are used frequently: the Industrial Source Complex Short Term (ISCST) model for rural or urban flat terrain and the COMPLEX I model for complex terrain applications, respectively.

The individual and population risks are expressed as the excess individual lifetime risks or the excess number of adverse effects such as cancers. In order to judge the significance of the risk, the USEPA currently applies the hazard index system, which is the ratio of the total pollutant concentration, including the ambient background, over the chemical-specific acceptable exposure levels (Trinh, 1991). For instance, the non-carcinogenic risk of acute and chronic health effects are considered as significant if the value of hazard index exceeds unity.

The risk characterization also contains a risk estimate for a specific exposure including the major assumptions, limitations, and uncertainties, which have been used in the risk assessment (Preuss, 1988; Trinh, 1991; USEPA, 1986a). For example, to estimate the long-term exposure effects resulting from the facility's air emissions, the risk characterization requires consideration of both the inhalation and the non-inhalation pathway exposures, called the multi-pathway exposure. The analysis of the multipathway exposure includes the air toxics deposited in soils, crops, and the surface waters (USEPA, 1986a). The primary or direct pathways are inhalation, ingestion, and dermal absorption. Secondary or indirect pathways of exposure derive from the food sources such as the mother's milk, crop, meat, and the dairy products.

Consequently, the risk characterization step is the final expression of risk derived from the risk assessment process. When health risks are weighed against other societal costs and benefits, the results of risk characterization are used by the regulatory decision-makers to determine an appropriate action known as the risk management.

Risk Management Decision Process

Once the risk characterization is completed, the next step focuses on risk management. This step includes the general process for the USEPA's decision-making, which is the central role of the regulatory agencies. In reaching a regulatory decision, the USEPA risk managers utilize the results of the risk assessment including some other factors such as technological, legal, economic, and social considerations (NRC, 1983; Preuss, 1988). These additional factors may also include efficiency, timeliness, equity, administrative simplicity, consistency, public acceptability, technological feasibility, and the nature of the legislative mandate (Beardsley, 1988; Preuss, 1988). The decision of which factors should be considered is mainly based on both the statutory mandates and their interpretation by the courts. Therefore, in general, the USEPA's risk management decisions have been made on a case-by-case basis (Berry, 1986; Jasanoff, 1986; Lave, 1981).

Under the CAA in the United States, air pollutants are divided into two categories, so-called the **criteria pollutants** and the **non-criteria pollutants** (See Table 3.1). In the case of regulating criteria pollutants (e.g., sulfur dioxide, particulate matter, carbon monoxide), no consideration of costs or benefits are required to justify primary and secondary ambient air quality standards based on the **"adequate margin of safety"** provision (CAA Section 108 and 109). For regulating non-criteria pollutants (e.g., benzene, asbestos), however, the USEPA Administrator has promulgated emission standards for specific industrial sources based on the **"ample margin of safety"** provision (CAA Section 112) and include consideration of the feasibility of technology based on

the "**Maximum Available Control Technology** (MACT)" provision under the CAA Amendment of 1990.

Regarding the institutional unit for risk management decision-making, the Division of Air and Radiation and the Administrator of the USEPA are responsible for air regulation decision-making under the CAA. Generally the Division of Research and Development has not participated in the USEPA's risk management process (Goldstein, 1985a). The Office of Health and Environmental Assessment under the Research and Development division is primarily responsible for performing the various types of risk assessment. Some groups and offices which jointly perform the risk assessment are as follows: the Environmental Criteria and Assessment Offices in Research Triangle Park, North Carolina and Cincinnati, Ohio, the Cancer Assessment Group and Reproductive Assessment Group located at the EPA headquarters in Washington, D.C.

In the case of carcinogen, the result of the risk assessment conducted by the Office of Health and Environmental Assessment is generally expressed as a numerical estimate of the amount of increased risk involved. For example, the estimate is usually expressed in two forms: 1) the number of deaths due to cancer from an exposure of 70 years at the point of maximum concentration in excess of what would be predicted without the exposure; and 2) the increased odds of one individual contracting cancer given that same scenario. For non-carcinogenic case, however, the **LOAEL** or the **NOAEL** are identified and compared to the exposure levels to find out whether adverse health effects are expected.

The next step usually involves review of the outcome of the risk assessment, which is generally conducted by the Office of Toxic Substances as an internal peer review and the Science Advisory Board (SAB)[9] as an external peer review (Lee, 1988). The USEPA officers begin to choose the management option based on the results of the peer review. As the regulatory criterion for cancer policy decisions, for example, most regulatory agencies including the USEPA have generally used one excess cancer in a population of 1 million as the limit for the acceptable risk (Whipple, 1987). By the late 1980s, however, a number of agencies considered raising the risk number to one in 100,000 as the general rule of thumb for the acceptable risk (Curlee, 1987).

Finally, according to Section 553 and 556 of the U.S. Administrative Procedures Act, the USEPA, like many other regulatory agencies in the U.S., provides for routine public hearings on the Agency's regulatory proposals. During this process, many interest groups and activist scientists are able to participate in the USEPA's decision-making process before the Agency reaches a final regulatory decision for controlling the chemicals of concern. After this, most regulations are challenged in courts because some groups think the regulation is too stringent and others think it is too lax. In general each challenge takes many years.

In summary, since the early 1970s when the USEPA was confronted with a range of decisions over how to implement such legislation as the CAA and SDWA, the USEPA's risk management decision has been based on a general analytical decision-making tool known as quantitative risk assessment which has been used by many people in many programs across the Agency. Many of the USEPA's statutes have been

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[9] The SAB does not review each case under all laws.

predicated on risk reduction, which requires more and better health risk and exposure analyses. Because of the possibility of overlapping and conflicting the risk analyses, Falco and Moraski (1989) suggested that a larger role of the Division of Research and Development be required for reviewing of the various types of risk assessments, for oversight of the process, and for the development of more detailed guidelines.

Therefore, as the sophistication and number of risk assessment practice increases, there is not only a greater need for the assurance of quality and consistency, but it is also expected that the USEPA will develop more comprehensive guidelines, and/or add more detail to existing guidelines. As a result, the risk management decision procedures will be strengthened for resolving scientific disputes, and the risk analysis techniques will serve the USEPA's decision-makers as a way of removing environmental decisions from the political arena.

The following figure 4.1 summarizes the USEPA's regulatory decision-making process for the management of generic air pollution. In general, it takes approximately one to three years to assess health risk and exposure, and another four months are needed for the SAB's review as an external peer review process. After being listed as a hazardous air pollutant under the Section 112 of CAA, it takes at least three years for state and local responsibility to be established.

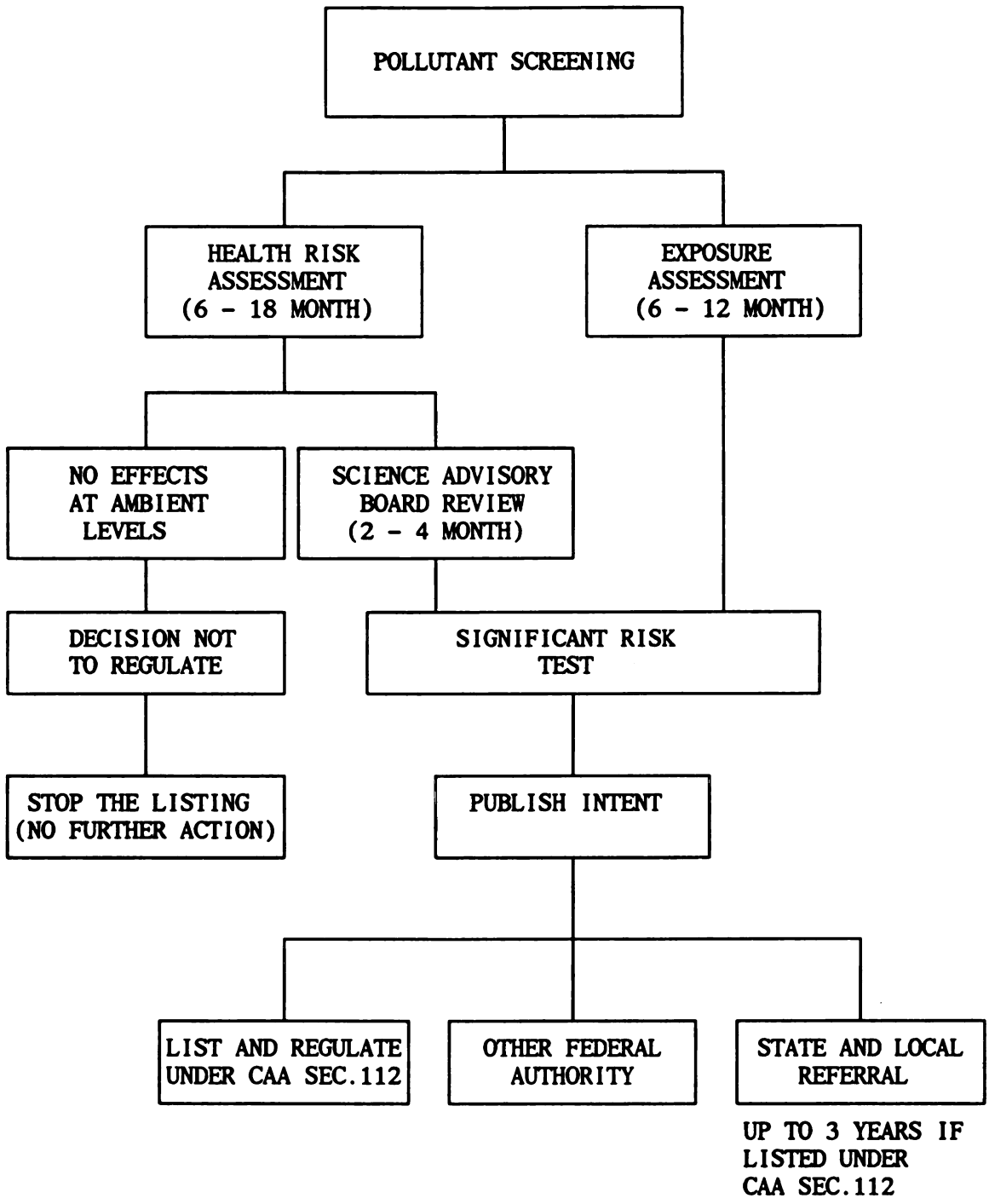

Figure 5.1 The USEPA Risk Decision-Making Process for the Management of Air Pollutants (Modified from Lee, 1988. p. 344.)

The Korea Ministry of Environment Approach

Since the early 1980s, the MOHSA has recognized that it is necessary to develop sound methods for assessing human health effects resulting from exposure to toxic chemicals in drinking water, ambient air, and food (KMOE, 1982). However, the former KEA had failed to develop any explicit guidelines relative to health risk assessment. Hence, health risk assessment did not play any critical role in the process of environmental regulation in the Republic of Korea.

Because of the rising concern over human health risks from environmental pollution, a few environmental scientists and toxicologists have started to research this field recently (Bae, et al., 1991; Chung, 1988; Chung et al., 1991; Kim, 1988b). In this section, the discussion will focus on the KMOE's health risk analysis policy, risk assessment techniques, and risk management decision process for regulatory purposes.

Risk Analysis Policy

Traditionally the Korean society considered the risks not as a scientific arena but as a religious domain. Shamanism has been widely practiced in the society for a long time. A shaman, called MuDang or GemSulGa in Korean, has dealt with the risk by using magic for the purpose of curing the sick, divining the hidden, and controlling events. Even today, a few shamans remain especially in rural areas.

Since the early 1980s, Korean society has exhibited increasing concerns over the risks affecting the human health especially resulting from the air and water pollution (Kim, 1988a,b). Although average life expectancy has been increasing continuously since the end of the Korean War, the KMOE (1991) reported that the mortality of the age

group between 40 and 50 is 2.5 times higher than that in Japan in 1988. Most Korean risk managers, including the environmental scientists, now suspect that high mortality of this specific age group may be correlated with the high level of air and/or water pollution along with the social stress (Kwon, 1990).

During the past decade, the Korean government has made various efforts to protect the human health from environmental pollution. For example, as mentioned earlier, the former KEA was upgraded to an independent ministerial level and expanded in terms of its budgets and the number of employees. In 1987, the Korean government even changed the title of its fifth 5-year economic development plan to the "Socio-Economic Development Plan" instead of the previous "Economic Development Plan" (Han, 1991). Thus, the goal of the 5-year development plan has shifted from the simple "economic development" to "socioeconomic development" including environmental conservation (Kwon, 1987).

In addition to the organizational improvement, the former EPL was replaced with the six new environmental laws. Each of these new laws manages a specific area of the environment and provides the basis for the KMOE's environmental regulations. Table 4.5 shows the current KMOE's risk management approaches under the major environmental statutes including the six new laws.

Table 4.5 The KMOE's Risk Management Approaches under Current Environmental Laws in the Republic of Korea.

Statute	Management Approaches
Basic Environmental Policy Law (BEPL)	Set standards
Air Quality Preservation Law	Set standards
Water Quality Preservation Law (WQPL)	Set standards
Noise and Vibration Control Law (NVCL)	Set standards; ban
Hazardous Chemical Substance Control Law (HCSCL)	Ban; label
Sewage and Livestock Waste Treatment Law (SLWTL)[a]	Prevent direct environmental discharge and/or release
Environmental Dispute Settlement Law (EDSL)	Mediation for remedy

[a] The SLWTL was enacted in 1986 and amended in 1991.

Because of such changes in risk analysis culture, the Korean society has begun to recognize that the scientific approach relative to risk assessment and risk management needs to be developed for regulating the various environmental chemicals. However, it was only recently that the Korean Government began to subsidize research in this field for the purpose of developing risk assessment techniques with assistance of a few environmental scientists and toxicologists (KMOE, 1992).

Risk Assessment Techniques

Although a broad recognition of the need for formal health risk assessment guidelines has existed since the middle of the 1980s, neither the former KEA nor the present KMOE has taken any sound action in this field until recently. At present, there are no KMOE official documents providing any guidelines associated with human health

risk assessment and management techniques (KMOE, 1992). Chung et al. (1991) pointed out that the current ambient air quality standards for protecting human health and environmental damage were established without any health risk analysis process. The air quality standards were merely based on the criteria adopted by some developed countries such as Japan and the United States and the World Health Organization (KMOE, 1987). Thus, it seems that scientific-based risk assessment itself did not play any critical role in the KMOE's regulatory decision-making process.

The term "health risk assessment" has just begun to be used in environmental policy-making in both the scientific communities and the regulatory agencies (KMOE, 1992). As for risk assessment techniques, most environmental scientists in Korea have focused their research on the USEPA's risk assessment guidelines (Chung, 1988; Chung et al., 1991; Kim, 1988b). Research associated with the human health risks has been done by a limited number of scientists, mainly environmental scientists and/or medical doctors.

Because there are no explicit KMOE guidelines as well as little scientific research data, it seems that the KMOE's risk assessment methods have evolved basically from developed countries' techniques rather than from its own criteria and methods. As Korean society currently shows increasing concern over human health risks from environmental pollution, it is clear that the KMOE's risk managers will be forced to establish specific guidelines including the techniques and criteria for assessing and managing various environmental risks in the near future.

Risk Management Decision Process

The KMOE's decision process for health risk management is based primarily on its interpretation of the various Korean environmental laws. As discussed earlier, the Basic Environmental Policy Law (BEPL) of 1990 provides the fundamental goal for national environmental policy and various environmental preservation plans including environmental standards. According to the BEPL [Para.1 Art.10], the government [Minister of KMOE] should establish environmental quality standards in accordance with two criteria: 1) to preserve the pleasant environment; and 2) to protect human health. However, the law itself does not contain any explicit statement regarding the degree of protection of human health and the level of preserving the pleasant environment. As a result, environmental quality standards have been set on the basis of the KMOE's arbitrary judgement.

For instance, the KMOE has set the ambient air quality standards for the seven common air pollutants under the Implementing Decree of the BEPL of 1991. On the whole, these air quality standards were less stringent than those of the United States and Japan (See Table 3.9). But it is difficult to find out how these environmental standards were set, and it is also unclear why the KMOE set the standards above the level of other countries.

According to the Air Quality Preservation Law (AQPL) and its Implementing Decree of 1991, currently 47 pollutants including the seven common air pollutants were classified as general air pollutants. Among these, 16 air pollutants such as; asbestos, dioxin, lead and its compounds, and cadmium and its compounds were categorized as special hazardous air pollutants.

As for health risk management in air pollution regulation, the Air Quality Planning Division (AQPD) under the KMOE has the principal responsibility for the periodic review of various information associated with human health risks resulting from the air pollutants (See Appendix B). In most of the cases, the Planning and Management Office distributes the information about certain chemicals or substances to the members of the AQPD whenever they obtain some toxicological data.

The primary sources of information for health risk analysis come from foreign rather than a native origin. Foreign countries, like the United States and Japan, are the major sources of scientific information primarily through various international environmental symposia and conferences.

After the internal peer review process, a review document generated by the AQPD members is sent to the Office of Environmental Health Research (OEHR) under the NIER in order to validate the toxicological information as part of the problem identification process (See Figure 5.2). A group of scientists in the OEHR analyzes chemicals or substances to establish whether those materials are dangerous to human health and the environment. Current exposure data which are reported by the six regional offices are also reviewed. In turn, the results of OEHR's research are sent back to the AQPD along with the OEHR's advice.

Once a hazardous chemical or substance has been identified, the Bureau of Air Quality Management recommends to the Minister of KMOE the most appropriate regulatory option in order to protect human health and the environment. In general, according to the recommendation from the Air Quality Management Bureau, the Minister

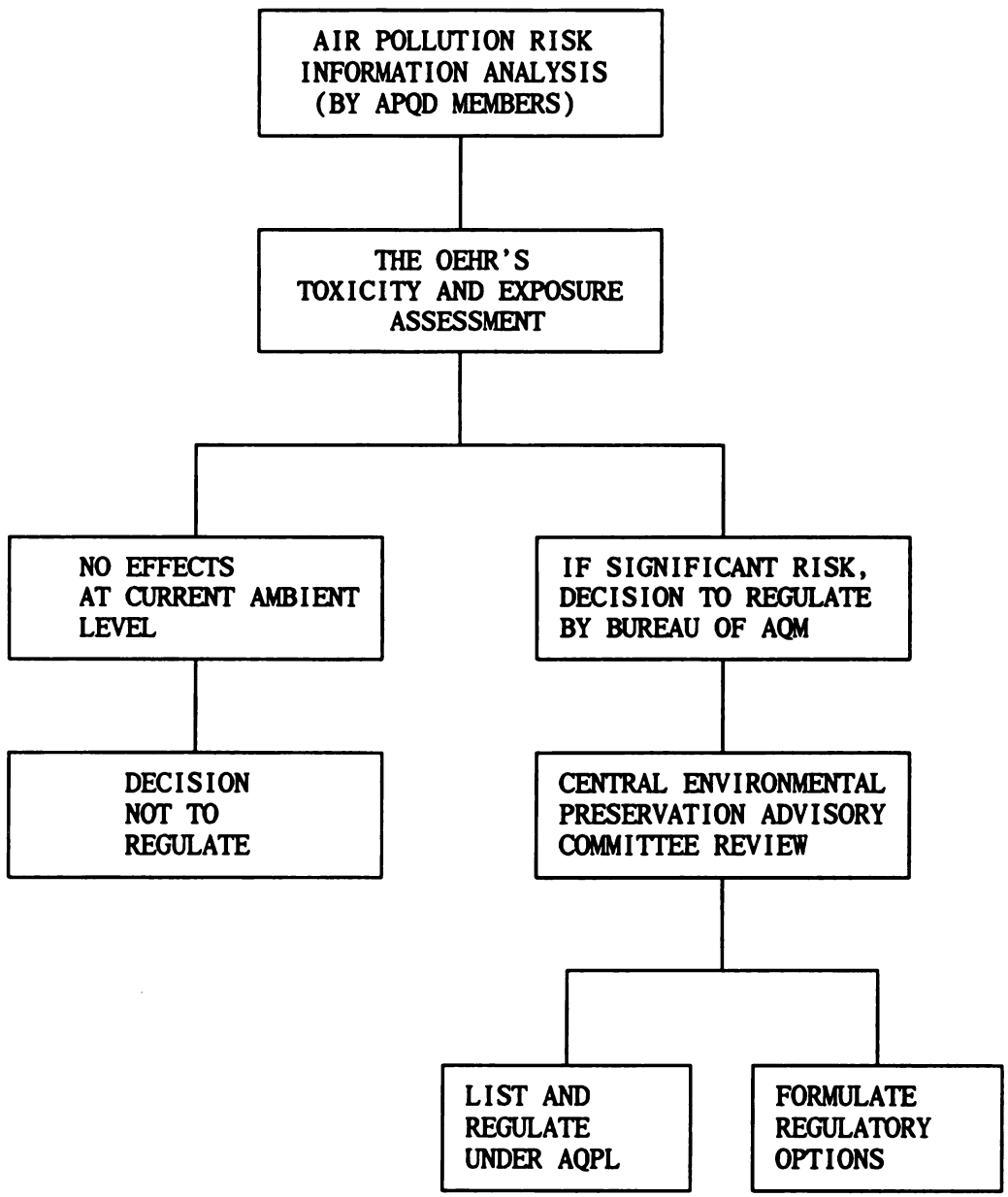

Figure 5.2 The KMOE Risk Decision-Making Process for the Management of Air Pollutants

of KMOE makes a decision of whether a suspicious chemical or substance needs to be classified as an air pollutant, and a draft document is created.

Under the Implementing Decree of the BEPL of 1990, the Central Environmental Preservation Advisory Committee (CEPAC)[10] has the authority to evaluate the draft document, and to recommend regulatory action. During this process, the CEPAC meetings are typically confidential and not open to the public. Because no requirements are placed on the CEPAC to explain publicly the reasons for their decisions, no formal opportunity is provided for the public to review or criticize the decisions and recommendations of the CEPAC. In most cases, the CEPAC's decisions depend largely on extra-scientific factors such as socioeconomic and political considerations rather than the scientific considerations (Chung, et al., 1991; KMOE, 1992). Finally, the Minister of KMOE makes a risk management decision in accordance with the CEPAC's recommendations

Consequently, the KMOE's risk management decisions are neither wholly scientific nor extra-scientific. As Somers (1984) pointed out, although the selection of the most appropriate means of responding to a specific problem may be difficult, Korean risk manager is generally required to evaluate a wide range of the scientific factors.

In summary, even though the health risks resulting from various environmental pollutants have existed in Korea since the late 1970s, the relevant techniques and the criteria for assessing and managing human health and environmental risks have not been

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[10] The 20 members of CEPAC are principally composed of academic scientists. But the chairman of the committee is always the Vice-Minister of KMOE. The committee examines the followings: 1) national environmental policy planning; 2) various environmental standards; 3) selection of special environmental preservation zone; and 4) distribution of pollution control costs (Implementing Decree of BEPL, Article 18).

appropriately developed. Most of the environmental laws have been developed on setting standards to reduce the unreasonable health risks. However, the criteria for protecting the human health risks are often ambiguous. Because of the possibility of argument about the present environmental standards, it is expected that a larger role of the NIER and the CEPAC will be required for a scientific risk analysis, for oversight of the process, and for the development of some explicit guidelines.

CHAPTER V

THE CASE STUDIES

Regulation of Sulfur Oxides and Suspended Particulates in ambient Air

Sulfur oxides[1] and suspended particulates[2] in ambient air have been widely recognized as significant human health and environmental risks (Biersteker, 1966; WHO, 1979). These air pollutants come from both natural and anthropogenic sources (Duffus, 1980; Miller et al., 1989). Today, many industrial nations including the EEC countries, the United States and the Republic of Korea, actively manage sulfur oxides and particulate pollution using various regulatory provisions (U.N. Economic Commission for Europe, 1987b).

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[1] Sulfur oxides, measured as SO_2 are sulfur dioxide and sulfur trioxide, usually emitted in a mass ratio of about 100 to 1. Sulfur dioxide is a colorless, nonflammable gas under normal environmental conditions, and sulfur trioxide is not normally found in the atmosphere because it reacts rapidly with water to form sulfuric acid. In general sulfur dioxide is of great concern to regulators.

[2] The term "Suspended Particulates" is used here to cover all small, solid particles and liquid droplets in the air. The suspended particulates are commonly measured as "total suspended particulates (TSP)" based on weight in the United States and the Republic of Korea.

In this section, sulfur oxides and suspended particulates are presented as an example of the regulation of non-carcinogenic chemicals to see how the differences in risk decision-making process affect specific regulatory outcomes in the United States and the Republic of Korea. The discussion will focus on the sources, toxicology, and the regulatory decision-making process used in both countries.

Sources of Sulfur Oxides and Suspended Particulates

Following the Industrial Revolution, it has been established that the combustion of fossil fuels and the by-products from the manufacture and use of chemicals have not only added greatly to the quantity but have also multiplied variety of pollutants in the air (UNEP, 1987). Although some sulfur oxides and suspended particulates may occur naturally in the air in large amounts, contributions from man's activities are generally of prime importance in urban areas (Miller et al., 1989; WHO, 1979). According to the World Resources Institute (1986), more than 90 percent of all sulfur in the ambient air comes from man-made emissions.

In general, the sources of sulfur oxides and suspended particulates can be divided into three broad categories: 1) domestic sources; 2) industrial sources; and 3) motor vehicles. Among these, industrial sources such as the combustion of fossil fuels, especially coal burning for power generation are responsible for most of the sulfur oxides and particulate pollution (UNEP, 1987).

The content of sulfur varies among the fossil fuels ranging from 0.1 to 0.3 percent for crude oil, and from 0.4 to 5 percent for coal (Miller et al., 1989). In 1986, the United Nations Environment Program (UNEP) estimated that on a worldwide scale

more than 100 million tons of sulfur dioxide are emitted every year, 70 percent of which result from coal burning, 16 percent from the combustion of petroleum products, and the remainder from petroleum refining and nonferrous smelting.

Table 5.1 Exposure Patterns of World Urban Populations to Sulfur Dioxide and Suspended Particulate in 1980s.

Level of Exposure	Sulfur Dioxide (Million people)		Suspended Particulate (Million people)	
Unacceptable	1,047	(44%)	1,345	(66%)
Marginal	595	(25%)	163	(8%)
Acceptable	737	(31%)	530	(26%)
Total	2,379	(100%)	2,038	(100%)

Note: WHO guidelines for air quality are used as the criteria for acceptability.
Source: World Bank (1992), p.52

Suspended particulate can result from volcanic activity, dust storms, or from strong winds blowing over the dry soil, and may include pollen from trees and other plants (UNEP, 1987; WHO, 1979). Although natural sources of suspended particulates are important, especially in arid regions with terrigenous soil and dust, artificial sources are of greater concern because particles have the potential to carry toxic trace substances including carcinogenic compounds, and the particulates themselves may be toxic (World Resources Institute, 1986). Also fine particulates can be found in aerosols in the atmosphere as secondary pollutants from gaseous emissions. The World Resources Institute (1986) reported that industrial processes and fuel combustion from stationary and mobile sources are the primary anthropogenic contributors to particulates.

Recently WHO and UNEP reported the global trends of sulfur dioxide and particulate pollution. In terms of the average annual concentrations, 27 cities out of the total 54 cities in which data are available on sulfur dioxide between 1980-84, exceeded or on the borderline of the WHO health guidelines.[3] High on the list of these cities were Tehran, Shenyang, and Seoul. A recent report by World Bank (1992) estimates that nearly a billion urban dwellers around the world are exposed to unhealthy levels of sulfur dioxide, and more than a billion to excessive levels of suspended particulates (See Table 5.1).

Table 5.2 Estimated Emissions of Sulfur Dioxide and Suspended Particulates by Source in the United States (1987) and Korea (1990).

Unit: 1000 tons/year

	Sulfur Dioxide		Suspended Particulate	
Source	U.S.	Korea	U.S.	Korea
Transportation	675	77	693	67
Industrial process	3,375	806	3,311	175
Power Generation[a]	18,450	280	3,234	67
Heating	-	336	-	101
Miscellaneous	-	112	462	10
Total	22,500	1,611	7,700	420

[a] The data from the U.S. includes heating sources.
Source: The Annual Environmental Report (KMOE, 1991). p.558-562. EPA Scorecard 1989 (USEPA, 1990). P.2.

[3] WHO guidelines for exposure limits for sulfur dioxide and suspended particulate matter are as follows: yearly and daily arithmetic average for sulfur dioxide are 40-60 and 100-150 $\mu g/m^3$, respectively, and for suspended particulate matter, 60-90 and 150-230 $\mu g/m^3$ based on the gravimetric high volume method (WHO, 1979, Environmental Health Criteria 8, p.86-92).

Despite continuous economic growth, it has been known that levels of sulfur dioxide and total suspended particulates in the air have declined significantly from the 1970s to the 1980s in many industrial countries (World Bank, 1992). In the United States, for example, annual sulfur dioxide concentrations at selected urban sites decreased 30 percent from 1970 to 1975. From 1975 to 1984, annual levels of sulfur dioxide dropped by an additional 36 percent, and that of particulates by 62 percent (Portney, 1990; USEPA, 1989). In the case of the Republic of Korea, national sulfur oxide emissions decreased by 39 percent from 1973 to 1989 (KMOE, 1991). Many Western European countries also significantly reduced their emissions in both categories from power plants, industries, and heating of the buildings (French, 1990). Table 5.2 summarizes the nationwide emissions of SO_2 and particulates in the United States and the Republic of Korea.

In general, it is believed that such reductions are the result of changing energy policies that stress the use of coal washing equipment, the conservation of energy, and the installation of dust control equipment. However, these impressive emission reductions have been offset by a corresponding increase in motor vehicle traffic since the 1960s (World Bank, 1992). In addition, the use of diesel cars, buses and trucks which generate significantly higher emissions of fine and toxic particulates, has increased in several countries.

Table 5.3 The General Characteristics of Sulfur Dioxide and Total Suspended Particulate (TSP).

Effects Category	Sulfur Dioxide (SO_2)	Total Suspended Particulate (TSP)
Health effects	Aggravates symptoms of heart and lung disease, obstructs breathing (particularly in combination with other pollutants); increases incidence of acute respiratory diseases including coughs and colds, asthma, bronchitis and emphysema	Carry heavy metals and cancer-causing organic compounds into the deepest, sensitive parts of the lung; with SO_2, can increase incidence and severity of respiratory disease
Welfare effects	Toxic to plants; can destroy paint pigments, erode statue, corrode metal, harm textiles; impairs visibility; precursor to acid deposition	Obscure visibility; soil materials and buildings; corrode metals
Major sources	Electricity generating stations, smelters, petroleum refineries, industrial boilers	Industrial Processes and combustion; about 7% from natural source (windblown dust, fires and volcanoes)
Control options	Switching to low sulfur fuel, flue gas scrubbers	Electrostatic precipitators in utility boilers, to trap particulate; cyclone collectors; bag-houses wet scrubber.

Note: Sulfur Dioxide as a gas, and TSP as solid particles or incorporated in liquid droplets. (Source: Modified from Tietenberg, 1988. p. 337)

According to the United Nations' report (1987b), many countries in the world have passed air pollution legislation since the early 1960s. However, it was not until the late 1970s that air pollution was actively managed. Table 5.3 summarizes the general characteristics of sulfur dioxide and total suspended particulate including their effects on health and welfare.

Toxicology of Sulfur Oxides and Suspended Particulates

It is well known that high levels of sulfur dioxide and particulate matter in ambient air are related to increased mortality and morbidity (Duffus, 1980; Ferris et al., 1976; Lave, 1982; Song and Shin, 1991; WHO, 1979). It is also recognized that sulfur dioxide contributes to serious material damage and particulate matter reduces visibility and contributes to property damage and soiling.

Because the respiratory tract is the most vulnerable area for effects from airborne materials, acute effects of sulfur compounds and particulate matter on both man and animals are mainly related to the respiratory system (Duffus, 1980; Lave, 1982). For example, both sulfur dioxide and particulate matter, either alone or in combination, can raise the incidence of respiratory diseases such as coughs, colds, asthma, bronchitis, and emphysema (Ferris, 1982; WHO,1979; French, 1990). Moreover, particulate matter can carry heavy metals into the deepest, most sensitive part of the lung (Duffus, 1980). In the United States, French (1990) reported that sulfur dioxide and particulate matter pollution may be responsible for as many as 50,000 deaths or about 2 percent of the total annual mortality every year.

Effects of sulfur dioxide and particulate matter on experimental animals have been examined to determine both the short-term (24 hr or less) and the long-term (more than 24 hr) exposure-effect relationships. Ferris (1982) and WHO (1979) have summarized the sulfur dioxide and particulate effects on human volunteers and experimental animals from some selected studies. According to the WHO report, when animals were exposed to sulfur dioxide alone for two hours, slight effects on respiratory function were

demonstrated at a concentration of 2.1 mg/m^3 (0.75 ppm)[4] but not at 1.1 mg/m^3 (0.37 ppm), while sulfuric acid mist affected respiratory function at levels as low as 0.35 mg/m^3. Synergistic effects on pulmonary functions were also reported from combined exposure to sulfur dioxide and hydrogen peroxide as well as sulfur dioxide and ozone (Ferris et al., 1976).

After 24-hour exposures at levels of 500 μg/m^3 of both suspended particles and sulfur dioxide, an increase in hospital admissions has been reported, especially for patients over fifty years old with cardiovascular disease (Ferris, 1982). At lower concentrations, a temporary decrease in pulmonary function has been reported. Table 5.4 summarizes the short-term health effects of 24 hr exposure to sulfur dioxide and suspended particulates. In general, the more severe responses occur at the higher pollutant concentration levels.

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[4] To convert gases to ppm or μg/m^3, one of the following equations may be used: $\mu g/m^3 = (ppm \times MW \times 10^3) / MV$, or $ppm = (\mu g/m^3 \times MV \times 10^{-3}) / MW$, where: MW=Molecular Weight, MV =Molar Volume (24.46 L /mole at 25 °C., 760 mm Hg). In this dissertation, 1 ppm of sulfur dioxide is equivalent to 2856 μg/m^3.

Table 5.4 Short-Term Health Effects of 24-Hour Exposure to the Air Polluted by Sulfur Dioxide and Total Suspended Particulate (TSP).

Effects	Sulfur Dioxide ($\mu g/m^3$)		TSP ($\mu g/m^3$)
Increase in hospital admissions of persons over fifty with cardiovascular disease	1,000	(0.38 ppm)	500
Slight increase in mortality	710	(0.25 ppm)	830 - 850
Increased symptoms in patients with chronic bronchitis	500	(0.18 ppm)	330 - 350
Temporary decrease in pulmonary function	300	(0.11 ppm)	220 - 240
Slight increase in asthmatic attacks, but these were more related to air temperature	200	(0.07 ppm)	150

Source: Modified from Ferris, 1982. p. 258.

Studies on the human health effects of chronic exposure to low levels of sulfur dioxide and suspended particulate show an increased incidence of respiratory infection (Ferris et al., 1976). At levels of 250 $\mu g/m^3$ (0.095 ppm) of sulfur dioxide and 360-380 $\mu g/m^3$ of total suspended particulate respectively, increased phlegm production has been reported (See Table 5.5). This is a particular hazard to those already suffering from respiratory deficiencies (Duffus, 1980). However, at levels of sulfur dioxide below 66 $\mu g/m^3$ and of total suspended particulate below 131 $\mu g/m^3$, no effects have been reported.

Table 5.5 Long-Term Health Effects of Exposure to Air Polluted by Sulfur Dioxide and Total Suspended Particulate (TSP).

Effects	Sulfur Dioxide ($\mu g/m^3$)	TSP[a] ($\mu g/m^3$)
Increased phlegm production	250 (0.095 ppm)	360 - 380
Increased respiratory illness in children	200 (0.076 ppm)	280 - 300
Increased lower respiratory tract illness in children	140 (0.053 ppm)	220 - 240
Increased respiratory symptoms, decreased pulmonary function in adults	55 (0.021 ppm)	180
None	66 (0.025 ppm)	131

[a] The value of TSP refers to exposure for 24-hour annual means.
Source: Modified from Ferris, 1982. p. 262.

At high levels, 1.6 ppm of sulfur dioxide will cause reversible bronchiolar constriction, and detectable respiratory effects increase above this level (Duffus, 1980). Because of the high aqueous solubility of sulfur dioxide, it dissolves in tissue water and is converted oxidatively to sulfuric acid and sulphate ions. The sulfates are much more powerful irritants than sulfur dioxide itself and the problem is enhanced by the presence of sulfate aerosols in the atmosphere wherever sulfur dioxide is produced (WHO, 1979).

Concentrations of sulfate as low as 0.002 ppm, for example, have been shown to have harmful effects on susceptible people, and it is still common for such concentrations in the atmosphere to be reached or exceeded (World Bank, 1992). Furthermore, the introduction of catalytic converter units in vehicle exhaust systems has led to an increased emission of sulfate, because the catalysts convert the trace amounts of sulfur oxides present into sulfuric acid.

Although there is some evidence that toxicants are generated either through the transformation of sulfur dioxide into other gas phase compounds or into particulate

aerosols such as sulfuric acid and acid salts, Middleton (1982) points out that more information about health effects related to specific transient or terminal transformation products is still needed. However, because the data for toxicological and epidemiological evidence of adverse health effects of sulfur oxides and suspended particulate exposure is clear, more than thirty countries in the world including the United States and Republic of Korea have set ambient air quality standards for both sulfur oxides and particulate matter to protect public health and environment (United Nations Economic Commission for Europe, 1987b).

The USEPA Approach for Sulfur Oxides and Particulates Regulation

In response to a growing awareness of human health effects due to air pollutants including sulfur oxides and particulate matter, the CAA of 1963 was passed authorizing the publication of air quality criteria as guides for municipal and state air pollution control authorities in the United States (Middleton, 1982; Rosenbaum, 1977). As a result, "Air Quality Criteria for Sulfur Oxides" was first prepared by the National Center for Air Pollution Control for the Department of Health, Education, and Welfare (HEW) in March 1967. This document was re-evaluated concurrently with "Air Quality Criteria for Particulate Matter" by the National Air Pollution Control Administration in 1969 (Middleton, 1982).

The publication of HEW's criteria documents for sulfur oxides and particulate matter was the first step in establishing air quality criteria to guide the states in developing their own standards governing these common pollutants from the combustion of fossil fuels. The criteria documents included scientific and technical data which

indicated what pollutants were associated with environmental damage and how different levels and combinations of pollutants would affect human health and the environment over specific time periods. For example, it reviewed the effects of sulfur oxides and particulate matter on materials, vegetation, and animals including human beings, and summarized the epidemiological record. According to the USEPA (1971), these documents were directly utilized to set ambient air quality standards for sulfur oxides and particulate matter.

Under the CAA Amendments of 1970, the Administrator of USEPA was given the authority to establish both National Ambient Air Quality Standards (NAAQSs) for common air pollutants and national emission standards for stationary sources and hazardous pollutants (USEPA, 1971).[5] Under the CAA Section 109, discussed in Chapter III, the primary air quality standards were chosen to protect the public health with "an adequate margin of safety,"[6] and the secondary standards were set to protect the public welfare from any known or anticipated adverse effects.

In selecting a margin of safety, USEPA considered such factors as: the nature and severity of the health effects involved, the size of the sensitive population at risk, and the kind and the degree of the uncertainties that should be addressed (USEPA, 1988). Thus

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[5] See Table 3.1 in Chapter III for the U.S. NAAQSs.

[6] The U.S. Court of Appeals for the D.C. Circuit held that the requirement for an adequate margin of safety for primary standards was intended to address scientific uncertainties and to provide a reasonable degree of protection against hazard (Lead Industries Association v. EPA, 647 F.2d 1130). The selection of any particular approach to providing an adequate margin of safety is a policy choice left specifically to the Administrator's judgement (Lead Industries Association v. EPA, 647 F.2d 1161-62).

the "margin of safety" requirement, by definition, only came into play where no conclusive showing of harm existed.

On April 30, 1971, the USEPA formally adopted the first NAAQSs for sulfur oxides and particulate matter. The numerical values for these standards were based on the original criteria documents. The guidelines considered effects on sensitive populations in compromised environments, and identified the lowest symptomatic or physiological effect level (USHEW, 1970; Middleton, 1982).

The primary standards for sulfur oxides, measured as SO_2, were set at 80 $\mu g/m^3$ (0.03 ppm) annual arithmetic mean, and 365 $\mu g/m^3$ (0.14 ppm) as a maximum 24-hour concentration not to be exceeded more than once per year.[7] The secondary standards were set at 60 $\mu g/m^3$ (0.02 ppm) annual arithmetic mean, and 260 $\mu g/m^3$ (0.1 ppm) as a maximum 24-hour concentration not to be exceeded more than once a year and 1,300 $\mu g/m^3$ (0.5 ppm) as a maximum three-hour concentration not to be exceeded more than once a year (USEPA, 1971).

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[7] Ambient air quality standards for both particulate sulfate and sulfur dioxide were also considered but rejected because of lacks of data for supporting such standards. Primary standards were scheduled to be achieved by 1975, and secondary standards "within a reasonable time"
respectively.

After court remand,[8] however, annual secondary standards were revoked by the USEPA in 1973. The standards for annual arithmetic mean and maximum 24 hr concentration were canceled. The three-hour standard, 1,300 $\mu g/m^3$ (0.5 ppm) not to be exceeded more than once per year, remained as a secondary standard.

As for the particulate matter, the original primary standard was set at the level of 75 $\mu g/m^3$ annual geometric mean, and 260 $\mu g/m^3$ as a maximum 24 hr concentration not to be exceeded more than once a year. The secondary standard was set at 60 $\mu g/m^3$ annual geometric mean, and at 150 $\mu g/m^3$ as a maximum 24 hr concentration not to be exceeded more than once a year.

In 1987 the USEPA promulgated the new particulate matter (PM) standards using PM_{10} (particles less than 10μ in diameter) as the new indicator for suspended particulates in accordance with the PM NAAQS (USEPA, 1990). According to the PM NAAQS of 1987, both the primary and the secondary standards were set at the same level; $^{5}0$ $\mu g/m^3$ annual arithmetic mean and 150 $\mu g/m^3$ as a maximum 24 hr concentration not to be exceeded more than once a year.

The basis for a 24 hr health standards derived largely from the epidemiological studies conducted in London in the 1950s and 1960s, a time when both sulfur dioxide and particulate matter were present at higher concentrations in London than in the U.S. (USEPA, 1971). Based on these studies, the USEPA staff recommended a 24 hr standard

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[8] Kennecott Copper Corporation attacked the national secondary standards for sulfur oxides, promulgated by the USEPA in 1971. The major issue was that the standards were not based on the underlying air quality criteria (U.S. Court of Appeals, D.C. Circuit, 1972, 462 F.2d 846).

for the sulfur oxides in the range of 0.14 to 0.19 ppm and for particulate matter in the range of 260 to 350 $\mu g/m^3$, respectively.

As for considering the "adequate margin of safety" provision, the USEPA Scientific Advisory Committee (SAC) for clean air recommended selection of a value in the lower portion of the range that is 0.14 ppm as a 24 hr standard for sulfur oxides and 260 $\mu g/m^3$ for particulate matter (See Table 4.4). With growing evidence of the health effects of particulate matter, however, the 24 hr standard was re-evaluated and changed from 260 to 150 $\mu g/m^3$ in 1987 (USEPA, 1989).

The USEPA also recognized that long-term standards [annual standards] for both sulfur oxides and particulate matter were necessary because the scientific data suggested that high annual sulfur oxides, measured as sulfur dioxide, and particulate exposures might lead to potential health effects not readily observed in the short-term human studies. Based on the HEW's criteria documents, the USEPA staff suggested the possibility of respiratory health effects as a result of persistent exposures to sulfur oxides and particulate matter (USEPA, 1971). The SAC also agreed that there is a need for protection against an increase in chronic exposure. Finally, the annual primary standard for sulfur oxides was set at 0.03 ppm and for particulate matter at 50 $^{\prime\prime}g/m^3$, respectively.

The basis for the welfare related 3 hr secondary standard stemmed from the studies documenting acute effects on sensitive plants (USEPA, 1973). The effects of concern included plant damage such as growth reduction, yield loss, and foliar injury. The USEPA staff assessment supported a 3 hr secondary standard on the basis of the scientific data summarized in the criteria document. After the internal peer review process, both the USEPA staff and the SAC recommended a 3 hr standard at or slightly

below 0.5 ppm although there was some evidence suggesting effects at lower levels (USEPA, 1982a).

Considering the assessment of effects on vegetation and the staff recommendations, the USEPA Administrator decided to set the 3 hr standard at 0.5 ppm to adequately protect against the damage to vegetation from high short-term sulfur dioxide level near major point sources (USEPA, 1971).

Under the Air Quality Act of 1967 and the CAA Amendments of 1970, which expanded the potential for citizen action to clean up the air, the USEPA had provided a number of opportunities to review and comment by organizations and individuals outside the Agency. For example, in the period 1967-1970, it was reported that more than 25,000 citizens participated in the public hearings required under the Air Quality Act of 1967 (USEPA, 1971). Thus, the many drafts generated by USEPA staff were made available for the external peer review process. The SAC also held a number of public meetings which were attended by many individuals and representatives of organizations who provided critical reviews and new information for consideration (USEPA, 1982a). In the United States, consequently, a broad spectrum of American society including industrialists, labor leaders, environmentalists, conservationists, civic leaders, citizens and students provided input into the selection of air quality goals for their communities.

After setting air quality standards, the next issue was setting emission standards which were at the cutting edge of the pollution abatement effort (Rosenbaum, 1977). In the United States, under the emission standards of CAA of 1970, there existed some differences between "Old" and "New" sources. As discussed in Chapter III, there had been no requirement to permit old sources until the CAA Amendment of 1990 was

passed. However, new facilities had to apply not only New Source Performance Standards (NSPS) but also must employ Best Available Control Technology (BACT). The application of BACT to all major new facilities promoted the development of air pollution control devices in the United States (Schulze, 1991).

One important impact of air pollution regulations in the United States resulted from the attack by the Sierra Club on the USEPA's approval of the state permit system for new sources.[9] It resulted in the **"Prevention of Significant Deterioration"** (PSD) program. According to the preamble of the CAA of 1970, the purpose of the Act was stated as follows:

> to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and productive capacity of its population.

In 1972, the Sierra Club interpreted the phrase "protect and enhance" to mean that no new sources could be constructed since air quality could not be allowed to deteriorate. As a result, the Sierra Club argued that the USEPA's approval of state permit systems for new sources was void.[10] In 1973, a compromise was reached whereby USEPA agreed to prevent significant deterioration (PSD). Further the CAA Amendments of 1977 expanded requirements to attain and maintain national air quality standards for sulfur oxides and particulate matter including four additional common pollutants, and to

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[9] The Sierra Club was founded in 1892 by the American naturalist John Muir. The club asserts a hard-line "preservationist" viewpoint that opposes destruction of any wilderness area for almost any purpose.

[10] Sierra Club v. Ruckelshaus, 344 F. Supp 253 (D.C. Cir. 1972).

prevent significant deterioration of air quality, especially from the sulfur oxides and particulate matter (Middleton, 1982).

In the United States, the states have fundamental responsibility for ensuring the attainment and maintenance of ambient air quality standards once USEPA has certified them. To obtain USEPA certification, under Section 110 of the CAA, states have to submit a **"state implementation plan"** which demonstrates how attainment and maintenance of such standards will be accomplished by control programs directed at sources of the pollutants involved. The states, in conjunction with the USEPA, also administer the prevention of significant deterioration program for these pollutants. In addition, nationwide reductions in emissions of sulfur oxides and particulate matter result from the Federal Motor Vehicle Control Program, which regulates automobile, truck, bus, motorcycle, and the aircraft emissions.

The regulatory history of sulfur oxides and particulate matter in the United States started off with the establishment of NAAQSs to protect health and welfare. The NAAQSs are the preeminent environmental goals which underlie U.S. control policies for sulfur oxides and particulate matter in the ambient air. They are to be set without regard to the costs of attainment much like the zero-risk approach. According, this policy differs from the control policy for non-criteria air pollutants. On the whole, various implementation plans for air quality control such as permit systems, the Prevention of Significant Deterioration program, and New Source Performance Standards with BACT requirement have worked well through the close partnership between the states and federal government.

The KMOE Approach for Sulfur Oxides and Particulates Regulation

In the Republic of Korea, air regulation was originally intended to reduce factory fumes in specific air preservation zones in the residential areas (Koo, 1985). As a result, the emission standard for managing smoke was the only regulatory criterion that existed in the early 1970s under the Pollution Prevention Law (PPL) Amendments of 1971 (KMOE, 1982).

As a result of growing evidence of environmental pollution in air and water resources throughout the nation, the Korean Government promulgated the first comprehensive environmental law, the Environmental Preservation Law (EPL) in 1977. The Ministry of Health and Social Affairs (MOHSA) had the primary responsibility for administering and enforcing the EPL of 1977. To conduct MOHSA's scientific research relative to environmental pollution, the National Institute of Environmental Research (NIER) was also established under the MOHSA's jurisdiction in 1978 (See Figure 3.2 in Chapter III).

Under the EPL of 1977, the Minister of MOHSA had authority to establish environmental quality standards including ambient air quality standards to **"preserve the pleasant environment"** and to **"protect human health"** against the environmental pollution (EPL Article 4). As a result, in February 1979, the first ambient air quality standards for sulfur dioxide were adopted formally as follows: 133 $\mu g/m^3$ (0.05 ppm) as the annual arithmetic mean, and 400 $\mu g/m^3$ (0.15 ppm) as the maximum 24-hour concentration not to be exceeded more than three times per year (KMOE, 1982).

In August, 1983, after creation of the former Korea Environmental Administration (KEA) under the EPL Amendment of 1979, the ambient air quality standards[11] for particulate matter were set at 150 $\mu g/m^3$ as the annual arithmetic mean, and 300 $\mu g/m^3$ as the maximum 24 hr concentration not to be exceeded more than three times per year (KMOE, 1986).

In contrast to the United States situation, however, there were no official criteria documents published for sulfur oxides and particulate matter in the Republic of Korea. According to the KEA report of 1982, the ambient air quality criteria for these standards were based extensively upon the "Environmental Health Criteria Document for Sulfur Oxides and Suspended Particulate Matter," which was generated by a WHO Task Group in 1976 (KMOE, 1982).[12] In order to understand the Korean regulatory decision-making process, therefore, it is necessary to review briefly the WHO's health criteria document first.

Through the evaluation of the literature on the health effects of sulfur oxides available in 1976, the WHO Task Group produced two different sets of criteria, one relating to the effects of short-term exposure as 24-hour average concentration, and the other to the effects of long-term exposure as annual means (WHO, 1979). Based on their judgment of the lowest adverse effect levels for short-term exposures, the group selected

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[11] The ambient air quality standards for carbon monoxide, nitrogen oxide, oxidants, and hydrocarbons were also set at that time. For standards for these pollutants, see table 3.9 in Chapter III.

[12] The WHO task Group on Environmental Health Criteria for Sulfur Oxides and Suspended Particulate Matter met in Geneva from 6 to 12 January 1976. This meeting was held as part of the WHO Environmental Health Criteria Program (WHO, 1979).

a 24-hour mean concentration of 500 $\mu g/m^3$ (0.18 ppm) for sulfur dioxide. This was the level at which excess mortality might be expected among elderly people or patients with pulmonary diseases. It was also concluded that a concentration of 250 $\mu g/m^3$ (0.09 ppm) for sulfur dioxide was the approximate level at which the condition of patients with respiratory disease might become worse (WHO, 1979).

For the long-term exposure criterion, the group selected an annual mean concentration of 100 $\mu g/m^3$ (0.035 ppm) for sulfur dioxide. This was the lowest concentrations at which adverse health effects such as increases in respiratory symptoms, or respiratory disease incidence in the general population might be expected (WHO, 1979).

On the basis of above evaluations, the WHO Task Group developed the sulfur dioxide guidelines for the protection of the public health as follows (WHO, 1979): 100 - 150 $\mu g/m^3$ for a 24-hour average, and 40 - 60 $\mu g/m^3$ for an annual means respectively. According to the WHO environmental health criteria document (1979), the guideline values were calculated by considering a safety factor of two below the lowest adverse concentration levels for short and long-term exposures. To account for the uncertainty surrounding their estimates, they included a range of 20 percent.

Because of the limited amount of data available, it was suggested that interim guidelines might be of the order of 60 - 90 $\mu g/m^3$ for the annual arithmetic mean and 150 - 230 $\mu g/m^3$ for the 24-hour average, respectively, although the task group did not generate any definite guideline for total suspended particulates (WHO, 1979). The range of guideline values for TSP was later generated considering the same safety and uncertainty factors applied for sulfur dioxide case. However, the WHO task group

emphasized the fact that the toxicological significance of TSP might vary depending on their chemical composition and particle size (WHO, 1979).

During the process of setting air quality standards, sulfur dioxide became the first target for air pollution abatement because its concentration in ambient air was very high at that time. In 1980, for example, the annual average concentration of sulfur dioxide in Seoul was measured at 0.09 ppm, and during winter season it reached 0.16 ppm (KMOE, 1986).

In early 1978, the Division of Air Preservation under MOHSA evaluated the WHO Task Group's guidelines for sulfur dioxide in ambient air. Two departments under the NIER, the Air Quality Research Department and the Environmental Health Research Department, also reviewed available information on the biological effects of sulfur oxides, and provided the scientific basis for decisions aimed at the protection of human health and environment from the adverse consequences of exposure to sulfur oxides in the environment (See Figure 3.2).

After careful evaluation, both staffs concluded that two standards, a short-term and a long-term standard, were necessary to preserve the "pleasant environment" and to protect "human health" under the requirements of Article 4 of the EPL of 1977. Furthermore, they reached agreement that the WHO guidelines were adequate and reasonable to protect human health from adverse effects of sulfur dioxide (KMOE,1982).

Their recommendations for sulfur dioxide standards, however, were not accepted by both the CEPAC members and the economic planners in the Korean government (Koo, 1985). In late 1978, the Minister of MOHSA announced that the WHO guidelines were too strict to achieve within a reasonable time limit, and emphasized that any

standard should to be set at a level "technically practicable and economically feasible" (Koo, 1985). As a result, the present sulfur dioxide standards, less strict than the WHO values, were included in Article 6 of the Implementing Decree of EPL in 1979.

Consequently, it seems that the current standards for sulfur dioxide were set on the basis of economic feasibility rather than on the basis of health risk assessment. As Koo (1985) pointed out, environmental policies in Korea, like many other developing countries, had been developed within the framework of economic planning as subordinate entities. In 1983, the current air quality standards for particulate matter were also set in the same manner as for sulfur dioxide. Therefore, the environmental quality standards prescribed in Article 4 of EPL were only a goal which was desirable to achieve and to maintain so as to protect human health and to conserve environment from the air pollution.

Since early 1980, as stated in Chapter III, various regulatory programs have been established to implement environmental quality standards. These are as follows (KMOE, 1982): utilization of low-sulfur containing fuels; desulfurization of flue gases; substitution of clean fuels for dirty fuels; energy conservation including heat insulation; and application of central district heating systems. In early 1981, for example, the government decided to supply low sulfur containing Bunker-C oil (1.6 % sulfur concentration) to all stationary sources in Seoul and its surrounding areas which consumed more than 1000 KL (about 264,000 gal) of Bunker-C oil per year.[13] In addition, major power plants located throughout the nation switched from high sulfur

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[13] In 1990, it is reported that the city of Seoul consumed more than 660,000 gallons of Bunker-C oil each year.

containing Bunker-C oil to low sulfur containing Bunker-C oil (less than 2.5%).[14] During the last decade, sulfur oxide emissions have been reduced significantly, and as a result, the sulfur dioxide concentration in ambient air has decreased continuously (KMOE, 1992). For instance, the annual average sulfur oxides (measured as sulfur dioxide) concentration in Seoul has dropped from 0.094 ppm in 1980 to 0.054 ppm in 1986, and to 0.043 in 1991 (KMOE, 1992). The level of total suspended particulate also has decreased significantly. The average concentration of TSP in Seoul, for example, was 216 $\mu g/m^3$ in 1985, but decreased to 121 $\mu g/m^3$ in 1991.

In addition to fuel use control, some other management methods and techniques have contributed to the implementation and maintenance of environmental quality standards in Korea. These are environmental impact statements, special combat zones, monitoring, and so on. Most of these implementation programs have been performed by the central government. On the whole, it is generally accepted that all of the methods and techniques for implementing environmental policies, directly or indirectly, have played important roles in maintaining and enforcing air quality standards in Korea.

Regulation of Benzene in the Air

In the previous case study, regulation of sulfur oxides and suspended particulate in ambient air was presented as an example of how non-carcinogenic chemical is assessed and managed by USEPA and KMOE. In this section, benzene is offered as an example of the regulation of carcinogenic chemicals. The discussion will focus on: 1) sources of

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[14] As for considering significance of air pollution and local economic impact, the government set the two different values of sulfur concentrations in Bunker-C oil.

benzene in the air, 2) the basic concepts of benzene toxicity, especially leuchemogenicity, and 3) the regulatory decision-making process as used in USEPA and KMOE. In addition, the formal risk assessment performed by the USEPA's Carcinogen Assessment Group (CAG) will be outlined to examine how it affected the USEPA's risk management decision.

Sources of Benzene in the Air

Since benzene[15] was discovered in 1825 by Michael Faraday, it has been used in many different industries as a multipurpose solvent, a fundamental unit in organic synthesis, and a component of fuels (Bartman, 1982). Benzene (C_6H_6) is a clear, colorless, flammable liquid at room temperature, and has an aromatic odor. The liquid is volatile with vapor pressure of 100 mm Hg at 26.1 °C (Howard, 1990). Thus, benzene's volatility contributes to both its utility as a solvent and its easy transport in the environments. Benzene is also readily biodegradable in the presence of activated sludge (Ikeda, 1988).

Benzene occurs naturally in substances such as natural gas, crude oil, and plant volatiles (Howard, 1990; Kamrin, 1988). Originally, commercial production of benzene was based on recovery from both coal and petroleum sources. Today, most production of benzene is based on refinement from petroleum (IARC, 1983). It is estimated that more than 90 percent of benzene production in the United States and 85 percent of that

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[15] The chemical and physical properties of benzene are as follows: boiling point: 80.1 °C, melting point: 5.5 °C, molecular weight: 78.11, log octanol/water partition coefficient: 2.31, water solubility: 1791 mg/L, vapor pressure: 95.19 mm Hg at 25 °C, Henry's Law Constant:5.43 x
10^{-3} atm-m^3/mole (Howard, 1990).

in Korea are from petroleum sources (IARC, 1983; KMOE, 1987). According to a report from the United Nations (1987a), total world production of benzene reached around 17.6 million tons in 1985. In the same year, the Unites States produced about 5 million tons of benzene (28 % of world total production) and the Republic of Korea 170 thousand tons (1% of world total production), respectively.

Benzene is used as a raw material for the production of various chemicals such as cyclohexane, cumene, ethylbenzene, styrene, nitrobenzene, maleic anhydride, and chlorinated benzenes as well as detergents and pesticides (Bartman, 1982; Ikeda, 1988). It is also used in a variety of industries such as printing, rubber fabricating, varnish, and adhesives (Kamrin, 1988). Its application as an organic solvent is very limited. In Japan, for example, Ikeda (1988) reported that the amount of benzene used as solvent is less than 1 percent of its total production.

Benzene enters the atmosphere primarily from fugitive emissions and exhaust connected with its use in gasoline (Howard, 1990). The next most important source is emissions associated with its production and use as an industrial intermediate. In general, automobile gasoline contains benzene at various concentrations. For example, gasoline contains benzene at average 0.8 percent in the U.S., 1.4 percent in Japan, and 5 percent or more in Korea and Europe (Brief et al., 1980). In the United States, benzene comprises about 4 percent of the total automobile exhaust from a gasoline engine (USEPA, 1983). Table 5.6 shows the amounts of annual benzene emissions from selected sources in the United States.

Table 5.6 U.S. Annual Benzene Emission from Selected Sources.

Unit: Thousand tons/year

Sources	Emission of Benzene	Remarks
Gasoline	40 - 50	
Production of other chemicals	44 - 56	
Indirect production	23 - 79	coke oven, oil spills, etc.
Production from petroleum	1.8 - 7.3	
Solvents and miscellaneous use	1.5	
Total	110.3 - 193.8	

Source: International Agency for Research on Cancer (IARC), 1983. p.93.

Atmospheric concentrations of benzene vary from country to country, and even within a country, especially between urban and rural environment. In the United States, during 1977-1980, for example, the average concentration of benzene was 1.4 ppb in rural areas and 2.8 ppb in urban areas, respectively (Howard, 1990). In the Republic of Korea, currently there are no nation-wide monitoring data available associated with concentration of benzene in air. However, Chung et al., (1991) reported recently that atmospheric concentrations of carcinogenic chemicals, including benzene, in metropolitan area of Seoul are high enough to cause significant health risks.

When benzene is released to the atmosphere, it generally exists predominantly in the vapor phase. As Howard (1990) reported, gas-phase benzene reacts with the photochemically produced hydroxyl radicals with a half-life of 13.4 days; calculated using an experimental rate constant for the reaction. If the atmosphere contains nitrogen oxides or sulfur dioxide, the reaction time in the atmosphere is accelerated and the half-life is reduced to 4-6 hours (Howard, 1990). As a result of the photooxidation reaction,

phenol, nitrophenols, nitrobenzene, formic acid, and peroxyacetyl nitrate will be produced as final products. In addition, it is known that benzene can be removed from the atmosphere by wet deposition because benzene is fairly soluble in water.

Toxicology of Benzene

Since its discovery in the 19th century, it has been recognized that benzene is causally related to two major hematological disorders: aplastic anemia[16] and acute myelogenous[17] leukemia (Goldstein, 1985b; Harigaya et al., 1981; Laskin and Goldstein, 1979; Snyder and Kocsis, 1975; Snyder et al., 1980). The respiratory route is believed to be the major source of human exposure to benzene in the work place as well as gasoline vapors, and automobile emissions. Because the majority of benzene is lost during production escapes into the atmosphere, inhalation is the major route of human exposure. Thus, benzene toxicity is most frequently caused by inhalation of benzene in the ambient air (Laskin and Goldstein, 1979).

Aplastic anemia, which has a 50 percent mortality rate, results from the toxic effect of benzene upon bone marrow precursor cells resulting in the decrement in all of the formed elements of the blood such as red blood cells, white blood cells, and platelet (Snyder and Kocsis, 1975). General symptoms of mild anemia are fatigue, dizziness, headaches, and shortness of breath. Lesser forms of aplastic anemia are generally known

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[16] Anemia refers to a diminution in the number of red blood cells and/or in the amount of available hemoglobin.

[17] Myelogenous refers to blast cells in the myeloid cell line, which give rise to all of the blood cell types except lymphocytes.

as pancytopenia.[18] Recovery is likely in a mild case of pancytopenia if benzene exposure is halted, although there have been a few reports of leukemia developing after apparent full recovery (Bartman, 1982).

There is also much evidence that supports the causal relationship between benzene and human acute myelogenous leukemia (Goldstein, 1985b; Harigaya et al., 1981; Snyder and Kocsis, 1975; Snyder et al., 1980). It is generally accepted that a benzene-induced aplastic anemia is gradually changed into preleukemia and then into frank acute myelogenous leukemia. According to Aksoy (1980), for example, occupational exposure to a benzene-containing glue in the Turkish leather industry led to cases of aplastic anemia and then of acute myelogenous leukemia. It was found that replacement of benzene-containing glue led to a decrease in the incidence of these disorders in the population.[19] Thus, it has been concluded that myelogenous leukemia is the terminal stage of pancytopenia (Bartman, 1982).

Laskin and Goldstein (1979) reported that benzene's influence on the blood-forming tissues may weaken the human immunological system. As a result, the immunological defenses may be overwhelmed by other disease. Thus, it is suggested that benzene may allow the development of acute myelogenous leukemia by hampering the immune surveillance function that normally weeds out abnormal cells. However, there is evidence that a relatively small percentage of workers with pancytopenia will develop serious effects, even if occupational conditions are improved (Snyder et al., 1980).

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[18] Pancytopenia means the diminution of all types of blood cells.

[19] After banning the use of benzene-based glues in the late 1960s, Aksoy (1980) reported that the incidence of leukemia among shoe workers declined markedly by the mid-1970s.

Relative to the dose-response relationship, Goldstein (1985b) reported that the effect of benzene on the hematopoietic system follows a standard dose-response curve with an apparent threshold in animals. For severe pancytopenia cases, which may be accompanied by hemorrhagic effects, a similar dose-response effect including a threshold appears to occur in humans with the possibility of fatal bleeding (Laskin and Goldstein, 1979).

While the association of benzene with changes in the human hematopoietic system seems well established, Bartman (1982) indicated that the data at relatively low doses are insufficient to determine the shape of the dose-response curve. Although animal studies have given insight into the mechanism of benzene's effects on blood, the inconsistent results of past animal studies have led to uncertainties about dose-response.

In the case of acute exposure at high doses, benzene also affects the central nervous system, quickly inducing a light anesthesia followed by depression and respiratory failure (Bartman, 1982; Snyder et al., 1980). According to Bartman (1982), the narcotic threshold is 1,000 ppm and acute toxic effects follow exposure to concentrations below 10,000 ppm. A subacute dose leads first to change in the bone marrow, slowing the maturation process of red blood cells, and inhibiting the production of white blood cells (Bartman, 1982; Snyder et al., 1980). The 1000 ppm threshold level has served as the basis for past benzene standards, especially for occupational levels in workplace air.

Table 5.7 Experimental Results of the NTP Bioassay of Benzene in Rats.

Sex	Dose (mg/kg)	Incidence of tumors (percentage)[a] Carcinoma (Zymbal gland)	Squamous cell Carcinoma (skin)	Squamous cell Papilloma (skin)	Squamous cell Carcinoma (oral cavity)
Male	0	4	0	0	0
	50	12	10	4	18
	100	20	6	2	32
	200	34	16	10	38
Female	0	0	-	-	2
	25	10	-	-	10
	50	10	-	-	24
	100	28	-	-	18

[a] Rats were exposed in groups of 50 to benzene in corn oil by stomach tube at the doses listed, 5 days per week, for 103 weeks.

Source: National Toxicology Program (NTP), Technical Report on the Toxicology and Carcinogenesis Studies of Benzene in F344/N Rats (U.S. Department of Health and Human Services, 1983).

Chronic benzene exposure is associated with both the occurrence of pancytopenia and interference with cell production in the marrow (Laskin and Goldstein, 1979; Snyder et al., 1980). It is believed that exposure to benzene may shorten the survival of the circulating cells and reduce the counts of particular cell types or combinations of cell types (Snyder et al., 1980). In chronic inhalation studies, however, attempts to set up a correlation between concentrations and effects of benzene have produced inconsistent results.

Despite some clear evidence that benzene is genotoxic, benzene had been consistently negative in all short-term bacterial and mammalian tests for genetic effects until the late 1970s (Snyder et al., 1980). Tice et al. (1980) only found that the compound promotes sister chromatid exchange both in vitro and in vivo. However,

according to the recent research of Maltoni (1986) in Italy and of the Department of Health and human Services (1983) in the United States, benzene was shown to be a carcinogen in laboratory animals in organs unrelated to the hematopoietic system. Inhaled benzene appeared to induce four types of tumors including zymbal gland tumors, liver tumors, mammary tumors, and lymphoreticular leukemia. This result raised the possibility that benzene might also pose carcinogenic risk to different human organs through completely different mechanisms. Table 5.7 summarized the NTP's experimental results of benzene toxicity tests in rats.

Consequently it seems clear that humans and animals exposed to benzene suffer damage to their bone marrow. Most of epidemiological studies and case reports have shown that relatively high exposures to benzene in the workplace caused deaths from aplastic anemia and leukemia. It is generally accepted that most toxic effects of benzene on humans are caused by inhalation of benzene in the air. In spite of much evidence of benzene toxicity, there is still disagreement over whether relatively low exposures can cause human deaths. This sort of uncertainty makes it difficult to set emission standards for various sources. The next two sections will discuss how the USEPA and the KMOE reached their regulatory decisions for benzene as a known human carcinogen.

The USEPA Approach for Benzene Regulation

The history of benzene regulation, especially in the workplace, is relatively long in the United States. Before the USEPA addressed the regulation of benzene emissions in the late 1970s, the American Council of Government Industrial Hygienists (ACGIH) recommended a benzene exposure limit of 100 ppm in 1946 and the Occupational Safety

and Health Administration (OSHA) set the standard of 10-ppm as the benzene exposure limit for the workplace in 1971 (Kamrin, 1988).[20]

Regarding the USEPA's involvement in the benzene regulation, the Office of Air and Radiation and the Administrator of USEPA has considered benzene emission control under the CAA. Under Section 112 of the CAA, as discussed in Chapter III, the USEPA has authority to evaluate the potential adverse effect of chemicals present in the air, the so called hazardous air pollutants. Based upon a consideration of such effects, the USEPA Administrator can promulgate emission standards from specific sources and consider the technical feasibility and costs of control as decision-making criteria (Merrill, 1986).[21] These emission standards must provide "an ample margin of safety" to protect the public health from such hazardous air pollutants.

After benzene was listed among the ten high-volume industrial chemicals in 1975, fast assessments were undertaken by the USEPA (Goldstein, 1985a). In order to set regulatory priorities,[22] the assessments considered the sources of emissions, the populations exposed, and the potential control technology. Subsequently, the USEPA

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[20] With the growing evidence implicating benzene as a human carcinogen, however, the OSHA proposed a 1 ppm standard in 1977 and suggested 0.5 ppm as an action level in 1985.

[21] This differs from the approach used for control of the so-called criteria air pollutants such as sulfur dioxide and particulate matter in which the initial focus is on setting a national ambient standard, not on controlling specific sources of emissions, and for which costs are not considered.

[22] The USEPA policy recognized that, to maximize the public health benefits obtainable with limited resources, priorities should be established with respect to both the listing procedures and the development of standards.

identified benzene as a high priority based on the biological hazards and the environmental impacts of benzene's toxicity (Merrill, 1986).

In 1976 the National Institute of Occupational Safety and Health (NIOSH) recommendation that an emergency standard be issued for benzene added momentum to the USEPA's effort. Furthermore, on April 4, 1977, the Environmental Defense Fund petitioned the USEPA to list benzene as a hazardous air pollutant under section 112 of the CAA. Following consultations with the OSHA and NIOSH, the USEPA finally listed benzene as a hazardous pollutant on June 8, 1977 in response to the petition.

In 1978 the CAG of the USEPA Office of Research and Development performed an assessment of benzene's leukemogenic risk which was published in "Assessment of Health Effects of Benzene Germane to Low-Level Exposure." Also the Stanford Research Institute, commissioned by the USEPA, published an "Assessment of Human Exposure to Atmospheric Benzene" including the uncertainty resulting from the paucity of information used and the exposure modeling technique employed (Anderson, 1983). These assessments primarily depended upon three epidemiological studies as follows: Muzaffer Aksoy in Turkey in 1978; M.Gerald Ott of DOW Chemical Company in 1978; and Peter F. Infante of NIOSH in 1977.[23]

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[23] For more detailed information about these epidemiological studies, see Bartman (1983), "Regulating Benzene," pp. 120 - 134.

Table 5.8 Carcinogenic Potency of Benzene Based on Nonlymphatic Leukemia Mortality Rates.

Database	Lifetime risk (per ppm)	Lifetime risk (per $\mu g/m^3$)
Infante et al. (1977)	1.33×10^{-2}	4.09×10^{-6}
Aksoy (1978)	1.82×10^{-2}	5.60×10^{-6}
Ott et al. (1978)	4.64×10^{-2}	1.43×10^{-6}
Geometric mean	2.23×10^{-2}	7.08×10^{-6}

Note: Lifetime risk were calculated based on the unit ppm or $\mu g/m^3$ of benzene in air (Modified from Goldstein, 1985a. p.297).

For calculating the unit risk numbers, the CAG quantitative risk assessment was based on extrapolation to low exposures on the axis of the linear nonthreshold model. Table 5.8 summarized the assessments of individual health risk calculated from the three epidemiological studies. As shown in Table 5.8, the mean lifetime risk computed from the three epidemiological studies was 2.23×10^{-2} per ppm; that is equivalent to 7.08×10^{-6} per $\mu g/m^3$. The CAG also found that epidemiological studies demonstrated reasonably good agreement with the assessments done on animal studies.[24] These data were directly used by the USEPA as the basis for the benzene emission control strategies from various sources proposed in 1980 (Bartman, 1982; Goldstein, 1985a). As a first step, the USEPA proposed a "National Emission Standard for Hazardous Air Pollutants; Benzene Emissions from Maleic Anhydride Plant" on April 18, 1980. This was done because maleic anhydride plants ranked high on the priority list. It was estimated that the proposed standard would require 97 percent control (100 % for new plants) of benzene emissions with best available technology from maleic anhydride plants (Goldstein,

[24] The mean of the lifetime risk estimations derived from animal studies revealed 2.4×10^{-2} per ppm (7.3×10^{-6} per $\mu g/m^3$).

1985a). Consequently, it was expected to result in 0.03 to 0.19 death a year and estimated to cost $6.6 million in capital, $2.5 million in additional annual costs, possibly lead to one plant closing, and cause a 1.2 percent price increase for maleic anhydride (Bartman, 1982).

Hearings on this proposed standard were held in August, 1980. Comments by interested parties included the claim that using the same data and modified assumptions, the USEPA's risk assessment model showed that the risk of benzene exposure at ambient levels was not significant (Bartman, 1982). Subsequently the USEPA did not make its maleic anhydride standard final, but did propose standards for other emission sources. For the same reasons, the national emission standards for both ethyl benzene and styrene plants and benzene storage vessels were also withdrawn. Regarding the individual risk from these three sources, it was estimated that the number of leukemia cases saved range from 0.0051 to 0.015 per year, which means from one case per 200 years to one case of leukemia per 66 years (Goldstein, 1985b).

After review of the various data generated by the CAG and the other agencies, in June 1984 the USEPA Administrator promulgated national emission standards for fugitive sources of benzene. It was estimated that benzene fugitive emissions might produce 0.45 leukemia cases per year and the proposed control measures would decrease that to 0.14 estimated cases per year. In addition, the national benzene emission standards for coke by-product recovery plants were proposed but no further action has been taken because it would cost $30.9 million in capital but would save only $1.3 million per year. Moreover, the Reagan Administration left USEPA's proposed policy for the carcinogenic air pollutants to die without adoption until late 1980s.

By 1986, the Agency had become less reluctant to list hazardous pollutants but bolder in reinterpreting the statutory standards for control measures. It declined to propose controls for pollutants whose risk was assessed as not "significant," based on qualitative risk assessment. For hazardous pollutants and/or sources warranting control, the USEPA identified the level of control achievable with "best available technology," and then considered whether more stringent controls should be warranted in light of the residual risks and added costs (Lee, 1988).

By 1989, the USEPA had issued new rules cutting 20,000 tons of benzene emissions annually from industrial sources. Also it is expected that the proposed rules for additional industrial sources of benzene may cut benzene emissions by another 14,000 tons annually. In summary, industrial benzene emissions for sources covered would be reduced by 90 percent from 1988 emission levels (USEPA, 1990). Currently benzene emission sources from petroleum refineries and chemical manufacturing plants are controlled as follows: monthly monitoring of valves and pumps; installation of leak-prevention equipment; and repair of leaks within 15 days.[25]

Consequently, the benzene case in the United States provides an excellent example of the use of risk assessment for risk management purposes. The quantitative risk assessment, developed after the listing of benzene in 1977, has been used as supplementary evidence in support of a finding of significant risk. It helped the USEPA to set priorities for regulation of particular source categories and to determine the degree of control required in final emission standards for those source categories. Thus, the

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[25] Code of Federal Regulations, Title 40, Part 61.

USEPA has used the quantitative risk assessment technique in a general balancing of the risks and costs of options to arrive at its final standard.

The subsequent history of the USEPA's quantitative risk assessment indicates the ultimate limit on the use of quantitative method. The commenters at the USEPA's maleic anhydride hearings, having criticized specific assumptions underlying the USEPA's calculations, concluded that the same data, but under somewhat modified assumptions, would show that in fact, no risk is associated with atmospheric exposure to benzene. Some of the USEPA's assumptions were necessarily influenced by its policy of conservative interpretation of risk. Therefore, it is safe to conclude that once a quantitative showing of risk has been factored into the decision-making process, the judgement on whether the risk is significant is basically a matter of policy.

During the reaching of its regulatory decision, in general, it seems that risk assessment and risk management have been separated functionally. Majority of scientific-based risk assessments has been performed by the CAG of Office of Research and Development but policy-oriented risk management has been taken place in the Office of Air and Radiation and the Administrator of the USEPA. However, choice of carcinogenicity model is a risk management decision. It seems that the USEPA scientific staffs dealing with the benzene issue did not feel any political pressure for the listing of benzene as a hazardous air pollutant.

The KMOE Approach for Benzene Regulation

In the Republic of Korea, as discussed in Chapter III, four ministries have been responsible for the regulation of chemicals used for various purposes. These are

MOHSA, MOL, MAF, and KMOE. The regulation of benzene started with the setting of exposure limits for workers by MOL. Under the Industrial Safety Preservation Law (ISPL) of 1980, the MOL has the authority to regulate chemicals which are common in workplaces in order to protect occupational safety and health for workers. In 1982 the MOL set the benzene level of 10 ppm as the threshold limit value (TLV)[26] for employees who work in benzene production industries. Currently 52 chemicals are listed as occupational hazardous chemicals under ISPL. Some examples are ammonia, carbon monoxide, carbon disulfate, PCB, particulates, and so on.

Before the creation of KMOE in 1990, the Administrator of the former KEA was responsible for setting emission standards for various environmental pollutants under the EPL Amendment of 1983. Thus, emission control was the most popular technique in the air pollution abatement policy in the Republic of Korea (Koo, 1985). The establishment of emission standards was considered by many policy makers to represent an ideal legislative approach, because theoretically it may be left to the owner's discretion in choosing the type of equipment or fuel to be used. On the whole, the Korean environmental law specifies 1) types of pollutants, 2) emission standards, 3) types of sources to be controlled, and 4) methods of measuring pollutants (Koo, 1985).

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[26] TLV is defined as airborne concentrations of substances that represent conditions under which it is believed that nearly all workers may be exposed day after day without adverse effect (Andrew and Snyder, 1986). In general TLVs are calculated based on the best available information from industrial experience, and studies in animals and in human volunteers. Currently benzene TLVs vary from country to country: Hungary 6 ppm; USA 10 ppm; UK 50 ppm; Italy 25 ppm; Poland 31 ppm; Switzerland 10 ppm (Howard, 1990). Most of these countries set TLVs in the early 1970s.

Under Article 2 of the EPL Implementing Decree of 1983, benzene was listed in "General Environmental Pollutants."[27] Among the 55 general environmental pollutants, 17 chemicals were classified into "Special Hazardous Pollutants"[28] under Article 4 of the EPL Implementing Decree. As shown in the sulfur oxide and particulate case, for national ambient air quality standards the six common air pollutants were set in the early 1980s (See Table 3.5).

It is interesting that benzene was not listed as a special hazardous pollutant. There were no explicit statements as to why benzene was not categorized as a special hazardous pollutant. It seems that there was not enough information relative to benzene toxicity and exposure at that time to make a decision.

With respect to the KEA's benzene regulation, the Bureau of Air Quality Management and the KEA Administrator had primary responsibility for benzene emission control under the EPL Amendment of 1982 (KMOE, 1987). Due to the lack of nation-wide monitoring data, however, in 1983 the Director of NIER recommended that the Administrator of KEA set a temporary emission standard until the six regional environmental monitoring offices could aggregate additional information relative to benzene concentration in the ambient air (KMOE, 1987).

Based upon the NIER's recommendation and the KEA's judgement, a temporary emission standard from all sources including using or producing benzene, was set at 200

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[27] According to the Article 2 of the EPL Amendment of 1982, pollutant was defined as "the substances which cause air pollution, water pollution, and soil pollution."

[28] Under Article 13 of the EPL Amendment of 1982, the special hazardous pollutants were defined as "the substances which cause the risks to human health, welfare, and farm products directly or indirectly."

ppm in 1984 (KMOE, 1987). However, no further action was taken until 1990. It is of note that the temporary standard was established not on the basis of health risk analysis, but just on the basis of economic and technical feasibility. Similar to the USEPA case, the KEA Administrator did not set any quantitative standards which would directly regulate the levels of benzene in the ambient air.

Due to the growing complexity of environmental problems, in 1990 the former KEA was upgraded to cabinet level - Korea Ministry of Environment, and the mode of environmental legislation changed from the eclecticism to pluralism. The former EPL was a single legislation but with several sections responsive to different kinds of pollution and environmental policies. In late 1990, the former EPL was replaced by six new laws (See Table 4.5). This legislative approach is very similar to the U.S. mode of environmental legislation. Under the new Air Quality Preservation Law (AQPL) of 1990, 47 pollutants were listed as **"General Air Pollutants,"** and benzene was one of those pollutants. Among those, 16 were listed as **"Special Hazardous Air Pollutants"**[29] but again benzene was not listed in this category.

Under Articles 8 and 31 of the AQPL, the Minister of KMOE has the authority to set emission standards for general air pollutants either from stationary sources or mobile sources. According to the Implementing Decree of the AQPL, among 47 general air pollutants, emission standards have been set for total 25 air pollutants, 16 gas-type substances and 9 particle-type materials.

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[29] Under the Article 2 of AQPL of 1990, the special hazardous air pollutant is defined as "air pollutant which cause risks to human health, welfare, and animal and/or plant growth directly or indirectly."

Table 5.9 Emission Standards for Some Selected Chemicals Listed in Gas-typed Substances in the Republic of Korea.

Pollutant	Emission sources	Emission standards (ppm)		
		until 1994	1995-1998	after 1999
Ammonia	Chemical fertilizer manufacturing industries	150	100	50
	Dye manufacturing facilities	100	70	70
	Others	200	200	100
Chlorine	Incineration facilities or incineration boilers	80	60	60
	Others	10	10	10
Carbon disulfate	Rayon yarn manufacturing industries	100	100	80
	Others	30	30	30
Formaldehyde	All emission facilities	20	20	20
Phenol	All emission facilities	10	10	10
Benzene	All emission facilities	50	50	50

Source: The Implementing Decree of the AQPL of 1991 (Hong, 1992).

Considering economic and the technological factors, the KMOE has set emission standards differently for various the sources and applied different phases for its application (See Table 5.9). Considering economic and technological factors, the time for implementation is broken down into three phases ie. until 1994, 1995 - 1998 and after 1999. In the case of benzene, for example, the KMOE has set the emission standard at the level of 50 ppm from all sources through all three phases of application. Table 5.9 summarizes the emission standards for some selected chemicals under the Implementing Decree of the AQPL of 1991.

As another technique of controlling benzene emission in the ambient air, the KMOE started to regulate the benzene concentration in gasoline in 1990. Under the Section 87 of the AQPL Implementing Code, the KMOE has the authority to control fuel additives. As a fuel additive, the concentration of benzene in gasoline is limited to less than 6 percent by volume between 1993 to 1995, and less than 5 percent after 1996 (KMOE, 1992). But no reason has been stated anywhere why different levels of benzene concentration has been set.

In summary, benzene was designated as an general air pollutant under the AQPL Implementing Decree of 1991, and the emission standards to limit the amount of benzene in the air was promulgated for all industrial sources using or producing benzene. Also, the concentration of benzene in gasoline has been regulated since the early 1991. However, because of limited information about benzene exposure in the ambient air, currently there is no quantitative standard which directly regulate the levels of benzene in the ambient air.

The emission standards generally require process changes, emission control devices, monitoring, and other activities designed to reduce emissions from target sources. Although the KMOE approach covers all sources as control targets, it is difficult to learn which sources meet current standard due to the lack of monitoring data. Consequently, it seems that decision-making process is to let the determinations of benzene's risk emerge not from the scientific process but from the administrative process. Moreover, the government does not feel compelled to explain its analysis of the scientific and policy issues on benzene in explicit detail.

CHAPTER VI

DISCUSSION AND CONCLUSIONS

Regulatory Frameworks

In both the United States and the Republic of Korea, the role of government in managing human health and environmental risks has increased remarkably during the past three decades. This was accomplished by first setting up the legislative framework, and then creating the institutions to deal with these risk management responsibilities. Both institutions and laws played critical roles in the regulation of environmental risks in both countries.

Legislative Framework

With respect to air pollution regulation, as discussed in Chapter III, the CAA Amendments of 1970 were the most important pieces of legislation for controlling nation-wide air pollution problems in the United States. By virtue of this legislation, the federal government assumed a much larger and stronger, direct role in human health and environmental risk management.

The central focus of CAA was on the regulation of the most common air pollutants (criteria pollutants) during the 1970s. Under the CAA, for example, the USEPA Administrator established NAAQSs for six common air pollutants; sulfur

dioxide, particulate matter, carbon monoxide, nitrogen oxide, ozone, and lead during the 1970s (See Table 3.1 in Chapter III). These standards set legal ceilings on the allowable concentration of the pollutant in the ambient air averaged over a specified time period. The primary standard was designed to protect human health and the secondary standard was designed to protect other aspects of human welfare.

Recognizing the possible harm from localized emissions, the CAA also set up a special process for dealing with hazardous pollutants. Under the Act, the USEPA Administrator was given the authority to make and periodically update a list of hazardous pollutants. By 1980, the USEPA had listed seven hazardous air pollutants: mercury (1971), beryllium (1971), asbestos (1971), vinyl chloride (1975), benzene (1977), radionuclides (1979), and inorganic arsenic (1980). As discussed in benzene case study, however, some sources of these pollutants still remain unregulated.

In the Republic of Korea, the EPL served as the first comprehensive environmental legislative framework after it was passed in 1977. The EPL covered the following areas of the environmental pollution: air, water, soil, and noise. After the passage of the BEPL and AQPL in 1990, the KMOE was given the primary authority to control air pollution under these two laws. The BEPL, which clarified the nation's fundamental environmental policy, invested the central government with more power in this area and enlarged the categories of pollution to be controlled.

Starting with the sulfur dioxide standard in 1979, the ambient air quality standards for six additional pollutants were also set during the 1980s. These are: particulate matter, carbon monoxide, nitrogen oxide, oxidants as ozone, hydrocarbons, and lead. These seven common air pollutants are regulated currently under the BEPL of 1990 (See Table

3.5). For more than 10 years, the standards have served as the national environmental administrative goals for ambient air quality. These standards were not legal ceilings on allowable ambient concentrations but rather limits to be achieved in the future. There was no indication of the specific timetable provided in the legislation. In addition to common air pollutants, twenty five general air pollutants such as benzene, chlorine, formaldehyde, and phenol are considered hazardous and their emission sources are controlled with permissible emission standards set under the AQPL of 1990 (See Table 5.9).

Comparing the NAAQSs of both countries, it can be seen that the substances regulated in the United States and Korea are exactly the same except for the hydrocarbon. However, the air quality standards for each pollutant are slightly different. For example, the United States NAAQS for particulate matter is 50 $\mu g/m^3$ annual arithmetic mean level and 150 $\mu g/m^3$ 24-hour mean level, respectively. But the Korean NAAQS for total suspended particulate is 150 $\mu g/m^3$ annual arithmetic mean and at 300 $\mu g/m^3$ 24-hour mean level, respectively. Furthermore, in the United States, the 24-hour standard is attained when the expected number of days per calendar year above 150 $\mu g/m^3$ is equal to or less than 1. In the case of Korea, however, the 24-hour standard is attained when the expected number of days per calendar year above 300 $\mu g/m^3$ is equal to or less than 3. In most cases, the Korean NAAQSs are less strict than those of the US. It seems that these differences stem primarily from differences in the application of "the margin of safety" to protect human health and the environment.

Institutional Framework

Since the beginning of the 1930s, the need to protect human health from the adverse effects of chemicals in the workplace, the marketplace, and the environment has been recognized in the United States. The first risk management action was taken in the area of the workplace safety with the setting of permissible limits for toxic chemicals based in the concept of acceptable levels of exposure to chemicals (Paustenbach and Langner, 1986). With respect to the prevention of human health risks from environmental pollution, the creation of the USEPA as an independent agency in 1970 was the turning point for active management of environment in the United States.

Since its creation, the USEPA has enforced the pollution regulations in the areas of air, water, solid waste, pesticides, radiation, and toxic substances (Portney, 1990; Schulze, 1991). The major role of the USEPA was to abate and control pollution by monitoring, standard setting, and enforcement activities. The Agency has also coordinated and supported research on environmental problems (USEPA, 1986f).

The ten regional administrators throughout the nation have had the primary responsibility for carrying out the national environmental program objectives. They have served as the Agency's representatives in each respective region and kept contact with the various groups representing academic institutions, the environment, industry as well as public and private groups.

The Republic of Korea, although the first Pollution Prevention Law was passed in June, 1963, the creation of any institution to deal with pollution problems did not take place until 1973. In March, 1973, the first pollution control division was organized as part of the Bureau of Sanitation under the MOHSA. Later, this bureau was renamed the

Bureau of Environmental Management with three divisions in the areas of environmental planning, air pollution control, and water pollution control (Koo, 1985).

However, it is generally believed that the creation of the KEA as the first quasi-independent central government environmental agency in 1980 was the turning point for active management of the environment in the Republic of Korea. Under MOHSA's authority, the KEA dealt with environmental pollution problems in the areas of air, water, soil, and solid wastes for over a decade (KMOE, 1989). The major role of the KEA was to manage the national environment by setting environmental standards such as national air quality standards, emission standards, and industrial effluent discharge permit standards.

The six regional environmental monitoring offices were set up under the KEA in July, 1980. In 1986, these regional offices were enlarged and reorganized as the Regional Environment Offices, responsible for the inspection, monitoring, and the data collection.

After ten years of existence, however, it was found that the KEA was not the appropriate organization, in terms of size and authority, for dealing with environmental pollution problems (Koo, 1985). Thus, the KEA was upgraded into an independent ministry, the KMOE, in January, 1990. The KMOE is headed by a cabinet minister and so has more authority to control national environmental problems.

Although the accuracy of the KMOE's nation-wide monitoring data has been questioned, it is reported that the overall national air quality has slightly improved throughout the country (Chung et al., 1991; KMOE, 1992; Kwon, 1990). Table 6.1 presents a comparison of air pollution risk management approaches, including the legislative basis, currently used in the United States and the Republic of Korea. Although

the primary regulatory framework for health risk management relative to air pollution seems very similar between the two countries, some fundamental differences exist in several points such as; the degree of protection from the human health and environmental risks, the principles used for air quality standard-setting, and the factors influencing risk management decisions.

Table 6.1 A Comparison of Air Pollution Regulation Approach Used in the United States and the Republic of Korea.

	The U.S. Approach	The Korean Approach
Legislation (Agency)	CAA since 1970 (USEPA)	EPL before 1990 (KEA) BEPL/AQPL after 1990 (KMOE)
Basis of the legislation	Risk, technology, balancing of cost - benefit	Technology, economic impact consideration
Goal setting	To protect public health and welfare	To protect human health and environment
Degree of protection	Adequate margin of safety Ample margin of safety	No explicit statement
Air quality standards	Setting the NAAQs for 6 common pollutants with threshold assumption	Setting the MAAQSs for 7 common pollutants
Emission standards	Difference between old and the new sources	Uniform standards, step by step achievement policy
Implementation plan	Depended on state or local governments with USEPA approval	Relied largely on central government implementation plan

Principles Used for Standard-Setting

The USEPA and KMOE rules used for standard-setting are different in many aspects. The following discussion will focus on the three basic principles which have been used in the standard-setting process: 1) margin of safety, 2) threshold vs. non-threshold concept, and 3) the balancing of costs and benefits.

Margin of Safety Provision

At least in modern democratic societies, a regulatory agency's actions take place based upon its legislative mandates. Therefore, the criteria for managing human health and environmental risks should comply with the mandates of its various authorizing statutes. The regulatory agency must translate the goals and language of the environmental laws into criteria that are used to evaluate risks of specific pollutants and serve as the basis for regulatory decisions. There exists, however, the statute-to-statute variability in terms of factors that are considered in regulatory decision-making.

For example, in providing the basis for setting NAAQSs in the United States, Section 109 of CAA does not provide for any consideration of costs; instead, USEPA must set primary standards (health-related standards) that encompass an "adequate margin of safety."[1] The somewhat ambiguous language in this section of CAA has led to a great deal of controversy as well as litigation concerning the meaning of this mandate.

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[1] The amendments of SDWA, on the other hand, require the USEPA administrator to establish maximum contaminant levels that protect the public health from exposure to pollutants, and to consider cost as well. The FIFRA imposes a risk-benefit balancing test that allows manufacturers to register pesticides that "will perform [their] intended function without unreasonable adverse effects on the environment".

As discussed in the case studies, the USEPA's numerical values for the ambient air standards were based on the lowest symptomatic or physiological effect levels. Also the Scientific Advisory Committee on air pollution recommended the selection of a value in the lower portion of the adverse effect range. As a result, the margin of safety provision led the USEPA to set standards below levels at which adverse health effects might occur. This USEPA approach might be viewed as a zero-risk approach.

On the contrary, neither the former EPL nor present BEPL of Korea provide any explicit statements about the degree of protection needed for health and environmental risks. This is one of the fundamental differences in legislation between the US and Korea. Indeed, the case studies show that both the former KEA and present KMOE set the sulfur dioxide and particulate matter standards more on the basis of economic impact than on the degree of safety.

This result indicates that the voice of the economic development planners was louder than that of the environmental preservationists during the legislative process. Within the government agencies, the political power of environmentalists has remained weak until recently. As compared to the USEPA's standard-setting process, therefore, the use of "the margin of safety" to protect human health from air pollution was not an important issue during the standard-setting process in the Republic of Korea.

Threshold vs. Non-threshold Concept

In many regulatory agencies, the standard-setting is different for non-carcinogens and carcinogens. In the United States, the NAAQSs for the non-carcinogenic criteria pollutants was established using a margin of safety sufficiently high that no adverse

health effects would be suffered by any member of the population exposed to this air for a lifetime. By using a margin of safety, it is possible to infer that the USEPA approach for the non-carcinogens is based on the concept that a "threshold" exposure level exists.

For non-carcinogens, USEPA determines the lowest observed adverse effect levels (LOAEL) or no observed adverse effect levels (NOAEL) where possible. Using these decision parameters, the Agency calculates the Reference Dose (also called the Acceptable Daily Intake), which is a dose below the level at which adverse health effects are expected to occur. However, as Lave (1987) pointed out, in fact, some possibility still exists that adverse health effects can occur at pollution levels lower than the ambient air standards, especially for the sensitive population.

The basic assumptions used for setting emission standards for carcinogens is different. During the last decade, accumulated research in physiology, toxicology, and other health sciences suggests that for a number of environmental pollutants, particularly carcinogens, there may be no threshold concentrations below which exposures are safe. This implies that standards for these pollutants must be set at zero concentrations if the public actually is to be protected against all risks from these pollutants.

In the real world, however, it is impossible to eliminate all traces of environmental pollution without shutting down all economic activity at the same time. To set emission standards for airborne carcinogens, therefore, the USEPA has adopted a risk reduction approach based on the calculation of risk probability. Using quantitative risk assessment techniques, the probability of the risk associated with a given exposure level is calculated as the deciding factor in health risk management. However, as discussed in the benzene case study, for example, the USEPA did not base its final

maleic anhydride standard for benzene emission control on the result of the CAG's quantitative risk assessment.

In contrast, there is no distinguishable line between non-carcinogenic chemical regulation and the carcinogenic chemical regulation for protection of human health from air pollution in the Republic of Korea. According to the BEPL [para.1 Art.10], the government should establish environmental quality standards including air quality standards in order to "preserve the pleasant environment and to protect human health." As for setting environmental quality standards, however, the meaning of this provision is not clear. The criteria for protecting the human health from air pollution are very ambiguous. This has resulted in setting some standards at relatively high levels that appear to be hard to justify on any rational basis.

As discussed in the case studies of Korea, air standards for common air pollutants such as sulfur dioxide and particulate matter were set not on the basis of the "threshold" assumption but on the basis of the consideration of economic impacts. The reason is that both the KEA and KMOE have emphasized economic feasibility more than the degree of protection. In Korea, it seems that carcinogens were targeted for action when a combination of scientific evidence and political pressure necessitated such action, but the government did not feel compelled to explain its analysis of the scientific and policy issues in explicit detail. Although no explicit philosophy for carcinogen regulation exists currently, there is a clear desire to adopt quantitative risk assessment techniques as decision-making tools (Chung, 1988; Chung et al., 1991; KMOE, 1992).

Balancing of Costs and Benefits

Environmental policy decisions are usually based on the following techniques: cost-benefit analysis, contingent cost-benefit analysis, cost effectiveness analysis, and risk-benefit analysis (Heiberg and Tronnes, 1988). The methods chosen depend on both the regulatory agency's approach and/or the statute's requirements. For policy-makers and the public, therefore, a prime challenge is to formulate scientifically credible ways of dealing with health risks, because information about such risks is usually incomplete and subject to different interpretations.

Regulatory policy often has to strike a balance between the contributory positions of arriving at definite scientific proof and the costs of exposing the public to risk until such proofs are available. Cost-benefit analysis is a procedure for determining whether the expected benefits from a proposed action outweigh the expected costs. It is necessary that all costs and benefits be expressed in monetary units. For calculating benefits, market prices may be used. In other cases, it may be necessary to find a "surrogate market." Alternatively, people's willingness to pay may be obtained from surveys or interviews.

Under Section 112 of the CAA in the United States, the USEPA has authority to evaluate hazardous air pollutants and promulgate emission limits from specific sources. During this process, the Agency must consider the technical feasibility and the costs of control as major decision-making criteria along with an "ample margin of safety" to protect the public health from such hazardous air pollution.

The USEPA's decision process for regulating benzene emissions into the air provides a good example. When the national benzene emission standards for coke by-

product recovery plants were proposed in 1984, the result of the costs-benefit analysis led the USEPA not to take any further action (Goldstein, 1985a). At that time, the cost was estimated at $30.9 million in capital expenditures but the benefit was only $1.3 million per year. Thus, the USEPA used quantitative risk assessment technique to balance the risks and costs of control options to arrive at its final decision.

In Korea, the regulatory history of benzene emissions indicated that the KMOE set the emission standard not on the basis of quantitative risk assessment, but on the Ministry's arbitrary judgement along with the consideration of the economic impact and technical feasibility. Currently all sources of the benzene emissions are regulated under a uniform emission standard, 50 ppm (See Table 5.9) and is hard to evaluate whether this policy is cost-effective or not.

Factors Affecting Risk Decision-Making

During the regulatory process, many factors affect health risk decision-making procedure. Although the fundamental tools for risk decision-making appear quite similar in the two countries, practical application of the tools is different in many aspects. In this section, the following factors will be discussed as the major issues affecting risk decision-making: 1) court decision, 2) public participation, and 3) peer review.

Court Decisions

Basically, the characteristics of the U.S. and Korean legal system are different in many ways (Hahm, 1986). These differences have affected risk management decision-making in the two countries. In the United States, the making of public policy is primary

guided by the Constitution, Administrative Procedure Act, and a large number of environmental laws and regulations. Thus, the USEPA's environmental policies are often tested in the courts to determine whether or not they violate the Constitution and environmental laws. Industry and environmental groups frequently challenge the Agency's decisions in court. In many cases, the Agency's regulatory process itself is also tested in the courts to evaluate whether or not its actions follow the due process of law. Judicial reviews of Agency decisions are commonplace in the US.

Following the petition of the Lead Industries Association, for example, the U.S. Court of Appeals for the D.C. Circuit held that the requirement of an adequate margin of safety for primary standards under the CAA was intended to address uncertainties associated with inconclusive scientific and technical information available at the time of standard setting. The court decision unavoidably affected the action of the USEPA Administrator by supporting primary standards that provide an adequate margin of safety. It is interesting to note that the USEPA Administrator not only sought to prevent pollution levels that had been demonstrated to be harmful, but also to prevent lower pollutant levels that might pose an unacceptable risk of harm, even if that risk was not precisely identified as to nature or degree.[2]

In selecting a margin of safety, therefore, the USEPA considers such factors as the nature and severity of the health effects involved, the size of the sensitive population(s) at risk, and the kind and degree of the uncertainties that must be addressed. The policy choice that provides an adequate margin of safety is left to the USEPA

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[2] Lead Industries Association v. EPA, 647 F.2d 1130, 1154 (D.C. Cir. 1980); American Petroleum Institute v. Costle, 665 F.2d 1176, 1177 (D.C. Cir. 1981).

Administrator's judgement. Thus, court decisions in the United States have played a critical role in health risk management decisions.

On the contrary, in the Republic of Korea the making of public policy is mainly guided by the Constitution, environmental laws and regulations, and organized public demonstrations. Because there is no legislation which is similar to the U.S. Administrative Procedures Act, the KMOE's administrative process has never been tested in the courts. Moreover, because the law does not permit private legal action against the government, industry and environmental groups cannot challenge decisions of government agencies in court.

Environmental litigation against industrial complex areas has been very common since the early 1980s. These cases have been restricted only to the pursuit of compensation for property damage from environmental pollution (Koo, 1985; Lee, 1988). During the past ten years, for example, a total of 299 cases have been brought to the courts and 245 cases have resulted in compensation. Among the total number of cases, approximately 45 percent involved air pollution related litigation (KMOE, 1992).

In the Republic of Korea, there is no clear evidence that court decisions affect health and/or environmental risk management decisions. Consequently, court decisions have played a relatively minor role in formulating and shaping Korean environmental policy making as compared to that of the United States.

Public Participation

In the modern democratic society, it is of critical importance that any effective regulatory policy should be fully understood and accepted by the public. Sherrill and

Vogler (1977) indicated five reasons why this may not be the case: 1) people do not believe the system is open; 2) people lack information; 3) people do not believe they can be effective; 4) people think they are faced with meaningless choices; and 5) people lack the resources to participate effectively.

Regarding health risk decision-making, it is generally accepted that scientists and regulators must cooperate in communicating with the public about scientific findings, especially the uncertainties associated with scientific testing procedures and chronic health risk analysis (Jasanoff, 1986; Preuss, 1988). It is also true that public must be made aware of the fact that at low levels of exposure inherent limitations of science may exist. This is partially because assessing and managing chemical hazards is relatively new to both scientists and the general public.

As a result, the risk communication issues arise inevitably between scientists including the risk managers and the general public. In both the United States and the Republic of Korea, although degree and types of public participation seem different in many aspects in the two countries, public participation such as citizen action and involvement are very common parts of the risk decision-making process.

In the United States, many environmental citizen groups are very large and have a relatively long history, and use a wide variety of strategies and tactics to influence environmental policy decisions (Covello, 1983). Some common tactics used by the citizen groups include campaigns and demonstrations for political referendums, and financial support for political candidates and groups.

Under Section 304 of CAA, they also have direct access to decision makers and have made extensive use of the legal system and the courts to achieve their goals. Many

citizen groups are politically strong having their own salaried staff including lawyers and scientists. In general, non-governmental organizations (NGO) focusing on environmental issues have large memberships. Some examples of these organizations are: the Sierra Club, Friends of the Earth, Natural Resources Defense Council, and the Environmental Defense Fund. All of these environmental organizations have greatly influenced the USEPA's health risk decision process.

The USEPA (1971) reported that more than 25,000 citizens representing the various environmental groups participated in public hearings in the period between 1967-1970 and had influenced the selection of air quality goals for their communities, and thereby, influenced the formulation of USEPA environmental policy. Furthermore, the 1970 amendments of the CAA expanded the potential for citizen action to help clean the air.

By contrast, environmental citizen groups in the Republic of Korea have a relatively short history with a limited membership. Before 1980, for example, less than ten groups were organized at local or regional levels. Beginning in the early 1980s, many citizen groups (so called Seamin HwanKyung Undong) were formed. During the 1980s and the early 1990s, thirty eight non-government environmental organizations were founded. Their membership consisted mainly of individuals directly affected or likely to be affected by local or regional economic development projects. As a result, environmental groups in Korea appear to be politically weak, especially at the national level, and they tend to focus on specific types of environmental pollution such as the air, water, and the waste disposal issue. Although Korean officials are highly sensitive to public opinion, they prefer not to consult with citizen groups on important environmental

issues. Moreover, it is important to note that for a long periods, probably since the Japanese occupation of Korea in 1910, any kind of complaint against government actions is traditionally regarded as harmful to the nation and has been treated harshly.

As compared with the United States, Korean environmental citizen groups generally use a limited set of tactics and strategies to influence policy. These strategies include: the distribution of pamphlets, respectful requests for negotiations with government agencies, and organized demonstrations such as mass meetings and/or demonstrations. For example, during the decision process for controlling air pollution, there is no clear evidence that any citizen groups were involved. Nevertheless, because of various political and social reasons, the Korean government seems to be extremely sensitive to such mass citizen actions. Only in rare instances have Korean environmental citizen groups resorted to the legal system.

Internal and External Peer Review

In order to minimize errors, it is generally believed that the peer review process is essential. Under the CAA in the United States, identification and screening of a given hazardous chemical provides an excellent example of the use of peer review process. For instance, Section 117 of CAA requires consultation with an "appropriate advisory committee" prior to listing a hazardous air pollutant under Section 112. Therefore, the peer review process is an important step in reaching the Agency's regulatory decision.

After an initial review of literature on health effects, a draft health assessment document is prepared if significant effects appear likely with projected exposure to a substance. This document is subjected to an expert peer review workshop which is open

to the public (See Figure 5.1). Then a draft document is released to the public and the Science Advisory Board for final comments. During this review process, some critical parts of the studies are usually evaluated: unit risk numbers, LOAEL, and/or NOAEL. Sometimes, additional public workshops are held at USEPA including consulting authors and reviewers, as well as other scientifically and technically qualified experts selected by the Agency to discuss the outstanding issues.

A few months later, the final document is usually published incorporating appropriate comments. Based on this document, the USEPA proposes and promulgates regulations related to standard setting and enforcement activities (USEPA, 1986abc).

In contrast to the U.S. case, no formal peer review process exists in the Republic of Korea. As discussed in Chapter IV, the Central Environmental Preservation Advisory Committee (CEPAC) is only the unit which evaluates the KMOE's draft document and advises the KMOE as to the appropriate regulatory action under the BEPL Implementing Decree of 1990. Hence, the Minister of KMOE produces a final document in accordance with the CEPAC's recommendations.

The CEPAC is composed of 20 experts appointed by the Minister of KMOE with the KMOE Vice-Minister appointed by law as the chairman of the committee. The major role of the committee is to review and comment on the national environmental policy planning and environmental standard setting activities proposed by the KMOE.

The CEPAC meetings, however, are generally confidential and not open to the public. Because no requirements are placed on the CEPAC to explain publicly the reasons for their decisions, formal opportunity is not provided for the public to review or criticize the decisions and/or recommendations of the CEPAC. Consequently, it is

difficult to determine how much the CEPAC's review process has affected the KMOE's risk decision-making relative to air pollution. Relative to the United States situation, it seems that the peer review process probably does not play a critical role in air pollution regulation in Korea.

Conclusions

Over the past several decades, industrial nations world-wide have become intensively concerned about controlling human health and environmental risks resulting from various chemicals in the air (World Bank, 1992). Because these risks are very common in modern technological civilization, many countries have already made a significant effort to develop plausible regulatory policies in order to reduce unreasonable risks. However, efforts to reduce the risks have varied considerably because of different national attitudes about the characterization and control of such risks.

In the United States, the USEPA has the primary responsibility to control and abate pollution in the areas of air, water, solid waste, pesticides, radiation, and toxic substances. With respect to air pollution regulation, the Office of Assistant administrator for Air and Radiation is the fundamental unit for the development of national programs, technical policies and regulations. The Assistant Administrator for Research and Development serves as the principal science advisor to the USEPA Administrator and coordinator for the Agency's policies and programs concerning health and environmental issues.

Because strong national control legislation was introduced in the 1970 and 1977 amendments to the CAA, the USEPA's strategies for reducing human health and

environmental risks from air pollution have included detailed proscriptions for regulations, permit systems, inspections, and enforcement actions. In 1971, the USEPA adopted the first National Ambient Air Quality Standards (NAAQSs) for six common air pollutants, known as the criteria air pollutants. Two different standards were set: health-based primary standards, and welfare-based secondary standards. These standards represent the maximum permissible concentrations of common air pollutants in ambient air.

In order to protect public health from exposure to toxic air pollutants, the USEPA Administrator also set National Emission Standards so that the concentrations in the air would be low enough to provide an ample margin of safety against adverse human health effects. These hazardous and toxic air pollutants are known as non-criteria pollutants.

The USEPA's policies for assessing and managing air pollution risks are primarily based on interpretation of the CAA and scientific judgments derived from toxicological findings. In managing criteria air pollutants, the USEPA's policy is based on the assumption that there is an identifiable threshold exposure level. Thus, the NAAQSs were established without concern for the resulting costs and set at the levels [with an adequate margin of safety] at which no adverse health effects would occur.

In contrast, in regulating non-criteria pollutants such as carcinogenic chemicals, the USEPA set emission standards based on the assumption that there is no threshold exposure level. Using quantitative risk assessment techniques, the probability of the risk associated with a given exposure level is calculated. Further, the USEPA Administrator is required to balance some measure of the benefits from lowering the risk against the cost of control. During the process of risk decision-making, court decisions, public

participation, and peer review have significantly effected the Agency's air pollution management policy.

In the Republic of Korea, the KMOE is the basic government organization for controlling and abating environmental pollution in air, water, solid waste, hazardous chemicals, and noise and vibration. With respect to air pollution control, the Bureau of Air Quality Management is the unit most responsible for setting national air quality standards including emission standards, and for development of national policies and regulations. The National Institute of Environmental Research, as an independent organization under the KMOE, provides the KMOE's health related research and education in environmental science and technology.

Since the first comprehensive EPL was passed in 1977, the Korean government has taken two important steps relative to environmental management and control: institutional rearrangement and adoption of pluralistic approach in environmental legislation. After passing the BEPL in 1990, the KEA was upgraded to a ministry level, KMOE, and the EPL was replaced by six new laws. After the first national ambient air quality standard was set for sulfur dioxide control in 1979, six additional air pollutants were added under the BEPL. These standards were determined based on consideration of two criteria: 1) preservation of the pleasant environment, and 2) protection of human health. Thus, air quality standards have served as the primary objectives of the Korean environmental administration.

Under the AQPL of 1991, the KMOE currently listed 47 pollutants including benzene as "General Air Pollutants." Among these pollutants, 25 including 16 hazardous pollutants were selected in setting the permissible emission standards. In setting emission

standards, the selection of a target pollutant lies under the discretion of the KMOE Minister.

The KMOE's policy for air risk assessment and management is based primarily on the BEPL and the AQPL. Because environmental laws including BEPL and AQPL are generally ambiguous and their interpretation by KMOE is not commonly tested in the courts, ambient air quality standards including emission standards have been established on the basis of the KMOE's arbitrary judgement. Furthermore, there is no definite line separating risk management of carcinogenic chemicals and non-carcinogenic chemicals. Sometimes, the results of comparative analysis of relevant information from foreign countries are used as important measuring criteria. Frequently, data quality and analyses techniques are emphasized more than formal quantitative risk assessment and cost-benefit analyses.

Consequently, the USEPA's risk decision-making system is basically an open system based on explicit procedures and principles of law. This system makes it possible to communicate with a wide-range of public and environmental groups as well as industrial representatives during the risk decision process. As a result, scientific debates relative to the Agency's risk management decision are very common, and widely publicized by the media in the United States. Also the legal system itself plays a significant role in environmental risk management including air pollution policy.

On the contrary, the KMOE's risk decision-making system is essentially a closed system based on personal contacts within the Agency and principles of government confidentiality. This system does not permit public participation including various interest-groups. As a result, scientific controversies in risk management are generally

internalized within the Agency and/or government committees and the results seldom publicized by the media in the Republic of Korea. Because of Korean social tradition, the legal system plays a relatively minor role in environmental policy making except for compensation of property damage.

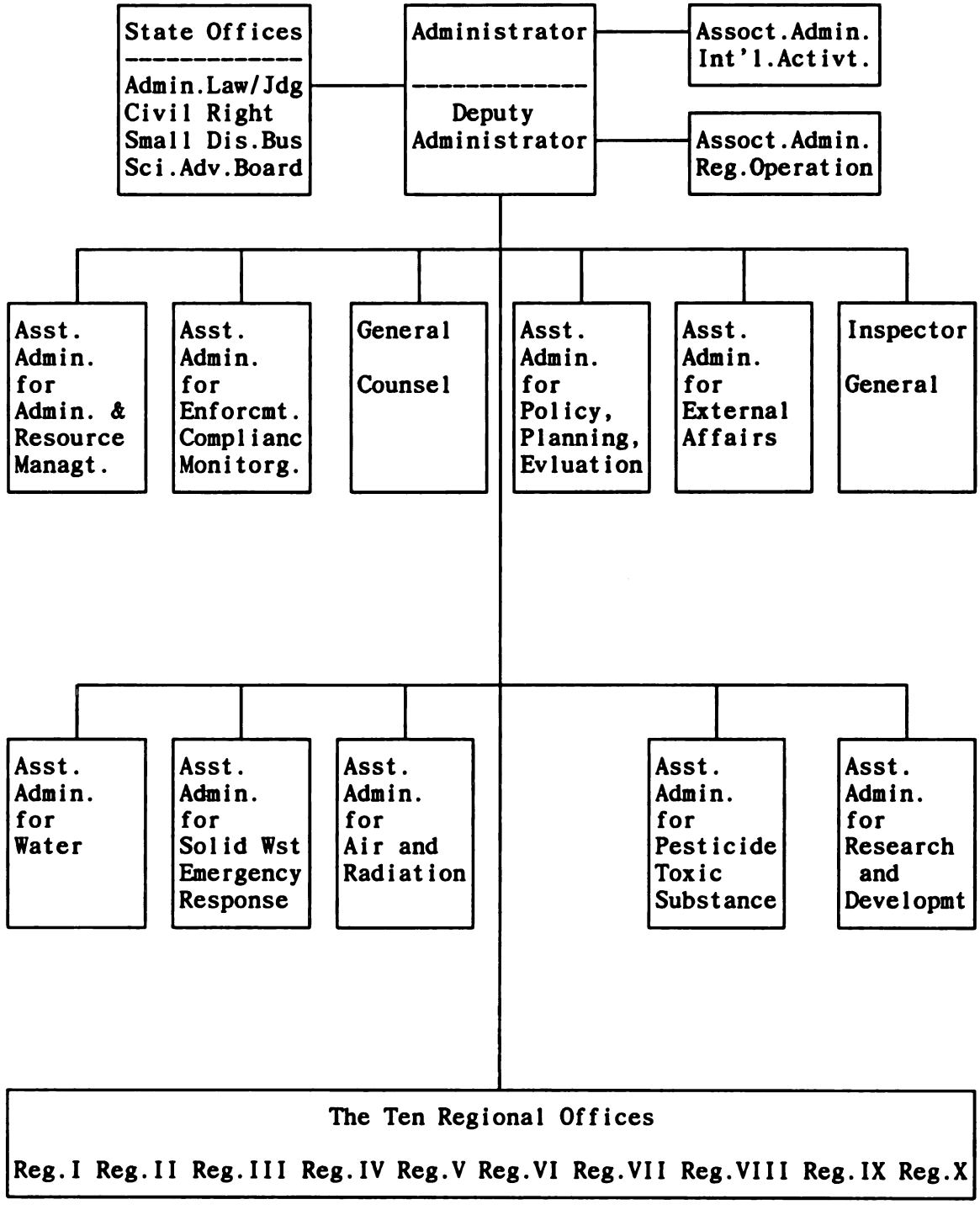
It is difficult to answer the question of which nation's approach is more effective in terms of the health risk decision-making process. In general, the USEPA's approach to risk management is largely based on scientific calculations of risk quantification and risk probability. Therefore, it may help preventing human errors in an important decision. However, it takes a relatively long time in reaching an appropriate decision. Sometimes, it is a time-consuming job and costly. On the contrary, the KMOE's approach to risk management is essentially based on socio-economic considerations rather than scientific calculations. In general, decisions are made quickly but there exists controversy after decision made.

Today, many nations in the world are strongly tending towards the scientific approach to managing human health risks from environmental pollution. However, there is no doubt that current scientific capabilities for dealing with risk assessment and management needs to be improved.

APPENDICIES

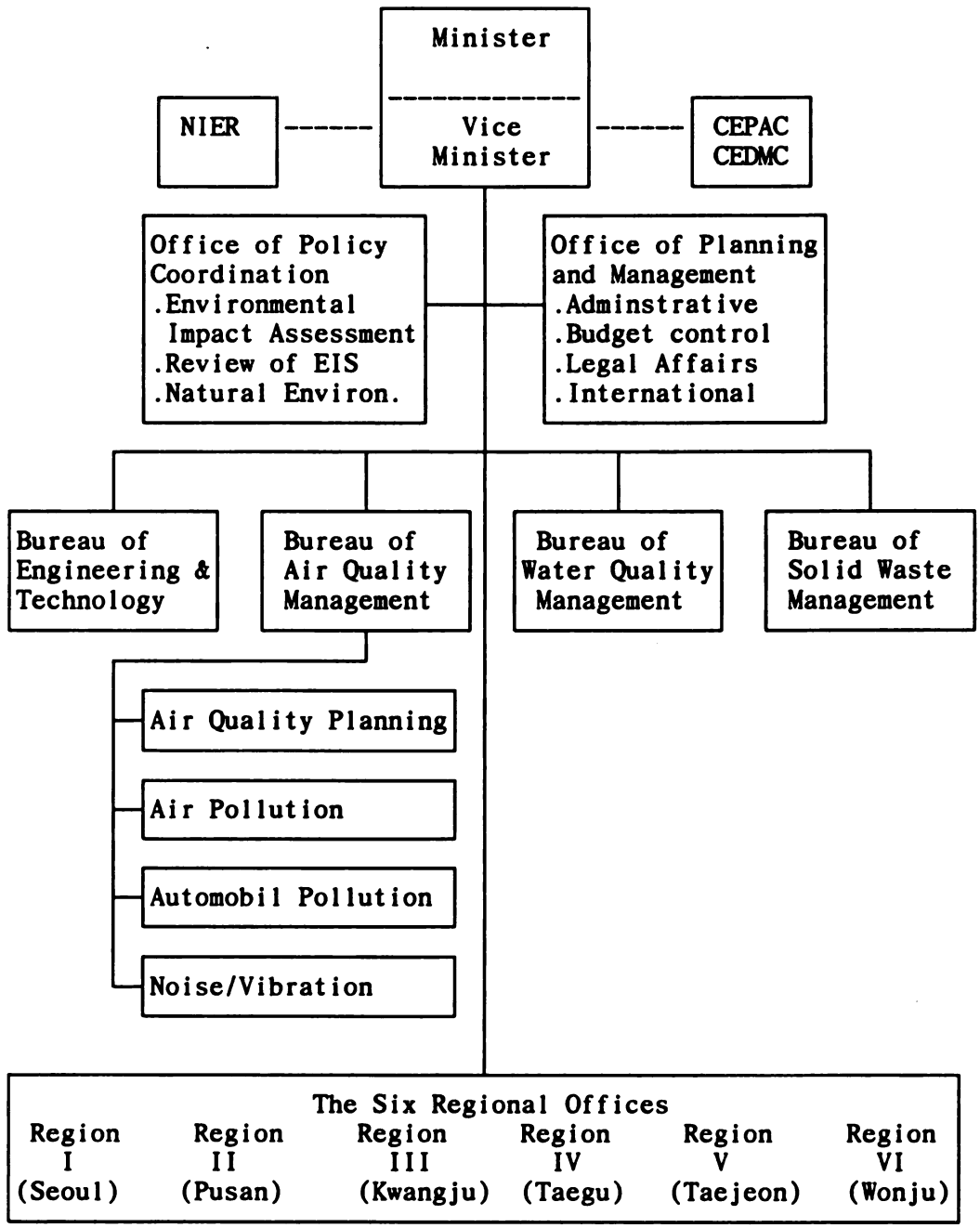
APPENDIX A

ORGANIZATION OF THE U.S. ENVIRONMENTAL PROTECTION AGENCY



APPENDIX B

ORGANIZATION OF THE KOREA MINISTRY OF ENVIRONMENT



Note: NIER ; National Institute of Environmental Research
CEPAC; Central Environment Preservation Advisory Committee
CEDMC; Central Environment Dispute Mediation Committee.

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