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THE ROLE AND METHODOLOGY OF ENVIRONMENTAL RISK ASSESSMENT: A FRAMEWORK FOR DEVELOPING COUNTRIES

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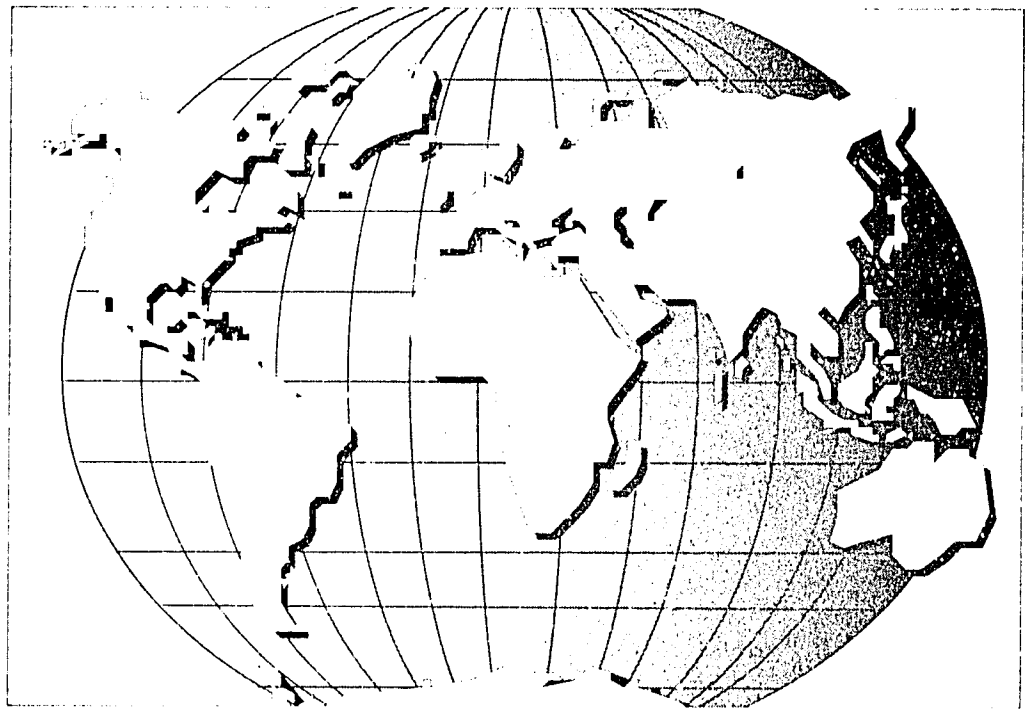

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THE ROLE AND METHODOLOGY OF ENVIRONMENTAL RISK ASSESSMENT: A FRAMEWORK FOR DEVELOPING COUNTRIES[1]

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INTRODUCTION

Environmental health has been defined to encompass those diseases and health problems that are environmentally determined and are increased through environmental degradation (Long, 1990). Such a broad definition would include health risk from both natural and man-made sources. Examples of environmental health risk from natural sources include death and injury from floods, hurricanes and other natural disasters; skin cancer due to over exposure to the sun's rays; and death and hypothermia attributable to extreme ambient temperatures. Although the sources of each of these health risks are natural, the risks themselves may be mitigated through human interventions such as land use planning that protects human settlements from floods, modification of behavior that leads to overexposure to the sun, and adequate housing and heating for protection against extreme temperatures. Environmental health risks from man-made causes include death and disease associated with exposure to toxic substances such as chemicals and infectious microorganisms in polluted water and air; solid, hazardous and radiological waste; occupational settings; and contaminated food. Each of these man-made environmental health risks is the result of many different factors including individual behavior patterns, market systems, and government intervention strategies. The availability of information and complexity of issues involved in managing or mitigating these environmental health risk in both developed and less developed countries (LDC) has resulted in an overloaded agenda for environmental managers. Not only are there many environmental problems to address, but there are limited resources to address any single problem. Thus, managers are faced with a need to identify and prioritize environmental issues and to understand the likely outcomes of various risk reduction strategies.

In the United States (U.S.) risk management has emerged as a principal analytic activity for environmental managers. The U.S. Environmental Protection Agency (EPA) and other Federal agencies have been in the forefront of developing risk assessment methodologies that provide a mechanism for incorporating scientific evidence and scientific judgement into the decision-making process. There are four main uses of risk assessments which might provide input to risk management decisions:

1. To estimate an acceptable ambient concentration for a specific chemical or toxic substance that will be protective of human health and the environment (e.g. ambient air standard for lead);

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2. To estimate the human health and/or environmental effects associated with current ambient concentrations of particular substances (e.g. number of cases of gastrointestinal illness attributed to the presence of fecal coliform bacteria in the water supply);

3. To estimate the human health and/or environmental effects associated with releases of one or more toxic substances from one or more sources (e.g. cancer cases associated with drinking water contaminated with toxic chemicals from nearby industries); and

4. To compare estimated risks from specific substances or sources in order to set priorities for regulatory actions or motivation for source mitigation.

The extent of the risk analysis needed will vary depending on the decision context. For example, a comparative risk analysis being conducted in order to set priorities and allocate resources will require a less rigorous analysis than a risk analysis being conducted in support of a regulatory action. The decision context, in large part, determines the methodological approach for the analysis.

The focus of this paper is to present an overview of the risk assessment methodology as applied to environmental health risk, to review current activities and knowledge in developing countries, to provide an overview of U.S. capabilities and methodological experience, and to present some potential linkages between risk assessment, policy and regulatory development, and project-type interventions.

OVERVIEW OF THE RISK ASSESSMENT PROCESS

Risk assessment is defined as the overall procedure by which potential adverse health effects of human exposure to toxic agents are characterized. It includes the following four components: hazard identification, exposure assessment, dose-response assessment, and risk characterization (U.S. EPA, 1987c; National Research Council, 1983). Figure 1 shows these components of risk assessment in relation to each other. Each of these components is further described below.

HAZARD IDENTIFICATION

Hazard identification is a qualitative determination of whether human exposure to an agent has the potential to produce adverse health effects. It involves an evaluation of all available toxicology data and other relevant biological and chemical information for the agent under consideration, including:

- Physico-chemical properties relevant to exposure
- Sources, routes and patterns of exposure
- Structure-activity relationships
- Metabolic and pharmacokinetic properties
- Short-term in vivo and in vitro tests
- Long-term animal studies
- Human exposure studies
- Human epidemiological studies

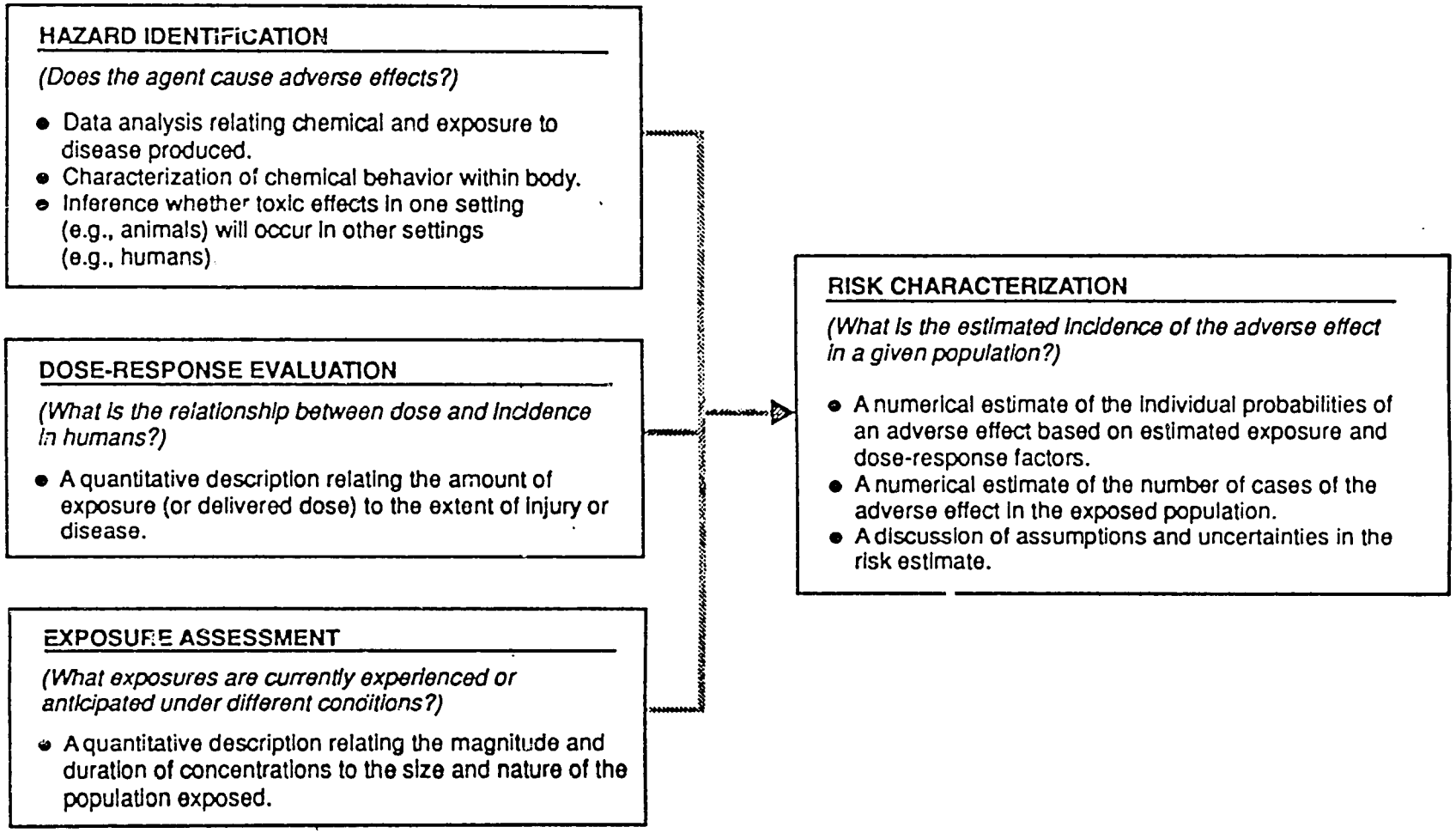

Figure 1. Traditional components of risk assessment (from Naugle et al., 1990)

Clearly, the most direct evidence for hazard identification comes from human studies. However, in most instances the preponderance of available information on toxic effects comes from animal studies. Thus, the identification of agents hazardous to human health usually requires assumptions regarding the biological similarity of various mammalian species, as well as assumptions about the applicability of toxicity test conditions (e.g., route of exposure; frequency, level and duration of doses) to estimated human exposure conditions. In general, unless there are human toxicity data or comparative metabolic data that refute animal toxicity data, human health effects are inferred from the results of animal studies.

The results of any hazard identification should include a summary of all key findings of the qualitative assessment and the rationale that forms the basis for the conclusion reached. All assumptions, uncertainties in the evidence, and other factors that may affect the relevance of evidence to humans should be presented. The U.S. EPA has developed a classification system based on the weight of the underlying evidence for carcinogenicity and reproductive toxicity. As an example, within the weight-of-evidence system for carcinogenicity, agents are categorized into six groups:

- Group A: Human Carcinogen (sufficient human evidence)
- Group B1: Probable Human Carcinogen (limited human evidence)
- Group B2: Probable Human Carcinogen (sufficient animal evidence; inadequate or no human evidence)
- Group C: Possible Human Carcinogen (limited animal evidence; inadequate or no human evidence)
- Group D: Not Classifiable as to Human Carcinogenicity (inadequate or no human and animal evidence)
- Group E: Evidence of Noncarcinogenicity for Humans (no evidence for carcinogenicity in at least two animal tests in different species or in both adequate epidemiologic and animal studies)

The hazard identification summary should include a weight-of-evidence categorization and a discussion of the nuances of the evidence that may not be evident from the classification.

EXPOSURE ASSESSMENT

Exposure assessment involves the characterization of the nature and site of various populations exposed to a toxic agent, and the quantitative estimation of the level and duration of their exposures. Current methods of exposure assessment are primarily medium- or route-specific, so that at present there is no single approach that is appropriate for all cases. Appropriate methods must be selected on a case-by-case basis, depending on the available data and the level of sophistication required.

In general, exposure assessment consists of four steps:

1. Determination of environmental concentrations;

2. Estimation of the magnitude, duration and frequency of human exposure;

3. Estimation of dose received, usually expressed as Maximum Daily Dose for acute, subchronic or chronic exposures to noncarcinogens, or as Lifetime Average Daily Dose for carcinogens; and

4. Characterization of exposed populations and individuals (e.g., by magnitude of dose received, age, sex, health status, time in life of exposure, other concurrent exposures) and identification of subpopulations with heightened sensitivity.

Ideally, independent exposure assessments are performed for each potential route of exposure (i.e., inhalation, ingestion, dermal absorption) within each identified population subgroup. These independent exposure assessments can then be aggregated over the different routes of exposure to estimate the overall exposure for each subpopulation. However, methods for aggregating exposures across different routes have not been standardized. A complete exposure assessment also should include a summary of all underlying assumptions and approximations, and a quantitative estimate of the level of uncertainty associated with the assessment.

DOSE-RESPONSE ASSESSMENT

Dose-response assessment is a quantitative process that involves (1) defining the relationship between the administered or received dose of a substance and the prevalence of an adverse health effect in an exposed population, and (2) using a mathematical dose-response model to estimate the probability of occurrence of the effect based on human exposure to the substance. Although biologically plausible models are highly desirable, the mechanisms of action of many toxic substances and chemical mixtures are not well understood. In such instances, statistical models that best represent the available data are used to model dose-response relationships.

If available, dose-response estimates based on adequate human data are preferable to those derived from animal data. In the absence of appropriate human studies, data from studies of animal species that respond most like humans should be used. When several studies are available for a given agent, all biologically and statistically acceptable data sets should be presented. The U.S. EPA Risk Assessment Guidelines (1987c) recommend placing the greatest emphasis on data sets from long-term animal studies showing the greatest sensitivity in order to account for sensitive human subpopulations. Some analyses, however, might stress biological similarity to humans over sensitivity.

The use of animal data to estimate risks from human exposure requires at least two major extrapolations: (1) interspecies dose extrapolation to adjust for differences between humans and laboratory animals in factors that may potentially affect the response to the toxic agent (e.g., site, genetic variability, life span, population homogeneity, exposure regimen, and pharmacokinetic effects such as absorption, metabolism, and excretion patterns); and (2) extrapolation of the dose-response relationship observed at the relatively high doses used in animal experiments to the much lower doses to which humans are likely to be exposed. In addition, where the exposure route in the animal

studies from which the dose-response information is obtained differs from the exposure route occurring in human exposures, a route-to-route extrapolation is required. Although methodologies have been developed for route-to-route extrapolations, often the data needed to apply these methodologies are not available and thus various simplifying assumptions must be made. All assumptions used in making these extrapolations must be consistent with existing metabolic and pharmacokinetic information. These assumptions should be clearly stated and presented with estimates of the uncertainties in the extrapolation and in the overall dose-response assessment.

RISK CHARACTERIZATION

Risk characterization is the quantitative estimation of human health risk due to exposure to harmful substances or organisms. This characterization requires that each of the first three components of the risk assessment process be evaluated in the most rigorous and scientifically defensible way, with all assumptions and uncertainties clearly documented in order to obtain the most reliable quantitative estimates of human health risk.

Numerical risk estimates of human health effects are typically presented either in terms of excess individual lifetime or annual risks, or excess risk in an exposed population in a given time period, or both. Other forms of expressing numerical risk estimates include relative risk, standardized mortality ratio and loss of life expectancy (Cohrssen and Covello, 1989). Figure 2 presents simplified equations to illustrate the differences among each of the various risk characterization measures.

Characterization of risk often depends on the data available and the way the analyst collects and organizes these data. The more common risk characterization estimates require a two-step procedure whereby a single point estimate is calculated for individual lifetime risk for an exposed population and point estimates aggregated across all exposed populations to get a population risk. Uncertainty in estimates of both individual lifetime risk and population risk should be addressed either qualitatively or quantitatively.

The existing methods for risk characterization are far from ideal, largely because of data limitations and incomplete knowledge of the biological mechanisms of action of toxic agents on the human body. There are four major sources of uncertainty in estimating point risks of adverse health effects:

1. uncertainty due to statistical sampling issues,

2. uncertainty in the exposure or dose-response models,

3. uncertainty in the input parameters for these models, and

4. uncertainty due to lack of completeness in the models.

At each point in the risk characterization process where an uncertainty exists, an assumption or scientific judgement must be made in lieu of firm scientific evidence. Specific examples of

Individual lifetime risk	=	Dose x Potency[a]
Population risk[b]	=	Individual lifetime risk x Population exposed
Relative risk	=	$\frac{\text{Incidence rate in exposed group}}{\text{Incidence rate in nonexposed group}}$
Standardized mortality or morbidity ratio	=	$\frac{\text{Incidence rate in exposed group}}{\text{Incidence rate in general population}}$
Loss of life expectancy	=	Individual lifetime risk x 36 years (avg. remaining lifetime)

[a] For substances with a threshold for exposure, potency of the substance is zero below the threshold. For substances with no threshold, a linear dose-response relationship is assumed.
[b] Population risk is the number of individuals adversely affected as a result of lifetime exposure to the substance.

Figure 2. **Risk characterization measures (adapted from Cohrssen and Covello, 1989).**

uncertainties that require the insertion of some assumption into the risk characterization process include those related to:

- extrapolation from animal to human exposures,
- extrapolation from high to low doses, and
- extrapolation from one route of exposure to another.

Under ideal circumstances each uncertainty should be assigned individual and joint probability distributions, from which average or worst case point estimates of adverse health effects are generated. In addition, these probability distributions should be used to perform a sensitivity analysis for the point estimates for each input parameter and to generate overall probability distributions for the estimated risks.

RISK ASSESSMENT IN DEVELOPING COUNTRIES

Although considerable uncertainties exist in risk assessment methodologies and their applications, risk assessment has been adopted by government agencies in the United States and elsewhere to provide a quantitative and consistent framework for systematically evaluating environmental health risks and options for their control. The major criticisms of the methodology are that the data requirements are both time and resource intensive and that scientific judgement is often presented as scientific fact. Both of these criticisms may have an impact on the application of risk assessment methods in LDCs. First, many LDCs do not have extensive environmental data bases. The information needed to quantify exposure does not exist and, in some instances, the availability of data may not even support logical assumptions to be made regarding exposure. Second, scientific judgement embedded in all risk assessments needs to be understood and communicated to decision makers and other users of the risk information. This requires those knowledgeable in risk assessment to be accessible and to have access to the decision makers.

Several efforts are currently under way to identify and review cases where risk assessment methodologies have been used to evaluate environmental health problems in LDCs. Currently there is no comprehensive list of such case studies. However, based on an initial review of a number of such case studies, it appears that most applications of risk assessment to environmental health problems in LDCs have been sponsored by donor agencies. Current activities include projects sponsored by the U.S. EPA, AID, and the World Bank, among others. Discussed below are two risk assessment methodologies that have been used in LDCs to evaluate environmental health problems.

The Environment and Policy Institute (EAPI) of the East-West Center held a three week workshop in 1987 to test the applicability of "Western" risk assessment methods to hazardous chemicals management in developing countries of the Asia-Pacific (Smith et. al., 1988). A description of risk assessment and a set of guidelines for its performance were developed during the workshop. A framework for ranking risks developed at this workshop is presented in Figure 3. This framework may be more applicable in characterizing environmental health risk in many developing countries than the more quantitative approach presented in the previous section due to the semiquantitative nature of the methodology. The framework provides a means of ranking risks based on their probability of occurrence and severity of hazard. Categories can be established in a semiquantitative way based on consequence to life or safety, time of interrupted operations, and monetary loss. The result is a flexible set of categories ranging from high risk to acceptable risk. The general risk assessment

Hazard severity	Potential consequences: Life/safety	Potential consequences: Mission downtime	Potential consequences: Monetary loss $	Probability of occurrence: Frequent, repeatable	Probability of occurrence: Reasonably probable, several times	Probability of occurrence: Occasional, sometimes	Probability of occurrence: Remote but possible
Catastrophic	Death or system loss	> 4 months	> 500,000	High risk: Imperative to reduce hazard before proceeding			
Critical	Severe illness, injury, or damage	2 weeks to 4 months	50,000 to 500,000		Medium risk: Proceed only with specific management approval of risk acceptance		
Marginal	Minor illness, injury, or damage	1 day to 2 weeks	1,000 to 50,000			Lower risk: Assurance of compliance with standards and safety criteria	
Negligible	No illness, injury, or damage	< 1 day	< 1,000				Acceptable risk with normal operating procedures

Figure 3. Risk ranking based on probability and severity (from Smith et al, 1988)

methodology described in the previous section is still applicable in the sense that all four components of the process are addressed. However, the level of quantitation is adjusted to fit the available data. Several examples of this risk assessment methodology are presented in the proceedings of this workshop.

In recent years, the U.S. EPA Office of Policy Analysis has conducted and supported a series of projects aimed at better integrating risk analysis into environmental priority-setting at EPA. These "Comparative Risk Projects" use estimates of risk as a common measure for comparing and setting priorities among environmental issues. The methodology was first applied at a national level to rank environmental health problems according to three criteria: health effects, ecological effects and welfare effects (EPA, 1987a, "Unfinished Business: A Comparative Assessment of Environmental Problems"). This comparative risk methodology has been or is being applied to all 10 EPA regions in the U.S. to better understand the environmental issues in the regions and how the regions may differ from one another (EPA, 1989a, "Comparing Risks and Setting Environmental Priorities: Overview of Three Regional Projects). Recently, the comparative risk methodology has been applied to at least one major city in an LDC.

To provide some perspective on the comparative risk methodology, Figures 4 and 5 present the results of several of these studies. Figure 4 shows the rankings of current environmental health problems in the Southeastern United States (Region 4) according to three criteria: human health effects, ecological effects, and welfare effects. It is important to note that these results are based on analysis that takes into account current environmental regulation; thus, the risk estimates are the residual risks remaining after current environmental controls are applied. As can be seen from the figure, the rankings differ substantially depending on which criterion one is considering. Figure 5 presents a comparison of the rankings based on the human health criterion for three studies which include the Southeastern United States, the Northwestern United States (Region 10) and a major city in an LDC. Although there are some similarities between the two U.S. regions, there are also some significant differences. However, the LDC city shows significant differences in the rankings.

These figures together point up several important considerations in the application of risk assessment methodologies to environmental health problems in widely diverse settings around the world. First, the methodology provides a systematic approach to determining relative rankings among a widely diverse set of problems and circumstances. Second, the use of a single criterion, human health effects, will give a different ranking than the use multiple criteria, as shown in Figure 4. Third, between countries and even within a single country there will be different rankings depending on geography, climate, human settlement patterns, economic development, and the extent of existing environmental programs as illustrated in Figure 5.

RISK ASSESSMENT AND RISK MANAGEMENT

The relationships between basic environmental research, risk assessments, and risk management, are shown in Figure 6. A few of the key research areas which provide the foundation to manage environmental risks are shown in the left column. This research is appropriately conducted in great technical depth and replicated by independent laboratories. For this reason, integration studies are also needed to combine individual research projects covering different technical disciplines and to draw general technical conclusions on both the risk to people and the

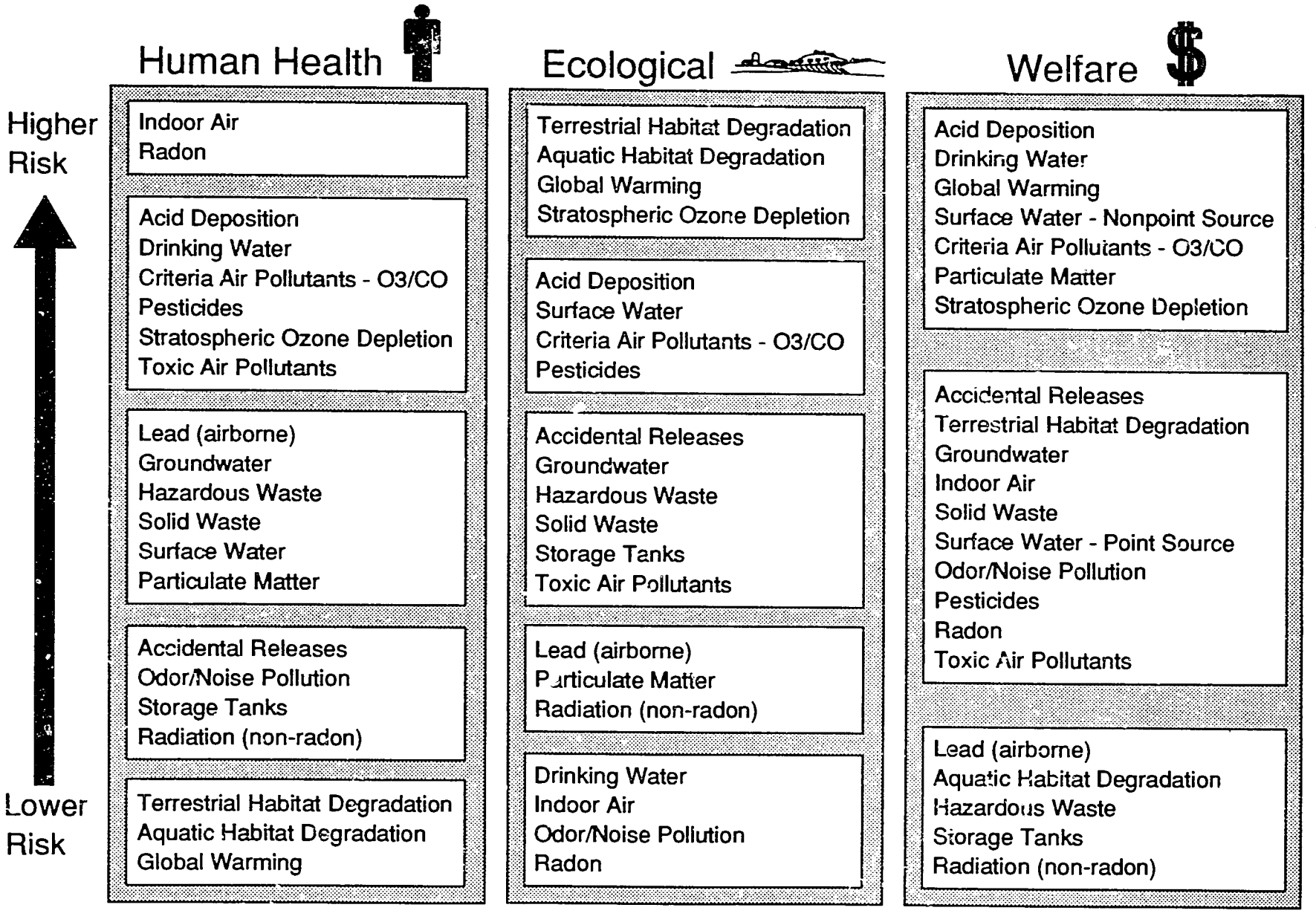

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Figure 4. Comparative Ranking of Current Environmental Problems - EPA Region 4

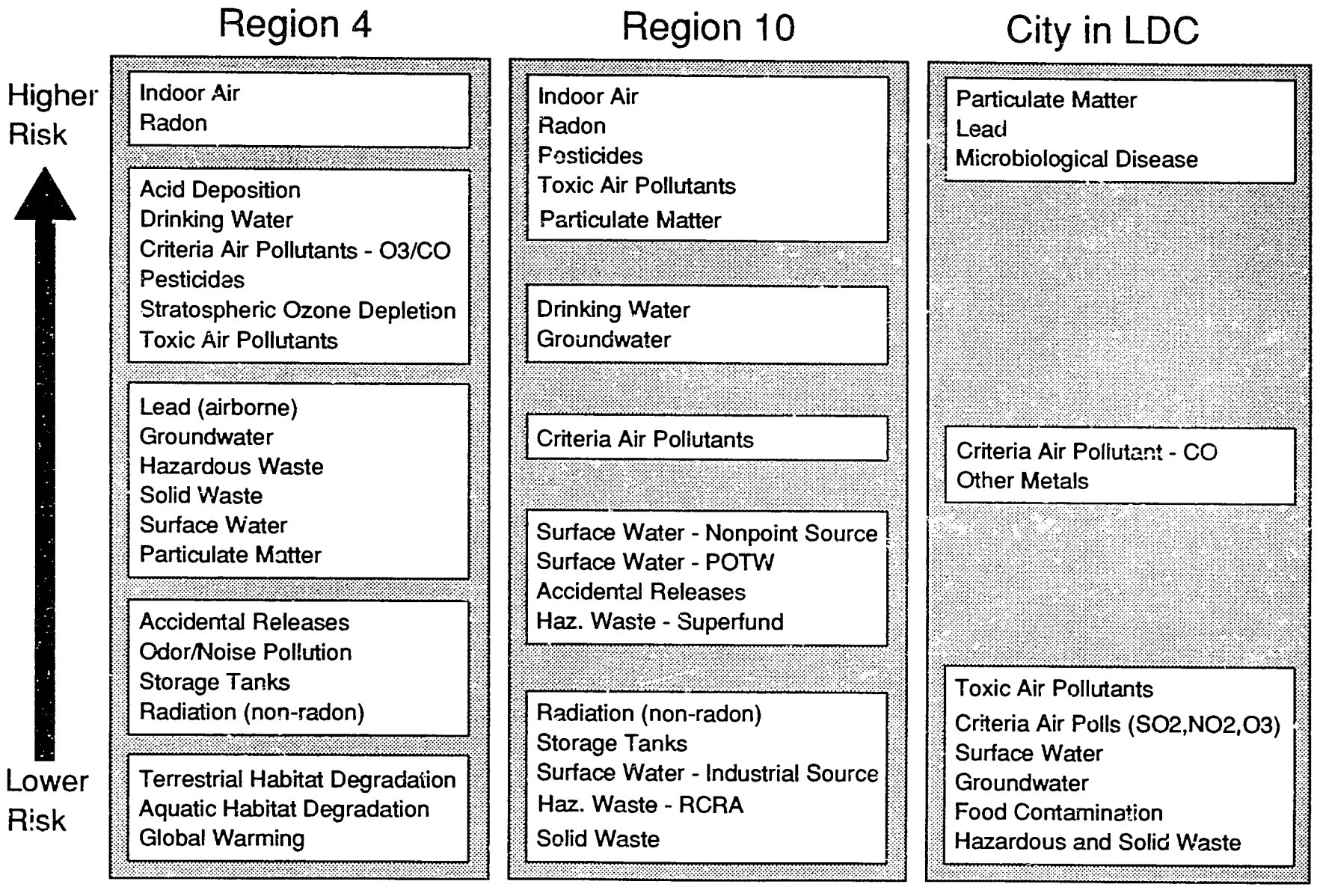

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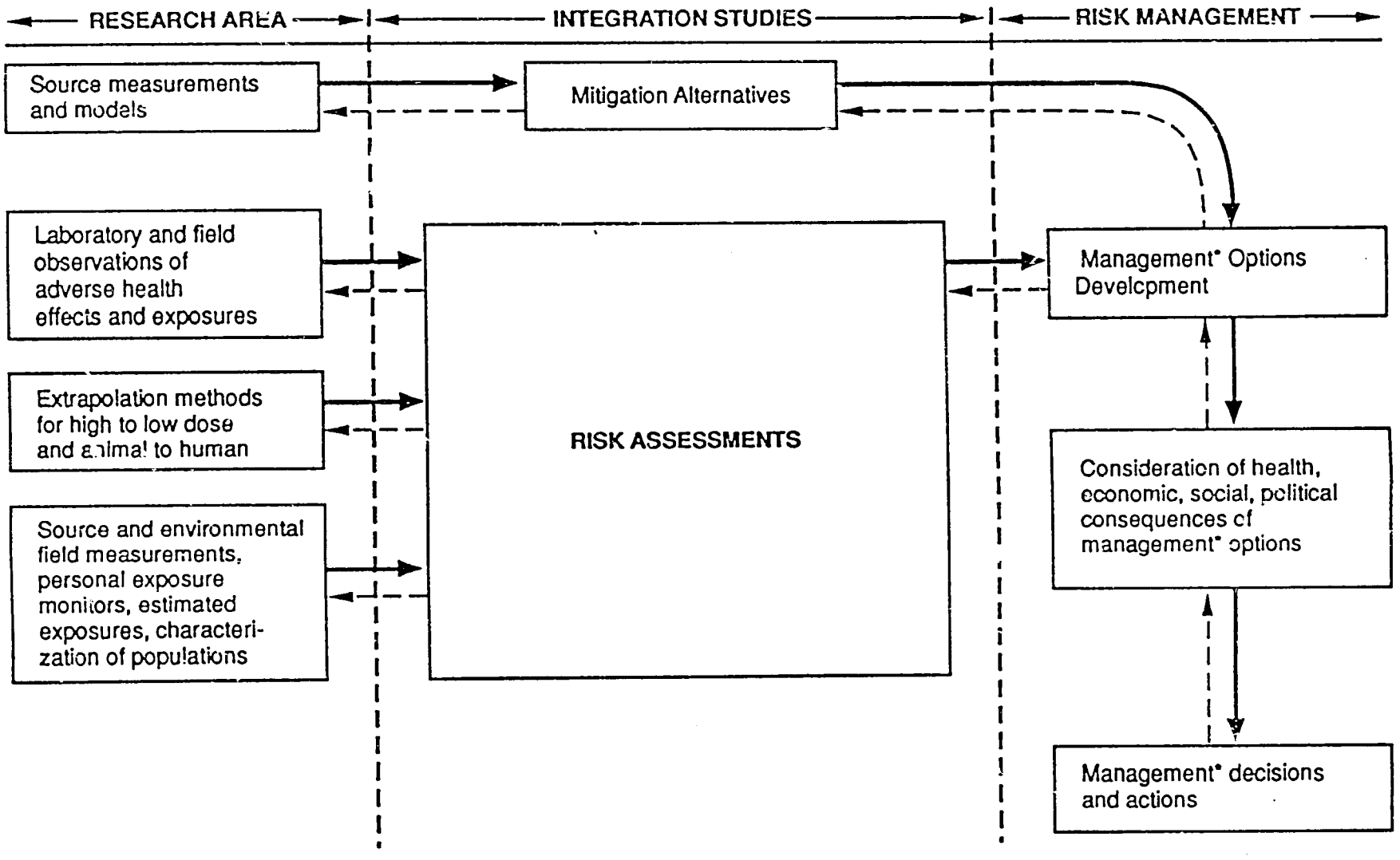
Figure 5. Comparative Ranking of Current Environmental Problems - Human Health



*"Management" can be within federal agencies, state and local agencies, industries or even households.

Figure 6. Relationship between research, risk assessment, and risk management

(from Naugle et al., 1990)

alternatives for mitigation. These integration studies form the basis for risk management options and decisions.

The risk assessment methodology provides a tool for synthesizing information on hazard identification, exposure assessment, and dose-response assessment into a characterization of human health and environmental risk. The methodology can be used to provide relative rankings of environmental health risks or, at a micro level of analysis, to identify the main factors contributing to the health risk posed by a specific environmental problem. Both the macro and micro level analyses are useful in identifying and evaluating management options that can be effective in addressing the problem.

Identification of data gaps and weaknesses in a study can also be used to prioritize future research. These research needs may include source measurements and models, health effects data, environmental and exposure data, among others. Thus, there is a natural feedback mechanism between the risk assessment process and research.

REFERENCES

1. Cohrssen, J. J., and V. T. Covello, (1989), Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. Washington, D.C.: U.S. Council on Environmental Quality, Executive Office of the President.

2. Long, A. D., (1990), "Environmental Health in the LDC Context: A Framework." Paper presented at the National Conference on International Health, June 19, 1990.

3. National Research Council, (1983), Risk Assessment in the Federal Government: Managing the Process. Washington, D.C.: National Academy Press.

4. Naugle, D.F., T. K. Pierson and J. M. Mauskopf, (1990), Development of a Risk Characterization Framework. U.S. EPA Environmental Criteria and Assessment Office, Office of Health and Environmental Assessment. EPA/600/8-90/040. August 1990.

5. Smith, K. R., R. A. Carpenter and M. S. Faulstich, (1988), Risk Assessment of Hazardous Chemical Systems in Developing Countries. East-West Environment and Policy Institute Occasional Paper No. 5, Honolulu, Hawaii: East-West Center.

6. U.S. Environmental Protection Agency, (1989a), Comparing Risks and Setting Environmental Priorities: Overview of Three Regional Projects. Office of Policy Analysis, Office of Policy, Planning and Evaluation.

7. U.S. Environmental Protection Agency, (1989b), Interim Methods for Development of Inhalation Reference Doses. Environmental Criteria and Assessment Offices, Office of Health and Environmental Assessment. EPA/600/8-88/066F, August 1989.

8. U.S. Environmental Protection Agency, (1987a), Unfinished Business: A Comparative Assessment of Environmental Problems. Office of Policy Analysis, Office of Policy, Planning and Evaluation, February 1987.

9. U.S. Environmental Protection Agency, (1987b), Integrated Risk Information System Supportive Documentation - Volume 1. Office of Health and Environmental Assessment. EPA/600/8-86/0320, March 1987.

10. U.S. Environmental Protection Agency, (1987c), Risk Assessment Guidelines of 1986. Office of Health and Environmental Assessment. EPA 600-8-87/045, August 1987.

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