Risk Prioritization: National Trends, Forecasts and Options For The Army

Army Environmental Policy Institute
Information Paper

Risk Prioritization

AEPI

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Risk Prioritization

National Trends, Forecasts and Options for the Army

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EXECUTIVE SUMMARY

In industrialized countries throughout the world, environmental concerns are exerting a moderating influence over consumption of natural resources for economic and societal gain. This influence is likely to increase as environmental problems become more global and require international cooperation. Governments are beginning to treat ecological stress induced by human activities on a par with human health concerns. This will have profound implications for the formation of future environmental policy by regulatory agencies in the United States and abroad.

Despite impressive progress in recent years, the Environmental Protection Agency (EPA) has been accused of reacting to public pressures and fears surrounding hazardous waste sites rather than scientifically proven health risks affecting much broader segments of the population. From a scientific perspective, it is argued that expenditures for clean-up of hazardous waste sites could be better spent on reducing the health risk associated with indoor air pollution. This has created considerable difficulty for the EPA in promulgating meaningful rules, and for federal agencies trying to establish long term environmental management goals and objectives.

There is a growing trend, however, to use a more rational set of policy considerations for long-term environmental planning. Environmental and health risk is being increasingly recognized as an effective criteria for setting long-term policy goals. Policy goals based on the concept of risk measurement and mitigation are attractive because they are easily translated into program management techniques.

Development and implementation of risk assessment methods require a multi-disciplinary team from the physical, and biological sciences. In the past, a major criticism of the risk assessment approach was the use of extremely conservative assumptions for input variables which frequently resulted in overestimating risks. The old "cook book" approach for the derivation of risks was based on default factors (toxicity parameters, exposure assumptions, and extrapolation models) which were less versatile for realistic exposure situations. Risk assessment as a tool in the decision-making process was unsatisfactory

because the assumptions used were unrealistic, yielding distorted risk estimates. This jeopardized efforts to classify serious hazards from trivial ones, and hampered the efforts of federal agencies to determine program priorities based on risk analysis. The trend now, however, is toward improved risk assessment methods.

Recognizing the need for an integrated and targeted national environmental policy based on the concept of health and ecological risks, EPA initiated a study in 1987, on the issue of relative risks and risk prioritization for a selected set of environmental problems on a national and global scale. A task force was commissioned to investigate these environmental problems and determine their priority on the basis of relative risks. The task force adopted a broad analytical approach based on the weight of available quantitative data and its expert judgement to:

(a) identify the major types of health and environmental risks,
(b) estimate the level of risk to health and environment for each problem area,
(c) rank the environmental problems in order of relative risk.

The selection criteria were based on how environmental laws affected each problem area. This modified approach was viewed by EPA as a better tool for evaluating programs based on risk prioritization rather than public perception. The results of the EPA task force study, and the subsequent EPA science advisory board review set the stage for a dialogue on risk-based prioritization. The EPA is now considering the value of relative risk as the basis for establishing priorities for long term environmental policy and planning options.

The trend in industry and in federal agencies is to focus on prioritization methodologies based on assessments of human health and ecological risk and monitoring efforts. The EPA Office of Research and Development (ORD) predicts the following major environmental growth areas in the next decade:

(a) programs to enhance development of core scientific knowledge in ecological risk assessment
(b) programs dealing with CO2 and global climate change
(c) programs for improving existing human health risk assessment methods
(d) programs on long-term pollution prevention and waste reduction
(e) monitoring programs to improve assessment of human exposure to pollutants

Army regulations provide guidance on environmental risk mitigation and minimization as priority issues in the development of environmental quality goals for some programs. As an example, the Army applies this guidance in the decision making process for determining site-specific quantitative risk assessments for waste-site remediation efforts. However, the regulations do not clearly identify a conceptual basis for developing a broad environmental policy and program strategy using the objective criteria of risk.

As part of an on-going effort to analyze environmental trends affecting the Army, the Army Environmental Policy Institute (AEPI) sponsored an Environmental Trends and Policy Workshop on August 19-20, 1991. Participants from many Army management levels, the EPA, academia, and private industry met to identify the emerging environmental trends of greatest significance to the Army. The participants concluded that determining the priority of environmental problems based on risk, was one the four most significant trends affecting the Army during this decade and beyond.

Following the workshop, the AEPI undertook an initiative to assess the concept of risk-based prioritization as a rational basis for developing environmental strategies and goals for the future. This paper provides an initial review of current trends in risk assessment and risk prioritization. This paper makes the distinction between risk assessment and risk prioritization and discusses the relevance of risk based analysis as a determinant for Army environmental policies and strategies.

There are at least two factors that the Army may want to consider in establishing priorities based on relative risk. First, scientific developments are expected to change existing risk assessment methodologies. This may significantly alter the approach to risk assessment in the future, and enhance the efficiency of risk mitigation. Second, military programs such as weapons development, production of propellants explosives and pyrotechnics, and depot level maintenance operations, pose unique challenges for the Army with regard to environmental compliance. These challenges as well as those associated with the development, manufacture, storage, transportation, and disposal of chemical and radioactive wastes are very complex. Basic research and development on hazard identification, monitoring techniques, and toxicity estimates, may provide the Army with sophisticated tools for effective assessment of human health and environmental risks.

CHAPTER 1

OVERVIEW ON ENVIRONMENTAL RISKS AND RISK PRIORITIZATION

1.0 INTRODUCTION

During the past three decades, extensive government policy and programs have been promulgated to control contamination of the environment. Following the passage of the National Environmental Protection Act (NEPA) of 1969, the Congress quickly enacted the Federal Clean Air Act of 1970 (and subsequent amendments of 1974, 1977, and 1977) and the Clean Water Act (formerly Federal Water Control Act of 1972; with amendments of 1977, 1978). During the 1980s, several unique environmental laws were added to protect human exposure to environmental contaminants. These laws stemmed from growing public concern over the health hazards associated with disposal of hazardous wastes. Specifically, the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980, the Resource Conservation and Recovery Act (RCRA) of 1984, and the Superfund Amendments and Reauthorization Act (SARA) of 1986, stipulated quantitative human health and environmental risk assessment and management (See Glossary for definitions of these terms) as a requirement in the remedial investigations and clean-up efforts of hazardous waste-sites.

1.1 BRIEF BACKGROUND

Prior to the formation of the Environmental Protection Agency (EPA), the Public Health Service and the State Health Departments were vested with the task to regulate environmental contamination. Historically, federal regulations on toxic contamination centered on human exposure to chemical toxicants present in food and drugs, and to chemicals associated with occupational exposures. Increased public perception and scientific data on the ecological and health effects of hazardous and toxic wastes in the environment resulted in the formation of the EPA and the subsequent passage of laws for regulating all environmental and health risks.

Despite impressive progress during recent years, the EPA has recognized that its environmental policies, regulations, and enforcement efforts were driven by public pressures, rather than by a coherent internal agency plan (EPA, 1987). This may have reduced the effectiveness of EPA policies and programs for addressing the most serious environmental problems. The EPA concluded that it was more advantageous to objectively assess and prioritize environmental risks on a broader dimension to effectively formulate environmental policy and programs for the coming decades.

The national expenditure on clean-up costs for contaminated sites in both the public and private sector is expected to escalate significantly. Apart from municipal and industrial sources, federal agencies such as the Department of Defence (DOD) and Department of Energy (DOE) are major contributors to the overall national toxic waste burden. A recent EPA, Office of Technology Assessment (OTA) study on a sample of DOE nuclear weapons facilities located nationwide, reported generation and storage of large quantities of high-level and transuranic radioactive wastes, as well as mixed radioactive and chemically hazardous wastes in the vicinity of DOE industrial complexes without adequate safety and environmental considerations (Johnson, 1992). In addition, millions of cubic meters of radioactive and hazardous wastes have been buried throughout these industrial facilities, resulting in documented contamination of groundwater, surface water, soil and sediment in the vicinity of the DOE facilities studied (Johnson, 1992).

Although DOE, DOD, and the private sector have demonstrated a willingness to comply with all the relevant environmental regulations, several scientific and engineering problems seriously limit principal and responsible party (PRP) efforts to effectively clean-up existing contamination. Such problems include:

- Difficulties in detecting and mapping the nature and extent of contamination at the site;
- Non-availability of suitable clean-up technology for contamination problems specific to DOE, and DOD sites;
- Uncertainties in the clean-up efficiency of existing technologies;
- Non-availability of health and environmental risk prioritization guidelines;

- Inadequacies in risk assessment methods to determine off-site health and environmental effects.

As part of an on-going effort to support effective environmental policies and to analyze environmental trends affecting the Army during this decade and beyond, the Army Environmental Policy Institute (AEPI) sponsored an Environmental Trends and Policy Workshop, on August 19-20, 1991. Participants were invited from various Army organizations (representing many management levels), the EPA, leading universities, and private industry. Study groups were formed to identify emerging environmental trends of greatest significance to the Army. Over 40 environmental trends were reviewed. Four trends were selected as having the most significant impact on future Army environmental policies and strategies. Prioritizing environmental problems based on risk, was one of the four most significant trends. The workshop participants concluded that the Army should explore human and ecological risk prioritization as a basis for decisions on environmental policy and programmatic strategies.

In response to the study group consensus, the AEPI engaged Science Applications International Corporation (SAIC) to conduct an initial investigation into the current use and future perspectives of risk based prioritization as a method for dealing with environmental problems. Crucial engineering limitations in achieving desired clean-up levels, and growing budgetary constraints are two compelling reasons for the Army to develop a risk based prioritization strategy to efficiently allocate resources for protection of human health and the environment.

1.2 STATEMENT OF PURPOSE

The purpose of this paper is to provide an **initial** investigation into the complex subject of risk prioritization. Specifically, the paper will address:

- Current trends in environmental risk assessment and development of risk prioritization methods;

- A general overview of existing Army environmental policy on risk prioritization;

- Future perspectives on risk prioritization and its potential significance to Army.

In the opinion of the authors, there is need for better communication and understanding between policy makers and scientists on the use of risk assessment and risk prioritization methods as management tools for decision makers. Policy makers tend to consider all relevant information in arriving at a decision, and tend to accommodate (qualitative) factors that are not statistically significant or scientifically proven. Scientists, on the other hand, may be prone to base decisions on the most statistically significant, scientifically proven (quantitative) data, while discounting other less significant factors that may not be scientifically proven. This paper will highlight the strengths and weaknesses of risk prioritization as a scientific tool for decision making and will try to draw some distinction between the qualitative and quantitative aspects of risk assessment and risk prioritization.

CHAPTER 2

CURRENT TRENDS IN RISK ASSESSMENT

2.0 INTRODUCTION

This chapter provides a brief introduction to risk assessment before dealing with the principle topic of risk prioritization beginning with Chapter 3. A discussion of future trends and scientific developments in risk assessment will also be presented. The subject matter in Section 2.4 and 2.5 is scientifically oriented to provide a more complete perspective of the issues surrounding the risk assessment process. For brevity, some readers may want to bypass this discussion and proceed to Section 2.6 for a summary of the main points.

2.1 OVERVIEW OF RISK ASSESSMENT

The risk assessment process is comprised of four components; (a) hazard identification*, (b) exposure assessment*, (c) dose-response assessment*, and (d) characterization of risk*, at projected levels and patterns of exposure. (For the benefit of those readers who may not be familiar with risk assessment or risk prioritization terms, an asterisk will be used to mark those which are defined in the Glossary at Appendix D). Qualitative risk assessment* involves only the first two components, and sometimes a limited toxicity assessment; whereas quantitative risk assessment* includes all four components with less consensus on the most appropriate animal models, data sets, and conversion factors to use in their calculation. This lack of consensus is causing some major modifications to quantitative risk assessment as discussed in Section 2.2. Nevertheless, there are compelling arguments favoring the use of animal data for quantitative risk assessment (NRC, 1989).

Risk assessment is an essential component of the Superfund RI/FS process. However, the analytical framework and methods described here are applicable to risk assessment methods involving all hazardous waste sites. The primary purpose of risk assessment has been for the protection of human health. This approach is being gradually displaced with a broader definition of risk assessment that includes both human and ecosystem receptors, with each considered equally susceptible, and each requiring comparable levels of protection. Significant resources have been committed by federal

agencies to reduce or mitigate health hazards stemming from a contaminated environment. Now, there is an emerging trend to apply human health and environmental risk assessment as the guiding criteria for prioritizing the expenditure of these resources to solve environmental problems. This trend has increased the volume and scope of human health and environmental risk assessment, substantially. For instance, an environmental problem of global dimensions such as stratospheric depletion of ozone (and its associated health effects) requires a significantly large environmental epidemiologic study to assess the nature and extent of the risk. On a smaller, but broader scale, the nature and extent of risk to human health is required for numerous hazardous waste sites under Superfund.

In an effort to evaluate the risk assessment process in the federal government and offer suggestions for improvement, the National Academy of Science, Committee on Institutional Means for Assessment of Risks to Public Health, published "Risk Assessment in the Federal Government: Managing the Process" (hereafter referred to as the NAS study). The NAS study on risk assessment resulted in a division of the risk assessment process into "risk assessment" and "risk management." It defines risk assessment as the "characterization of the potential adverse health effects of human exposure to environmental hazards, including characterization of the uncertainties inherent in the process of inferring risk" (NRC, 1983). The risk management process, on the other hand, is defined as the "regulation of risk, whereby the results of risk assessment are effectively incorporated into a remedial action plan." Risk management takes into account, political, social, economic, and engineering considerations in the decision-making process (NRC, 1983).

Although the primary focus of the NAS study was to evaluate and recommend improvements in assessing risks to human health, the scope and methodology of the study were broad enough to include assessment of environmental risk as well. As a result, the analytical components for risk assessment identified in the NAS study are applicable to almost any situation involving assessment of environmental risks. The risk assessment process also provided a rational basis for evaluating alternative clean-up plans to protect both human health, and the environment.

Prior to the NAS study, the general framework for Superfund site specific risk assessments was in accordance with the guidance on the **human health** evaluation activities conducted during the RI/FS (EPA, 1989). Based on the major components of risk assessment identified by the NAS study (1983), EPA issued "Risk Assessment Guidelines for

Superfund (RAGS)", for performing site-specific **human health and environmental** risk assessments for hazardous waste-sites under the Superfund program (EPA, 1989a). The three basic components of RI/FS evaluation are; (a) guidance for baseline risk assessment (RAGS, Part A), (b) refinement of preliminary remediation goals (RAGS, Part B), and (c) remedial alternatives risk evaluation (RAGS, Part C). EPA has also published several other guidance manuals which recommend methods for performing site specific risk assessments. A selected bibliography of these documents and other manuals on risk assessment is given in Appendix B.

2.2 OBJECTIVES OF RISK ASSESSMENT

The objective of risk assessment is to determine if public health or the environment is potentially at risk from any contaminants on, or emanating from, hazardous waste sites. As the analytical component of the process, risk assessment is performed to estimate the potential risks to humans and the environment due to exposure to potentially contaminated air, surface water, groundwater, surface soils, or sediments.

Under RAGS guidance, the objectives of the risk assessment process are:

- To estimate the baseline risks in order to determine whether there is a need for remedial action at the site;
- To identify a rational basis for determining "safe" levels of chemicals that are protective of public health;
- To compare potential health impact of various remedial alternatives;
- To provide a consistent method to evaluate potential public health threat due to exposure to contaminants from hazardous waste sites (EPA, 1989a).

RAGS provides broad guidelines to perform human and ecological risk assessments. However, baseline risk assessment is essentially site specific and therefore may vary in detail and extent depending upon the complexity and the prevailing characteristics at the site, as well as the availability of Applicable or Relevant and Appropriate Requirements (ARARs) and other criteria, advisories, and guidance. The general framework of baseline risk

assessment for Superfund sites involves four steps: (a) data collection and analysis; (b) exposure assessment; (c) toxicity assessment; and (d) risk characterization. These steps will be described in the next Section.

2.3 THE RISK ASSESSMENT PROCESS

EPA guidance for ecological risk assessment is imminent at this writing. The overall format and integrated tasks for ecological risk assessment are expected to be similar to those presented for human risk assessment (EPA, 1989b). The major components of human health and ecological risk assessment (as required under the Superfund waste site evaluation) are presented in Table 2-1. The table illustrates the scientific disciplines involved and the sequential interrelationship of the major components. Continual feedback occurs between each major component as information is gathered and refined. A brief discussion of how each component is accomplished is provided at Appendix C.

An examination of the tasks enumerated in Table 2-1 for various stages in risk assessment, (i.e., data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization) indicates that the tasks are complex and require specialized inputs from several disciplines within the basic physical, and biological sciences. A risk assessment team is expected to display unique abilities to understand and interpret, multifaceted data sets, and conduct a realistic risk assessment as stipulated in the guidance documents.

A major criticism of the existing risk assessment approach is the use of unrealistic assumptions for input variables resulting almost always in overestimating risks. Further, the "cook book" approach for derivation of risks based on default factors recommended by the EPA has rendered the existing methodologies less versatile for estimating marginal risks. The recommended method often describes plausible risks for a hypothetical exposure scenario with conservative exposure and toxicity assumptions resulting in upper bound risks that represent the 95th percentile (or above) of the exposed population (EPA, 1989a,b). The implications of adopting maximum risk estimates in risk mitigation decision-making are that point risk estimates tend to foreshadow the probability aspects of risk in the exposed population, with no provision to account for uncertainties inherent in the process.

These uncertainties stem from all of the risk assessment steps described above and extend to the final risk estimates which are based on a combination of field validated data,

Table 2-1

Major Components of Quantitative Risk Assessment *

Step 1

Data Collection and Evaluation
• Data Collection and Chemical Analysis: **a.** Field investigations and chemical analysis; **b.** Establish criteria for data quality. • Identify potential chemicals of concern: **a.** chemical structure, **b.** toxicological effects, **c.** environmental effects.

Step 2

Exposure Assessment
• Develop conceptual site model: **a.** Determine contaminant release pattern;**b.** Identify potentially exposed population,**c.** Establish critical exposure pathways. • Estimate Exposure dose/uptake

Step 3

Toxicity Assessment
• Identify qualitative and quantitative toxicity information for chemicals of concern. • Determine appropriate toxicity measures: **a.**reference doses (RfDs)**b.**cancer potency factors (q_1^*)

Step 4

Risk Characterization
• Characterize Potential for Adverse Health Effects:**a.** Non-cancer hazard quotients; **b.** Excess lifetime cancer risks. • Identify and enumerate the uncertainties in steps 1-4.

*Based on Risk Assessment Guidance for Superfund (EPA, 1989a).hypothetical exposure

assumptions, and expert judgement. Therefore, a qualitative uncertainty evaluation is customarily included in the baseline risk assessments and the final risk estimates have to be couched on the uncertainties associated with the models and assumptions used, parameters selected for fate and transport, and determination of exposure pathways. These uncertainties also limit the value of existing Superfund risk assessment methods as a decision tool.

There are limitations too, in the scientific methods that constitute the basis of risk assessment. Examples include problems with extrapolation of toxicity data from experimental animals to estimate human health risks, the variability in chronic toxic responses (dose-time-response) among populations, the mechanistic basis for carcinogenesis, and inconsistent exposure dosimetry. These are some of the more daunting basic science problems that increase uncertainties in the final risk values. There is also a general lack of; national or regional epidemiologic studies with reliable data on environmental contamination and human health risks, environmental epidemiology studies on human activity patterns related to exposure to environmental contaminants, and other factors. These scientific issues are discussed in the next section.

2.4 SCIENTIFIC ISSUES ON CONVENTIONAL RISK ASSESSMENTS

The evolution of new scientific ideas and methods is a constant process of intense scrutiny and debate by the scientific community. Conventional risk assessment methodologies for the evaluation of human health and ecological risks have crucial deficiencies due to fundamental problems in the basic sciences, and to limitations in obtaining optimal data. The deficiencies can be overcome, but until then, policy makers may not want to make decisions based on risk assessment methods shrouded with data gaps and uncertainties.

The importance of distinguishing risk assessment from risk management is being increasingly recognized by technical professionals and regulatory agencies. Federal activities involved in the development of risk policy and risk enforcement such as the Office of Science and Technology Policy (OSTP), and Health and Human Services (HHS) have acknowledged the critical differences in risk assessment and risk mitigation efforts (OSTP, 1985). In practice, risk assessment methods have defined policy considerations, and they are

usually based on conservative models and assumptions. More often, the assumptions used in conventional risk assessment are unrealistic, yielding distorted risk estimates.

Inappropriate assumptions could jeopardize efforts to classify serious hazards from trivial ones, and hamper federal agency efforts to prioritize risks. At Table 2-2 is a list of the most controversial scientific issues pertaining to the use of toxicity data from animal bioassay and human exposure assumptions in conventional risk assessment. These issues are expected to be resolved in the near future by the scientific community working with EPA. The following sections will highlight the scientific limitations of conventional risk assessment methods and the potential areas for future improvement.

Frequently, the use of conservative exposure and toxicity assumptions have resulted in overestimation of risks by several orders of magnitude. For example, experimental data has been obtained from sensitive experimental animals exposed to high concentrations of chemicals. The data is used to extrapolate effects on humans at a lower dose range. Conservative mathematical models have also been used for extrapolation of dose-response data resulting in exaggerated risk estimates (Ames, et al, 1987). Uncertainty factors are routinely included at various stages of risk assessment to conservatively account for deficiencies in the exposure and toxicity databases and the unknown synergistic reaction in humans to exposure of chemical compounds in the environment (See further discussion on synergistic affects in Section 2.5).

The issues presented in Table 2-2 will have a significant affect on risk prioritization and mitigation efforts with respect to re-shaping existing cancer risk estimation methodologies. Conservative assumptions in cancer risk assessment have often been criticized as a serious impediment for categorization of hazards as either serious or trivial. Deficiencies in databases and limited knowledge of carcinogenic mechanisms have resulted in the use of overly conservative assumptions in cancer risk characterization. The adoption of upper bound estimates as the basis of mitigation efforts precludes consideration of less obvious factors for prioritizing risks (See discussion on 95th percentile in Section 2.3). This compels risk assessors to opt for alternative methodologies to suitably address the existing deficiencies in the conventional risk assessment process.

Table 2-2

Scientific Trends in Risk Assessments and Areas For Modification in The Existing Methods*

Scientific Issues Pertaining to Use of Animal Bioassay Under Scrutiny for Modification	Scientific Issues Pertaining to Use of Human Exposure Estimates Under Scrutiny for Modification
Issues concerning the use of sensitive animals in bioassay	Use of worst-case environmental conditions to define exposure scenario
Selective use of positive relationships in dose-response while ignoring negative data	Methods used to identify the maximum exposed individual
Use of severe testing conditions in bioassay	Use of default conservative exposure assumptions versus real-world exposure data
Relevance of bioassay results for interpreting human health risks	Limited use of uncertainty analysis in the derivation of exposure data
Choice of dose-response model to infer toxicity at lower doses	

* Based on EPA (1987, 1990a,b); Rao (1992); Nichols and Zeckhauser (1986); Ames et al., (1987).

In cancer risk assessment, the use of carcinogenicity data from experimental animals and epidemiological studies has been widely criticized. Problems in the use of animal studies are:

- The protocols used in experimental carcinogenesis may not meaningfully describe real-life human exposure scenarios;
- Use of high dose exposure data as the basis to infer carcinogenicity at lower doses in humans;
- Conflicting interpretation of the experimental data from pathologic and histopathologic studies;
- Lack of information on threshold risks.

Epidemiologic studies are attractive since the focus is directly on humans, and realistic human exposure scenarios. However, epidemiologic studies have several shortcomings. Exposure data is commonly lacking, incomplete, imprecise, or affected by systemic recall or selective biases. In addition, these studies measure risks that are often marginal in comparison to background, thus making statistically significant observations less likely. The study design and statistical method chosen for the analysis have significant impact on the final study outcome. However, according to a National Research Council study on animals as sentinels of environmental health hazards, the use of animals as environmental monitors would allow the collection of a large database at lower cost and fewer ethical and legal issues (NRC, 1983).

The reasons for the use of highly conservative variables in risk characterization are three fold. First, uncertainties exist in the reference doses (RfDs) due to extrapolation of dose-time-response characteristics of toxicity data from experimental animals to assess potential health effects in humans. Second, extremely conservative default exposure assumptions are adopted due to a lack of more appropriate site-specific exposure data. Third, unrealistic mathematical models and data sets are being used in the derivation of cancer potency factors for cancer risk estimation. In the absence of a sound and legally defensible scientific basis for estimating risks, it is prudent for regulatory agencies to devise policy and develop programmatic guidance that provides maximum protection from long-

term adverse health effects due to exposure to environmental contaminants. Although this posture appears to be reasonable from the standpoint of risk assessment as a scientific process, its value as an effective and rational tool in the risk management decision-making process is limited.

Answering the question of "how safe is safe enough?" requires information on potential risks corresponding to the lowest concentrations of contaminants in the environmental media. This information cannot be obtained from the existing risk assessment methods. The scientific community and the regulatory agencies have developed strategies to meaningfully address the scientific issues concerning the use of conservative exposure assumptions and toxicity parameters. It is anticipated that future advancements in risk assessment methods will address these issues in greater detail.

2.5 TRENDS IN SCIENTIFIC DEVELOPMENTS

Although risk assessment applies credible scientific principles and statistical methods to estimate adverse health and environmental affects, the final outcome has substantial uncertainties. Federal regulatory agencies and policy groups have recognized the benefits and deficiencies in the application of new quantitative methods for risk assessment. Based on the weight of scientific research and increasing regulatory attention, the following subject areas are likely to receive increased attention in the coming years:

- Physiologically-based pharmacokinetic models and analysis for exposure dose and toxicity assessment;
- Multimedia, multichemical exposure assessment;
- Quantitative uncertainty analysis in risk characterization.

Physiologically-Based Pharmacokinetic Model (PBPK): PBPK analysis has been recently incorporated into risk assessments. PBPK models describe the dynamic distribution and bioavailability of chemicals and provide time-course concentrations of xenobiotic chemicals and their metabolites in various body tissues including the target tissues. PBPK models have been traditionally used in food safety evaluations, and in studies involving the kinetics and dynamics of drugs in body tissue compartments.

Use of PBPK in quantitative risk assessments is recognized as a valuable tool to more accurately estimate chemical concentrations in target tissues. Researchers have successfully combined PBPK analysis with multi-stage carcinogenesis models to account for dose, route, and interspecies differences in risk assessment (Andersen et al. 1987). In addition, PBPK is being used to discern relationships between excess cancer risks and target tissue exposure dose (Bois et al. 1987).

Multi-media and Multiple Chemical Exposure Assessment: Humans are exposed to a multitude of chemicals and chemical mixtures rather than single compounds. Some humans may experience a synergistic interaction upon sequential or multiple exposure to the combined effects of carcinogenic and non-carcinogenic chemicals. This phenomenon is increasingly recognized as an important area in quantitative risk assessments (Berenblum, 1985; Harrison and Heath 1986). Chemical interactions which yield enhanced toxic response have profound implications for quantitative risk assessment and are the primary research focus in problems related to multiple chemical exposure. Likewise, exposure to multiple chemicals often occurs via several exposure routes. Multimedia exposure involves inadvertent exposure, either simultaneously or sequentially, to contaminants present in more than one media by similar or differing routes. The existing risk assessment guidelines do not consider multi-chemical, multimedia exposure scenarios, thereby limiting the scope of exposure assessment to a set of hypothetical exposure scenarios involving exposure to individual chemicals.

Scientific research is underway on multiple chemical interactions, and multimedia exposure assessment. The results are expected to introduce major modifications in risk assessment. Various offices of the EPA have developed extensive databases on multiple chemical interactions (Arcos et al. 1988; Rao et al. 1989). These databases and associated software are being used to identify and classify carcinogenesis and systemic toxicity modification based on the functional properties of the interacting chemicals (Arcos, 1989; Tennent and Ashby, 1991). Efforts are being made to develop a weight-of-evidence scheme* to derive chemical class-specific interaction profiles* indicating the potential for interactive effects (Rao, 1992; Tennent and Ashby, 1991). Although, methods have been proposed to adjust the cancer slope factors based on the interactive data, it is pertinent to note that the ongoing efforts to characterize chemical interactions are largely quantitative and the results of these investigations have not reached a consensus. Therefore, they can not be directly incorporated to adjust final risks for combination effects. However, it is

anticipated that the final outcome may be similar to the weight-of-evidence scheme for classification of carcinogens for human carcinogenicity (EPA, 1989a). The weight-of-evidence for interactive effects may be used to rank cancer hazards at waste sites, or for conducting a preliminary structure-activity relationship investigation* on new hazardous materials with limited toxicity data. Application of PBPK methods in the derivation of exposure dose/intake* is expected to receive wider recognition in risk assessments for regulatory purposes.

Epidemiologic studies investigate the causal relationships between marginal carcinogenic risks and the incidence of an environmental risk factor. The difference between the marginal risk levels and the background incidence rates are normally so low that a statistically significant difference between the exposure and the background data is rare. Absence of a significant risk for a particular risk factor from a single exposure pathway may not be indicative of its potential risk characteristics. In order to address these deficiencies, studies have been performed to measure a composite exposure for multimedia pollutants (Hoar et al. 1986; Lawrence and Tylor, 1986). A recent paper has described a composite exposure methodology* in a retrospective cohort* to measure the effects of exposure to drinking water contaminated with volatile organic compounds (VOC) (Freni, 1987). This study has investigated the usability of the LD_{50}*, TD_{50}* (acute toxicity measures), NOEL (no-observable-effects-levels), and LOEL (lowest-observable-effects-levels) as measures of toxicity to assess risks of exposure to several VOCs in drinking water. It is anticipated that future epidemiologic studies will be designed to simultaneously measure multimedia contaminants in multiple exposure pathways to more accurately derive exposure dose estimates. These implications point to improved, more reliable human health risk assessments.

<u>Quantitative Uncertainty Analysis in Risk Characterization:</u> Existing risk assessment methods assume highly conservative exposure assumptions and toxicity estimates. By adopting conservative point estimates, the current EPA method does not allow the risk assessor an opportunity to quantitatively and more accurately address the broader range of less significant input variables. In other words, since the input variables are at or near the threshold level of sensitivity analysis they are not a significant influence on the final outcome. As stated earlier, risk estimates based on the worst-case exposure scenario do not provide risk managers with lower order risks corresponding to lower contaminant concentration and exposure assumptions.

Quantitative uncertainty analysis based on the Monte Carlo simulation method is being promoted as a realistic alternative to the conventional point risk estimate method. Instead of point values, a probability density function for distribution is adopted to characterize the range of distribution for the exposure and toxicity variables. Unlike point estimates, the Monte Carlo method yields a density function for the risk distribution that facilitates adjustments when input parameters change.

Probabilistic risk assessment methods are gaining acceptance by the EPA for hazardous waste site evaluations (Ebasco, 1990; Environ 1991). In a recent study, Burmaster and Stackelberg (1992) have presented a case-study to illustrate the use of Monte Carlo methods in risk assessments. The case-study investigated the influence of uncertainties in the exposure assumptions and the cancer slope factor of benzo[a]pyrene on the overall excess lifetime cancer risks. Figure 1 shows the results of this uncertainty analysis. This is a depiction of the cumulative distribution of excess lifetime cancer risk to humans due to variable dose intake estimates of benzo[a]pyrene. The variables included: contact rate, soil concentration, exposed skin surface area, skin soil adherence factor, and exposure duration. The graph illustrates cumulative excess lifetime cancer risks adjusted for all these input variables with a line drawn through the 50th, 95th, and 99th risk percentiles. The cumulative cancer risks represent a probable rate curve instead of a point estimate and provide useful information for the lower ranges of exposure. This method gives the mitigation team input variables that correspond to lower exposure and contaminant concentration levels. Acceptance of this method by scientists and policy makers will go a long way toward improving the reliability of risk assessment as a decision making tool.

2.6 SUMMARY OF RISK ASSESSMENT

In summary, risk assessment is the analytical basis for environmental risk mitigation. Although conventional environmental risk assessment was developed essentially for the Superfund RI/FS process, it has broader application (with certain modifications) for use in larger environmental epidemiologic studies.

The deficiencies in the conventional risk assessment method are largely due to fundamental problems in basic science and a general lack of exposure and toxicity data for

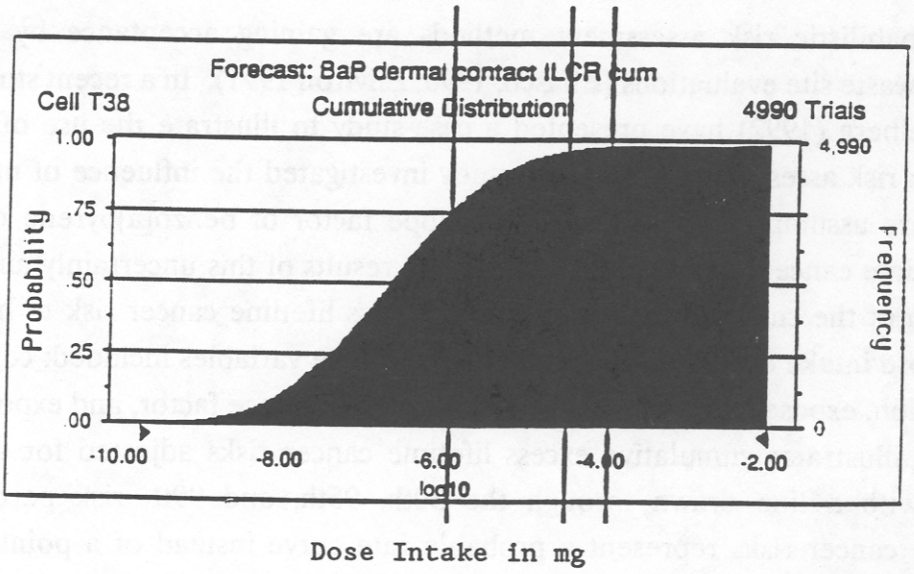


Figure 1

Cumulative Distribution of Incremental Lifetime Cancer Risks from exposure to Benzo[a]pyrene Using Quantitative Uncertainty Analysis*

* Based on Burmaster and Stackelberg (1992)

environmental contaminants. Scientific advancements in this area are anticipated to address some of these limitations. In particular, developments in physiologically-based pharmacokinetics, multimedia and multichemical exposure studies, probable risk assessment methods, and larger environmental epidemiologic studies associating human health and environmental effects with major environmental pollutants are expected to significantly enhance state-of-the-art of risk assessment in the future.

As the Army considers a risk based approach to environmental policy decisions it should realize that current risk assessment methodologies have scientific limitations and these must be weighed with other factors before arriving at conclusions. The learning curve may be steep and it may require some time before the Army can develop a reliable in-house capability for risk assessment and risk prioritization. In all likelihood, however, other federal agencies will be going through the same process.

CHAPTER 3

CURRENT TRENDS IN RISK PRIORITIZATION

3.0 INTRODUCTION

Risk prioritization and risk assessment are interdependent. As discussed in Chapter 2, **risk assessment** is an analytical process applied to assess the nature and extent of human health and ecological risks in an exposed population due to a specific environmental risk factor(s). **Risk prioritization** is a process based on a complex set of societal, economic and political considerations, in addition to human health and ecological risks.

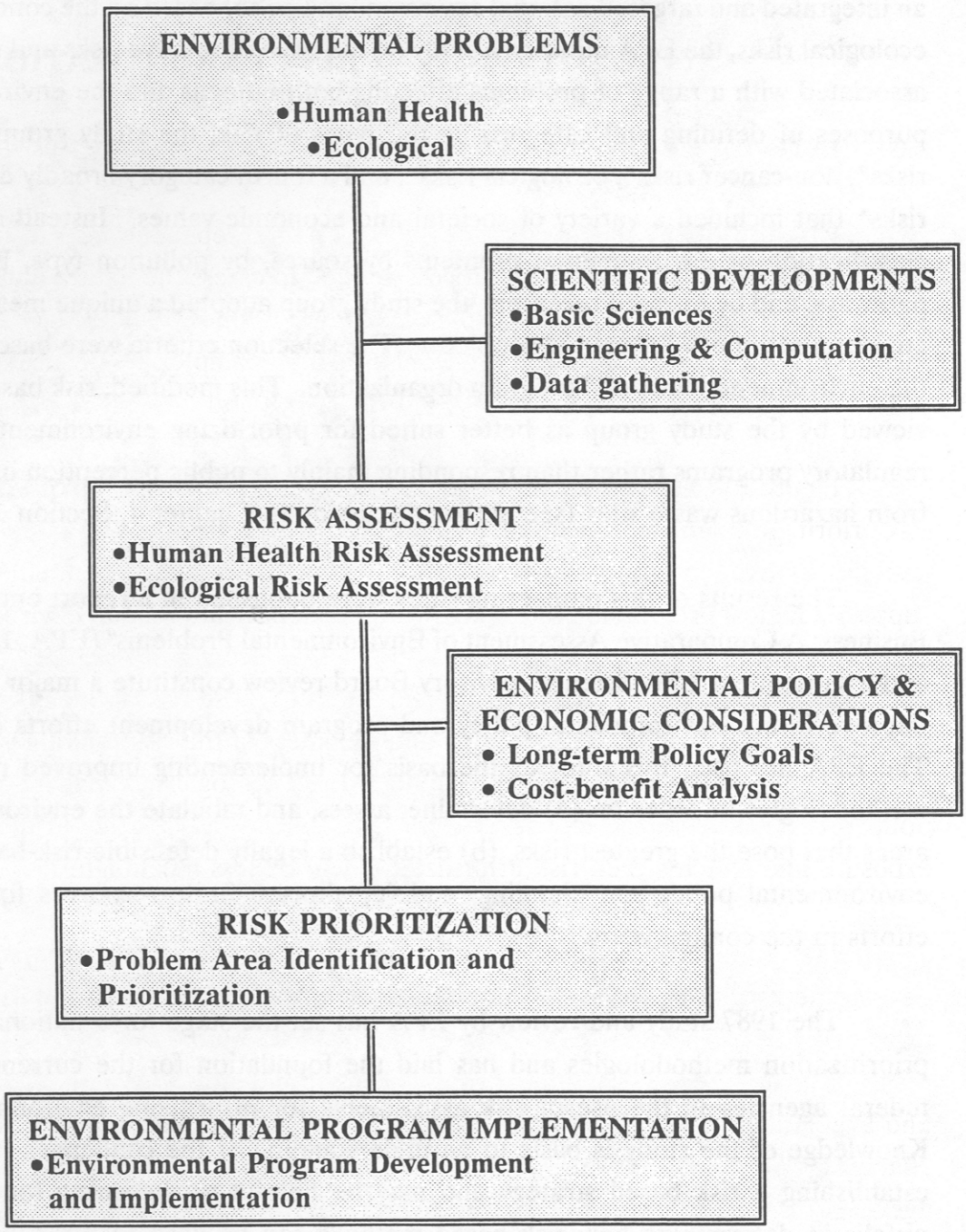
Figure 2 is a schematic representation of the interrelationship of risk assessment and risk prioritization in environmental problem mitigation. It should be evident from the figure that risk assessment and risk prioritization are mutually interdependent processes. They support a logical progression beginning with the identification of an environmental problem and culminating in the development and implementation of a solution. Ranking of risks presupposes a knowledge of the nature and extent of those risks (which is deduced from the risk assessment process). The strength and weakness of the risk ranking is at least partially dependent upon the data correlating human (and ecological) exposure to environmental pollutants and their toxic effects. If there are crucial deficiencies in the data on human exposure and toxicity, then risk prioritization will be less meaningful.

The trend in risk prioritization is therefore closely associated with scientific developments that enhance the state-of-the-art of risk assessment, and in efforts aimed at broadening the knowledge base on human exposure to environmental pollutants and resultant toxic effects. Long-term goals for environmental policy and program objectives, and availability of resources may directly define future trends in risk prioritization. This chapter will examine the trends in environmental risk ranking strategies by regulatory agencies.

3.1 IMPLICATIONS IN RISK PRIORITIZATION

The scope and dimension of problems relating to environmental protection have broadened considerably in the past decade. Apart from traditional water and air pollution control and municipal and industrial waste regulation activities, the EPA began to face

Figure 2



SCHEMATIC REPRESENTATION OF RISK ASSESSMENT AND RISK PRIORITIZATION ACTIVITIES IN ENVIRONMENTAL PROBLEM MANAGEMENT

environmental challenges of national and even global dimension. Recognizing the need for an integrated and targeted national environmental policy based on the concept of health and ecological risks, the EPA initiated a study on the issue of relative risks and risk prioritization associated with a range of problems effecting both humans and the environment. For the purposes of defining and categorizing the types of risk, the study group selected cancer risks*, non-cancer risks*, ecological risks*, and a fourth category broadly defined as welfare risks* that included a variety of societal and economic values. Instead of the traditional classification of environmental problems by source, by pollution type, by environmental pathways, and by exposed receptors, the study group adopted a unique method to select and analyze a set of environmental problems. The selection criteria were based on structure of the environmental laws and program organization. This modified, risk based approach, was viewed by the study group as better suited for prioritizing environmental problems and regulatory programs rather than responding mainly to public perception of health concerns from hazardous waste sites (see earlier discussion in Chapter 1, Section 1.0).

The results of this pioneering study were published in a report entitled "Unfinished Business: A Comparative Assessment of Environmental Problems" (EPA, 1987). This report and a subsequent EPA Science Advisory Board review constitute a major effort by EPA to improve future environmental policy and program development efforts (EPA, 1990 a-c). The EPA has used this study as the basis for implementing improved risk prioritization methodologies in order to: (a) determine, assess, and tabulate the environmental problem areas that pose the greatest risks, (b) establish a legally defensible risk-based rationale for environmental policy and planning, and (c) allocate finite resources for risk mitigation efforts in the coming years.

The 1987 study and review by EPA has set the stage for a national debate on risk prioritization methodologies and has laid the foundation for the current interest among federal agencies in the use of risk assessments for prioritizing environmental problems. Knowledge of the study is basic to an understanding of the challenges to be expected in establishing a risk based strategy and may be helpful to the Army for avoiding similar pitfalls in determining how risk based methods can be used to prioritize environmental problems. This chapter will review the EPA study and provide insight into the process the Army might follow if it decides to adopt a similar risk prioritization methodology. This chapter will also compare the risk prioritization techniques in *"Unfinished Business"* with the relative risk ranking methodology used in three EPA regional offices to prioritize

environmental problems unique to their region (EPA, 1989c). This may provide some insight into the challenges and opportunities for the Army in using these approaches to prioritize regional or systemic environmental problems which are influenced by regional, state, or local regulatory authorities.

3.1.1 The EPA Study on Ranking for Relative Risks - The EPA (1987) study group adopted a broad analytical approach based on the weight of available quantitative data and its expert judgement to identify the major types of health and environmental risks, set priorities for selected environmental problems, and estimate relative risks for human health and ecological impact as it exists today for a selected set of environmental problems.

Based on the analytical framework described in Section 3.1 above, the study group selected 31 problem areas for relative risk ranking and prioritization. These problem areas are listed in Table 3-1. Definitions and pollution categories identified under the 31 problem areas chosen for risk prioritization are provided in Appendix A. Several problem areas selected for prioritization lack clear boundaries with respect to the source of pollution, the physio-chemical characteristics of pollution, environmental media at risk for contamination, and risk categories affected by the problem area. For instance, the hazardous waste sites and releases from underground storage tanks are linked to drinking water contamination. Similar examples of intermedia transfer of contaminants could be used to contest the arbitrary boundaries of environmental problems identified in the study (EPA, 1987). Although several problem areas directly address ecosystem risks, considerations on wildlife and ecosystems risks were sporadic in the approach taken by the study group in classifying environmental problem areas.

For ranking of environmental problems based on risk categories, the EPA study group defined a general conceptual approach for comparing risk categories. The operational methodology for ranking was based on a combination of available data on the risk category (such as, evidence for carcinogenicity, systemic toxicity, wildlife toxicity, etc.) and expert judgement of the group. Cancer risk is a relatively straightforward criterion, whereas non-cancer and ecological effects required a detailed approach. Risk categories were identified and ranked for all problems according to the existing data on three risk categories. An operational descriptor for toxicity, defined as the severity index* was used in the ranking for

Table 3-1

Major Environmental Problems Areas Selected For Relative Risk Determinations

Environmental Problems for Risk Prioritization *
1. Criteria air pollutants from mobile and stationary source (including acid precipitation)
2. Hazardous/toxic air pollutants
3. Other air pollutants (including fluorides, total reduced sulfur, substances not included above that emit odors
4. Radon -- indoor air only
5. Indoor air pollutants -- other than radon
6. Radiation -- other than radon
7. Substances suspected of depleting the stratospheric ozone layer -- CFCs, etc.
8. Carbon-dioxide and global warming
9. Direct, point source discharges (industrial, etc.) to surface water
10. Indirect, point source discharges (POTWs) to surface water
11. Nonpoint source discharges to surface water
12. Contaminated sludge (includes municipal and scrubber sludge)
13. To estuaries, coastal waters and oceans from all sources
14. To wetlands from all sources
15. From drinking water as it arrives at the tap (includes chemicals, lead from pipes, biological contaminants, radiation etc.)
16. Hazardous waste sites -- active (including hazardous waste tanks (groundwater and other media)
17. Hazardous waste sites --inactive (Superfund) (groundwater and other media)
18. Non-hazardous waste sites -- municipal (groundwater and other media)
19. Non-hazardous waste sites -- industrial (includes utilities) (groundwater and other media)
20. Mining waste (includes oil and gas extraction wastes)
21. Accidental releases -- toxics (includes all media)
22. Accidental releases -- oil spills
23. Releases from storage tanks (includes product and petroleum tanks - above, on and groundwater)
24. Other groundwater contamination (includes septic systems, road salt, injection wells, etc.)
25. Pesticide residues on foods eaten by humans and wildlife
26. Application of pesticides (risks to applicators, which includes workers who mix and load, as well as apply, and also consumers who apply pesticides)
27. Other pesticide risks, including leaching and runoff of pesticides and agricultural chemicals, air deposition from spraying, etc.
28. New toxic chemicals
29. Biotechnology (environmental releases of genetically altered materials)
30. Consumer product exposure
31. Worker exposure to chemicals

Based on the EPA report on relative risk and ranking project (EPA, 1987). The serial listing is **not** a ranking order for risk priorities.

non-cancer effects. Individual study groups adopted different ranking formats for the other two risk categories. Ranking for cancer risks is simpler in comparison to the ranking approach used for non-cancer and ecological risks. As stated earlier, unlike cancer risk assessment, the guiding criteria used for non-cancer and ecological effects are far more complex, necessitating a broader and more complex ranking format. Table 3-2 is a final ranking of the 31 problem areas for cancer, non-cancer and ecological effects (EPA, 1987).

3.1.2 EPA Science Advisory Board (SAB) Review of Human Health Risk Prioritization in *"Unfinished Business"* - The SAB Subcommittee on Relative Risk Reduction Strategies (hereinafter referred to as the SAB Subcommittee) was commissioned to review the human health risk prioritization approach adopted in *"Unfinished Business"* and its implications on the environmental policy and programmatic developments for the future. The SAB Subcommittee was also asked to simplify and update the relative ranking procedure adopted in *"Unfinished Business"* (EPA, 1990a).

In its review (EPA, 1990a), SAB Subcommittee concluded that:

- The relative ranking approach for various risk categories adopted in *"Unfinished Business"* did not consider combined risks for risk categories. For instance, attempts were not made to combine cancer effects with other effects as a final ranking criteria for cancer effects;

- Increasing reliance on EPA programmatic policies and public perceptions of risk as the sole basis for risk ranking have introduced ambiguities in the hazard identification and categorization process;

- Data on hazard and exposure assessment for a few candidate contaminants were used for prioritizing problem areas comprising contaminants belonging to diverse chemical and toxicological classes;

- The ranking approach did not consider the magnitude of relative risks for individual problems, thereby limiting its scope for application in the policy and programmatic decision-making process;

- Data gaps and uncertainties in exposure assessment for relative ranking were inadequate.

Table 3-2

Relative Ranking of Environmental Problems For Risk Categories *

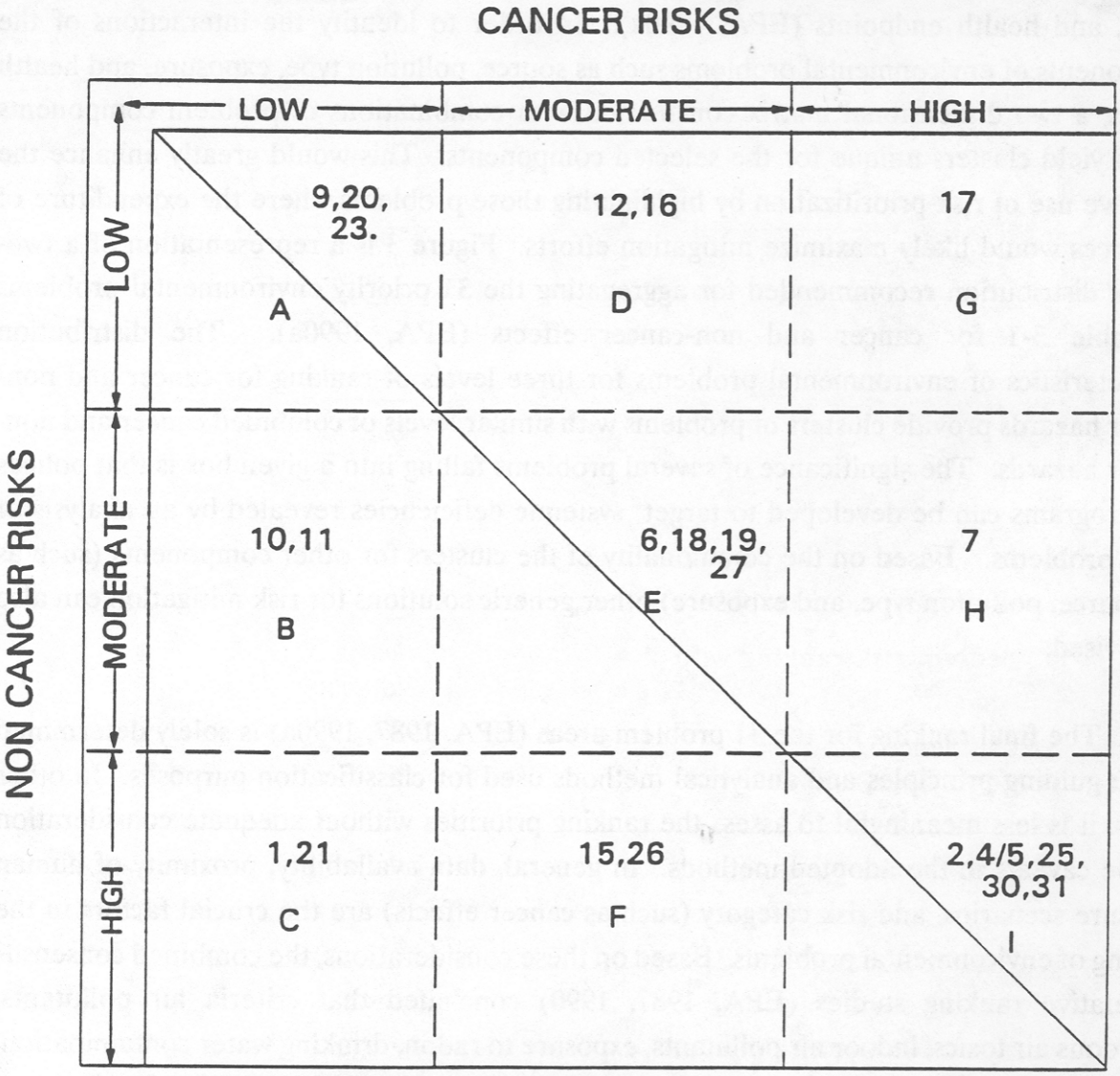
Relative Ranking for Population Cancer Risks	*Relative Ranking for Population Non Cancer Risks*	*Relative Ranking for Ecological Risks*
Rank Problem Area	**High Non Cancer Risks**	**Rank 1**
1 Workers exposure to chemicals	Criteria air pollutants	Stratospheric ozone depletion
1 Indoor radon	Hazardous air pollutants	CO_2 and global warming
3 Pesticide residues in food	Indoor air pollutants --Other than radon	**Rank 2**
4 Indoor air pollutants (other than radon)	Drinking water	Physical alteration of aquatic habitats
4 Consumer exposure to chemicals	Accidental toxic releases	Mining, gas, oil extraction and processing wastes
6 Hazardous/toxic air pollutants	Pesticide residues in food	**Rank 3**
7 Depletion of Stratospheric ozone	Application of pesticides	Criteria air pollutants
8 Hazardous waste sites (inactive)	Consumer product exposure	Point-sources discharges
9 Drinking water	Worker exposure to chemicals	Non point source discharges
10 Applications of pesticide	**Medium Non Cancer Risks**	Pesticides
11 Radiation (other than radon)	Radon -- indoor air	**Rank 4**
12 Other pesticide risks	Radiation -- not radon	Toxic air pollutants
13 Hazardous waste sites (active)	UV radiation/ozone depletion	**Rank 5**
14 Non hazardous waste sites (industrial)	Indirect discharges (POTWs)	Contaminated sludge
15 New toxic chemicals	Non point sources	Inactive hazardous waste sites
16 Non hazardous waste sites (municipal)	To estuaries, coastal waters, oceans	Waste sites (municipal)
17 Contaminated sludge	Non hazardous waste sites (municipal)	Non hazardous waste sites (industrial)
18 Mining waste	Non hazardous waste sites (industrial)	Accidental toxic releases
19 Release from storage tanks	Other pesticide risks	Oil spills
20 Nonpoint source discharge to surface waters	**Low Non Cancer Risks**	Other groundwater contamination
21 Other groundwater contamination	Direct discharges (industrial)	**Rank 6**
22 Criteria air pollutants	Contaminated sludge	Radiation (other than radon)
23 Direct point source discharge to surface water	To wetlands	Hazardous waste sites (active)
24 Indirect, point source discharge to surface water	Hazardous waste sites (active)	Underground storage tanks
25 Accidental toxic releases	Hazardous waste sites (inactive)	
26 Accidental oil spills	Mining waste	
27 Biotechnology	Release from storage tanks	
28 CO_2 and global warming		
29 Other air pollutants		

Based on the EPA report on relative risk and ranking project (EPA, 1987). Listing indicate the ranking order for risk categories. Cancer risk ranking for problem areas 1 and 4 were tied.

While criticizing the guiding principles adopted for relative ranking in *"Unfinished Business,"* the SAB Subcommittee suggested the use of a matrix method for ranking of environmental problems based on the sources of pollution, exposure situation, chemical agent, and health endpoints (EPA, 1990a). In order to identify the interactions of the components of environmental problems such as source, pollution type, exposure, and health effects, a two dimensional matrix constructed with combinations of problem components would yield clusters unique for the selected components. This would greatly enhance the effective use of risk prioritization by highlighting those problems where the expenditure of resources would likely maximize mitigation efforts. Figure 3 is a representation of a two-matrix distribution recommended for aggregating the 31 priority environmental problems in Table 3-1 for cancer and non-cancer effects (EPA, 1990a). The distribution characteristics of environmental problems for three levels of ranking for cancer and non-cancer hazards provide clusters of problems with similar levels of combined cancer and non-cancer hazards. The significance of several problems falling into a given box is that polices and programs can be developed to target systemic deficiencies revealed by an analysis of those problems. Based on the commonality of the clusters for other components (such as the source, pollution type, and exposure) other generic solutions for risk mitigation can also be devised.

The final ranking for the 31 problem areas (EPA, 1987, 1990a) is solely determined by the guiding principles and analytical methods used for classification purposes. In other words, it is less meaningful to assess the ranking priorities without adequate consideration for the caveats in the adopted methods. In general, data availability, proximity of human exposure scenarios, and risk category (such as cancer effects) are the crucial factors in the ranking of environmental problems. Based on these considerations, the combined consensus on relative ranking studies (EPA, 1987, 1990) concluded that criteria air pollutants, hazardous air toxics, indoor air pollutants, exposure to radon, drinking water contamination, exposure to pesticides and other chemicals in food, occupational exposure to chemicals are areas that are expected to receive major attention for future policy and programmatic development (EPA, 1990a). Table 3-3 ranks environmental problems for non-cancer effects in humans based on the level of confidence for the rankings. In this table, three levels of confidence (i.e., high, medium, and low) are combined with three ranking levels for the problem (high, medium, and low) to regroup the problems for weight-of-evidence toxicity data. There is inadequate data for lower order risks, as seen from the absence of rankings for problems of low and medium level concern but with a high level of confidence.

Figure 3



Two-dimensional matrix representation for risk priortization for combined cancer and non cancer effects.

Adopted from EPA (1990c)

Table 3-3

Level of Confidence in the Ranking of Environmental Problems*

Level of Confidence in the Ranking of environmental problems	*Ranking of Environmental Problems for Non-cancer effects in Humans*
High risk ranking with a **high level** of confidence	• *Criteria air pollutants* • *Drinking water* • *Accidental release of toxics* • *Pesticide applications* • *Workers exposure to chemicals*
High risk ranking with a **medium level** of confidence	• *Hazardous air pollutants* • *Other indoor air pollutants* • *Pesticide residues in food* • *Consumer product exposure*
High risk ranking with a **low level** of confidence	*None*
Medium risk ranking with a **high level** of confidence	*None*
Medium risk ranking with a **medium level** of confidence	• *Radiation (non-radon)* • *Indirect discharges (POTWs)* • *Discharge to estuaries* • *Municipal waste sites* • *Other pesticide residues*
Medium risk ranking with a **low level** of confidence	• *Indoor radon* • *Ozone depletion by UV radiation* • *Industrial waste sites*
Low risk ranking with a **high level** of confidence	*None*
Low risk ranking with a **medium level** of confidence	• *Direct discharges (industrial)* • *Contaminated sludge* • *Hazardous waste sites (active)* • *Hazardous waste sites (inactive)*
***Low risk ranking** with a **low level** of confidence*	*None*

POTW = Publicly owned treatment works;

*Based on recent EPA report on relative risk reduction project (EPA, 1990a-c).

However, problems with a high relative risk tend to have a higher level of confidence in the ranking assignment. This is in accordance with the results of EPA studies (EPA, 1987, 1990a).

3.1.3 EPA (SAB) Review on Ecological Risk Prioritization in "*Unfinished Business*"

Following the publication of *Unfinished Business,* the SAB Subcommittee turned their attention to the **ecological risk prioritization** procedures adopted in the *Unfinished Business* to develop alternative methodology for evaluating **ecologic** and **welfare** risk assessment, and **combine the ecological and welfare risks to a single aggregate rank for combined risks.** As with the human health risk prioritization review, the SAB Subcommittee also criticized the ecological risk selection criteria used in *"Unfinished Business."* The SAB Subcommittee review rightly pointed out almost complete omission of information on the source, pollution type, environmental media, and exposed receptors for categorizing problems (EPA, 1990b).

Similar to the earlier matrix, the SAB Subcommittee review adopted a matrix of ecological stress types versus ecosystem types as developed by Hartwell and Kelly (1986) to reclassify the relative ranking of ecosystem risks reported in *Unfinished Business* (Table 3-1). The revised classification approach adopted a scale of stress (defined as ecological stress at local, regional, and biosphere levels), transport media (air, water, terrestrial), and recovery time (recovery time in years, decades, centuries, indefinite) following removal of the stress factor from the environment. Based on these modified criteria, reclassification for ecological risks indicated that **habitat alteration** (a ecosystem problem not included in *Unfinished Business*), **global climate change**, and **stratospheric depletion of ozone** were ranked as the highest ecological risks (EPA, 1990b). Considering the similarity in the time-space dimensions and the estimated period of recovery for these problems, the conclusions of the SAB Subcommittee report appear reasonable. Although inclusion of a recovery criteria for ranking appears to be reasonable, data on recovery periods for the cited problems are not available. Considering the complexities of habitat alteration, effects on bio-diversity, and species population, it is almost impossible to deduce a meaningful quantitative measure for "recovery period".

The SAB Subcommittee concluded that ecological and welfare risks are interrelated, since the four types of welfare impact (i.e., ecological quality, resource sustainability, direct and indirect economic effects) are intricately tied to ecological processes (EPA, 1990b). For instance, an irreversible loss in the structure and function of an ecosystem, or reduction in the quality of ecological resources (due to direct or indirect human activities) could produce a long-term welfare impact. Likewise, adverse effects on the ecosystem for economic or non-economic reasons might affect long-term resource sustainability and ecological quality.

Based on the combined criteria for ecological and welfare risks, the SAB Subcommittee reclassified the ecological problem areas as shown in Table 3-4. In the modified approach adopted by the SAB Subcommittee, a quasi-quantitative (+,-) descriptor has been used to denote rankings for the extent of stress, impacted media, and recovery period. Unlike the ecological risk ranking in *Unfinished Business* (see, Table 3-2), the SAB Subcommittee has adopted a more sophisticated ranking criterion that correlates reasonably well with the more recent studies on ecological impact (EPA, 1990b).

Despite the impressive preliminary advances made on the scientific front to devise rational methods to identify and classify risks, the overall impact of risk ranking on ecological risk mitigation is of a qualitative nature. This is due to limitations in the existing data and the associated uncertainties. However, the EPA studies have provided an impetus for federal agencies to devise environmental policy and programs for the future based on risk prioritization. The environmental problems identified in the EPA study are of national and global importance but these problems may not be as important from a regional perspective. In order to examine whether the relative risk ranking depicted regional problem characteristics, the EPA Office of Policy, Planning, and Evaluation (OPPE) coordinated a follow-up study with three EPA regional offices. This study is an example of how the Army can tailor a risk based methodology for prioritizing regional or systemic environmental problems.

3.1.4 EPA Regions Risk Prioritization Project - Subsequent to the publication of *"Unfinished Business"*, OPPE and EPA regional offices in Boston (Region 1), Philadelphia (Region 3), and Seattle (Region 10), undertook a joint two-year demonstration project to apply the relative ranking methods reported in *"Unfinished Business"* to unique regional problems, and compare the risk priority characteristics for the EPA Regional Offices.

In this study, the Regional Offices independently chose 18-24 priority problems unique for the region and attempted to rank them according to the methodologies described in *"Unfinished Business"*. Instead of two risk categories for cancer and non-cancer effects (as described in *"Unfinished Business"*), the regional offices adopted a combined category, referred to as human health risks. OPPE published the results as a combined report comparing the ranking features of the three-region study (EPA, 1989c).

Table 3-4

Revised Ranking of Environmental Problems For Combined Ecological and Welfare Effects*

Environmental Stress	Extent of Stress			Media			Recovery Time		
	I	II	III	A	W	E	S	M	L
1. Global Climate	3+	3+	3+	3+					X
Habitat alteration**	2+	3+	3+	3+	3+	3+		X	X
Stratospheric ozone	3+	3+	3+	3+					X
Biological Depletion		2+	3+		2+	2+			X
2. Herbicides/pesticides		1	2+	2+	2+			X	
3. Toxics in surface water		1	2+		2+			X	
Acid deposition		1+	1+	1+				X	
Airborne toxics	1	2+	2+	2+				X	
4. Nutrients			1+		1+		X		
BOD			1		1		X		
Turbidity			1		1		X		
5. Oil		-1	1		1	-1	X		
Groundwater		-1	-1		-1				X
6. Radionuclides			-1	-1	-1			X	
Inputs to surface water			1+		1+			X	
Thermal pollution**			-1		-1		X		

Legends: 3+ = Highest; 2+ = Higher; 1+ = High; 1 = Medium; -1 = Low;

* Adopted from the report of the ecology and welfare subcommittee, relative risk reduction project (EPA,1990b).

** Problem areas not included in *Unfinished Business* (EPA, 1987).

Table 3-5 is a partial listing of the comparative risk rankings for ecological and human health effects by the three EPA regional offices. Although the report ranked the 18-24 problems in three risk categories, only the top five priority problems receiving high and low ranks are listed in order to highlight the similarity and distinction in the ranking orders for similar priority problems.

It may be interesting to note that the overall ranking for the three regions compared favorably with the ranking of problems in *"Unfinished Business"* (EPA, 1989). Despite regional differences in the relative ranking, the three regional offices consistently ranked indoor radon, indoor air pollution, pesticide residue in food, and drinking water contamination as high risk domains (EPA, 1990). Likewise, physical modification of habitat and nonpoint source discharges to surface waters were consistently ranked as high for ecological risks by all three regions. However, the unique regional characteristics of the environmental problems defined the ranking pattern for various risk categories. For example, Region 1 had higher ambient concentrations of criteria air pollutants, and Regions 1 and 3 had a higher potential for ecosystem damage by acid deposition. Region 10's ranking system was defined by dependence on surface water as the source of potable water supply which is facing increased contamination due to point and nonpoint source discharges to surface waters. The ranking order of the regional study corroborated with the *"Unfinished Business"* report, assigning a low priority to Superfund, RCRA, municipal, and industrial waste sites (see, Table 3-3). The results of this review support the initial contention that public's perception of health risks associated with hazardous waste sites, have over influenced the regulatory programs of EPA. Federal agencies have responded to this regulatory emphasis with the result that hazardous waste management has become the driving force behind their environmental programs and the main consumer of their environmental resources.

3.1.5 Implications of the EPA Study for the Army - The EPA initiatives on risk prioritization for policy and programmatic purposes offer significant implications for the Army, as evident from the identified problem areas and the adopted analytical methods to categorize and prioritize risks (EPA, 1987, 1990b). As the lead agency for management of national environmental problems, EPA has initiated a long-term policy strategy for pollution abatement based on relative risks. The concept of relative risk as the basis for long-term

Table 3-5

Relative Ranking of Priority Environmental Problems by the EPA Regional Offices for Human Health and Ecological Risks*

Ranking Level and Criteria**	EPA Region 1	EPA Region 3	EPA Region 10
High Risk Human Health	• Criteria pollutants (ozone) • Radon • Lead • Acid deposition and visibility • Other indoor air pollutants	• Indoor air • Indoor radon • Other pesticide problems • Radiation (other than radon) • Nonpoint sources of pollution	• Indoor radon • Other indoor air pollutants • Pesticides • Air toxics plus PM 10 • Non-public drinking water
High Risk Ecological Effects	• Criteria air pollutants • Acid deposition and visibility • Industrial point sources • POTW discharges to surface waters • Nonpoint sources of discharges	• Terrestrial habitat modification • Aquatic habitat modification • Nonpoint sources • Acid depositions • CERCLA sites	• Non-chemical degradation - terrestrial • Non-chemical degradation - aquatic • Pesticides • Nonpoint sources • Industrial point sources
Low Risk Human Health	• Industrial waste sites • Municipal waste sites • Superfund waste sites • RCRA waste sites • Radiation from other sources	• Aquatic habitat modification • USTs • Terrestrial habitat modifications • Solid wastes • Air toxics	• Other radiation • Releases from storage tanks • Industrial point sources • Current hazardous waste sites • Non-hazardous waste sites.
Low Risk Ecological Effects	• Radon • Industrial air pollution • Drinking water • Lead • Asbestos	• Water supply • Other pesticide problems • Other groundwater • Indoor air • Indoor radon	• Release from storage tanks • Non-hazardous waste sites • Other radiation • Superfund waste sites • RCRA waste sites

* For definitions on environmental problems and the contaminant categories, see Appendix A.

** For the purposes of illustrating the EPA Regional Offices comparative ranking, only the top five problem categories have been listed for human and ecological risk prioritization (EPA, 1989c).

policy and planning is expected to receive widespread acceptance in public and private sectors. The problem areas and risk ranking approach presented in *"Unfinished Business"* may not necessarily reflect the environmental problem characteristics of the Army. However, the Army could adopt a similar process for identifying and prioritizing those environmental problems unique to its operations and interests. In proceeding, the Army might find it useful to first identify systemic or programmatic and develop appropriate ranking criteria. This effort could also factor in the influence and enforcement priorities of regional, state, or local regulatory agencies.

CHAPTER 4

OVERVIEW OF ARMY RISK PRIORITIZATION

4.0 INTRODUCTION

Apart from the traditional commitment to efficiently mobilize its resources to defend our nation from external threats, the Army has recognized an expanding commitment and responsibility to comply with the growing body of environmental legislation over the past two decades. In part, this response is due to a dramatic change in national environmental policy affecting hazardous waste disposal and environmental quality. The EPA has formed an Office of Federal Facilities Enforcement and new legislation threatens to increase inspections of federal facilities that once were subject only to substantive, but not procedural requirements of the law. The Army is now confronted with a plethora of intricate environmental regulations under federal, state and local governmental jurisdictions. Reacting to these pressures, the Army increased its environmental compliance efforts and focused its management resources to survey and investigate its hazardous waste sites to determine the extent of contamination and the potential public health hazards from migration of hazardous substances beyond the borders of Army installations and activities. As the DOD Executive Agent for the clean-up of Formerly Used Defense Sites, the Army is also faced with determining the extent of DOD involvement and liability for hazardous wastes at these locations. More recently, the Army has begun to re-examine its responsibilities in preventing pollution and conserving the natural resources under its control. An environmental strategy for the 21st Century is under development and environmental program management is being reviewed. The broadening scope of Army challenges will place greater demands on finite resources and stress the importance of setting priorities among real or perceived environmental problems. The Army will need dependable methods for setting environmental priorities, defending environmental resources, and developing environmental policies to carry out their strategic goals and objectives.

4.1 ARMY POLICY

In the most recent version of Army Regulation 200-1, Environmental Protection and Enhancement, the environmental goals of the Army are clearly stated (Army, 1990) in paragraph 1-33, as follows:

- "Demonstrate leadership in environmental protection and improvement";
- "Minimize adverse environmental and health impacts while maximizing readiness and strategic preparedness";
- "Assure that consideration of the environment is an integral part of Army-decision making";
- "Initiate aggressive action to comply with all applicable Federal, State, regional and local governmental environmental quality laws";
- "Restore lands and waters damaged through past waste disposal activities";
- "Support Army programs for recycling and reuse of materials to conserve natural resources, prevent pollution, and minimize the generation of wastes";
- "Pursue an active role in addressing environmental quality issues in our relations with neighboring communities".

The aforementioned environmental goals clearly show environmental risk mitigation and minimization as priority issues. The Army applies the results of site-specific quantitative risk assessment in the decision-making process for waste-site remediation efforts. However, the Army does not clearly identify a conceptual basis for risk assessments in its existing regulation on environmental protection and enhancement. Problem areas such as Water Resources Management, Air Pollution Abatement, Hazardous Materials Management, and Solid Waste and Hazardous Waste Management are structured according to the existing environmental laws without enunciating conceptual risk management (or cross-media pollution) interrelationships in the implementation of these environmental programs. This is largely due to the prevailing ambiguities in the existing environmental laws. As with other

federal agencies, Army policies suffer the same inconsistencies and shortcomings that are present in the environmental regulations. However, the implications for protecting human health and minimizing environmental risks expressed in the environmental goals offer unique opportunities to develop a broad environmental policy and program strategy based on objective risk criteria.

4.2 MOVING TOWARD RISK PRIORITIZATION

The recommendations of the EPA science advisory committee on the review of the relative risk ranking and prioritization of environmental problems (EPA, 1987) emphasized the need to target environmental protection efforts on the basis of relative risk reduction, and to reflect risk-based priorities in the budget process. The recommendations also emphasized making greater use of all the available tools to reduce risks (EPA, 1990c). The importance of risk-based approaches as the *prima facie* criteria for the management of environmental problems is being increasingly recognized by the Army.

There is a need for objectivity in prioritizing environmental problems, and the application of risk-based criteria is an acceptable method of achieving this from a scientific and policy standpoint. Unlike arbitrary compliance with the stipulated environmental criteria, the use of an objective parameter such as human health risk, or ecological risk, greatly enhances the credibility and defensibility of environmental mitigation efforts. In addition, the criterion of risk provides a quantitative measure for safety and protection with an attractive possibility that in some cases, media-specific and receptor-specific (such as most vulnerable population at risk, most sensitive species under stress) standards could be deduced by performing risk assessments.

CHAPTER 5

FUTURE PERSPECTIVES ON ENVIRONMENTAL RISK PRIORITIZATION

5.0 INTRODUCTION

Relative ranking of environmental problems based on risk, presupposes existence of sufficient knowledge base on the nature and extent of risk posed by various environmental problem categories identified for ranking (see, Chapter 3). Unfortunately, this is not the case as seen from Table 3-3 where environmental problem areas ranked for non-cancer risks do not correlate with the level of confidence (data on non-cancer effects in human population) in the relative ranking assignment. In other words, evidence of adverse effects in human populations is not the sole criteria in the relative ranking of environmental problems. Most often difficulties in ranking are due to the lack (or non-availability) of sufficient and reliable data on exposure and toxic effects.

Future perspectives on risk prioritization methods are being examined by both the scientific community and regulatory agencies for their validity and applicability in the development of more effective alternative criteria for environmental mitigation (EPA, 1990a-c). Until the EPA study on relative risk ranking in 1987, there was no documented evidence of major initiatives by the federal agencies to develop a paradigm based on relative risk for prioritizing environmental problems. Ongoing scientific initiatives are underway on two major fronts to; integrate sophisticated quantitative methods to modify the existing risk assessment methods, and to develop risk-based approaches to categorize and prioritize environmental problem areas for effective environmental policies and programs. This chapter will describe these and future perspectives in environmental risk prioritization from a scientific, programmatic, and policy standpoint (EPA, 1990d).

5.1 SCIENTIFIC PERSPECTIVES

The results of human health and ecological risk assessment have significant influence on several environmental policy and risk management considerations. In the decision-making process, a risk mitigation team is expected to address the questions "How safe is safe" and "How clean is clean", based on the findings from risk assessments. Unfortunately, the overly restrained exposure assumptions, and toxicity parameters used in conventional risk assessment have introduced large uncertainties in the estimated risks (Krewski and Van Ryzin, 1981; Finkel, 1990; Burmaster and Von Stakelberg, 1992). Chapter 2 described current scientific issues and trends pertaining to risk assessment and Table 2-2 listed the specific scientific problems under debate pertaining to the use of animal bioassay and human exposure estimates. Future scientific advancements in risk assessment will be addressing the deficiencies in existing methods.

Based on a recent EPA, Office of Research and Development (ORD) study on the long-range agenda for research and development in the areas of environmental risk assessment, scientists will be focusing on these four core research areas: ecological risk assessment, health risk assessment, risk reduction, and basic research and development (EPA, 1990d). The combined research efforts of academic, industrial and governmental agencies are expected to contribute to overall progress in these core areas. Table 5-1 lists anticipated trends in the core scientific areas associated with risk assessment and risk management for the next decade. The selection of specific core scientific areas for research and the individual research programs envisioned for the future have placed a high priority on identification of advanced methods for risk assessment, and development of technologies for risk reduction (Zenick and Clegg, 1989; Gaylor and Kodell, 1980; Gaylor, 1989; EPA, 1990d).

For the purposes of tracking future trends on the scientific front, ORD considered it more appropriate to segregate the four core research and development areas by the four major stages of risk assessment (i.e. hazard identification, exposure assessment, toxicity assessment, and risk characterization). Tables 5-2 through 5-5 list the anticipated scientific activities for each of the four stages. The tables identify the purpose, the methods, and the data requirements for each stage with pertinent footnotes concerning deficiencies in the existing methods and study areas.

Table 5-1

Core Scientific Research Areas of Risk Prioritization Poised For Growth in The Next Decade*

Ecological Risk Assessment	Health Risk Assessment	Risk Reduction	Basic Research and Development
• Define the types of ecosystems at risk and develop common measures to indicate the condition of this system; • Programs to monitor the status and trends in ecosystem; • Long-term effects of pollution on the structure and function of ecosystem;	• Effects of pollutants on human health; • Mechanism of non-cancer toxicity endpoints; • Effects of exposure to multiple chemicals; • Develop biomarkers to estimate exposure; • Studies to include a quantitative measure on the severity of toxic effects; • Methods to estimate risks based on dose delivered to target tissues; • Use of animals as environmental monitors.	• Methods to identify the sources of major pollutants; • Promote changes in industrial processes and products to prevent pollution; • Educate individuals and institutions to make changes needed to reduce risk; • Develop effective and efficient technologies for controlling the generation of pollutants; • Use of animals as environmental monitors.	• Stimulate projects in fundamental knowledge upon which the applied programs feed; • Train future environmental researchers and managers; • Increase the probability of early detection of environmental problems; • Use of animals as environmental monitors.

* Based on the report on long-range research agenda of EPA, ORD (EPA, 1990d).

Table 5-2

Anticipated Scientific Developments in The Existing Risk Assessment Process
Step 1: Hazard Identification

Risk Assessment Process	Purpose	Methods	Requirements
Hazard Identification[a]	Field investigations to determine the nature and extent of contamination	Review of available background information, including use of animals as monitors.	• RI/FS scoping information • site inspection data
		Sampling objectives, sampling locations[1]	• site model[1] • QA/QC measures
		Sample analysis	• Analytical QA/QC
		Analytical data validation	• QLP procedures • EPA methods
		Tentative list of chemicals of concern: • compare with ARARs • compare with background data	• Federal and state ARARs, and other standards • Background analytical data
		Preliminary classes of chemicals of concern for health hazard[2]	• Toxicity information[2] • SAR information[2] for chemicals with little toxic information

[a] Hazard identification is critical in defining the objectives of risk assessment. Existing methods lack a consistent approach for hazard identification for the problem categories selected for relative ranking (EPA, 1987). This is an area with tremendous potential for future activity.

[1] Data quality objective methods may be modified in future.

[2] Hazard classification methods are preliminary in existing risk assessment methods. Newer methods involving chemical structural, structure-activity relationship (SAR), and toxicity information can be expected.

Table 5-3

Anticipated Scientific Developments in The Existing Risk Assessment Process
Step 2: Exposure Assessment

Risk Assessment Process	Purpose	Methods	Requirements
Exposure Assessment	To estimate the magnitude of contaminant exposure (or other biotic receptors) by direct or indirect methods	• Conceptual exposure model	• Background site information • Sampling and analytical info. from earlier step
		• Contaminant release pattern and exposure pathways	• Site-specific information on intermedia transport • Transport and fate characteristics • Potential exposure points of contact as determined from land use pattern
		• Identification of exposed population[1]	• Site-specific demographic information[3] • present and future land use plans
		• Quantify exposure dose/intake[2]	• site-specific or default exposure factors for human activities[4] • RAGs exposure dose derivation equations[5]

[1] Development of site-specific regional databases are expected to replace the conceptual methods used in risk assessment.

[2] Probability methods are being proposed to replace the existing methods.

[3] Lack of site-specific information is a major limitation of risk assessment. This is an area for future activity.

[4] EPA default assumptions are conservative. Modification is possible.

[5] EPA may propose using a distribution function instead of point estimates in RAGS equations for exposure dose.

Table 5-4

Anticipated Scientific Developments in The Existing Risk Assessment Process

Step 3: Toxicity Assessment

Risk Assessment Process	Purpose	Methods	Requirements
Toxicity Assessment	To weigh the evidence of toxicity of contaminants and select a quantitative dose-response parameter to assess potential adverse effects upon the exposed population	• Identify qualitative toxicity effects	• General toxicity information obtained from hazard identification step
		• Select appropriate quantitative measures to determine dose-dependent adverse effects for: a. Non-carcinogenic effects: oral and inhalation reference doses (RfDs)[1] b. Carcinogenic effects: Derivation of cancer slope factors; Weight-of-evidence for human carcinogenicity	• EPA has developed reference doses for systemic effects: a. Reference dose for oral route (RfD) and reference dose for inhalation route (RfC)[1] b. Oral and inhalation cancer slope factor (or potency factors) for carcinogens[2].
		Uncertainty analysis on derivation of toxicity parameters[3]	Uncertainties in the RfD and Slope Factors due to: a. Extrapolation method used b. Selection of toxicity data sets c. Choice of mathematical model used for extrapolation

[a] Guidelines for neurotoxic, developmental, and reproductive toxicity, and for short-term toxicity assessment are expected to be modified in the future.

[1] Reference doses for oral and inhalation routes have large uncertainties. Newer methods to more adequately characterize uncertainties are expected to be developed (see, text for details).

[2] The cancer potency factor (q_1^*) is an arbitrary measure of potential carcinogenicity and uncertainties in q_1^* are expected to be reduced (see, text for details).

[3] Integration of sophisticated methods, such as chemicals mixture effects and PBPK analysis, into risk assessment is anticipated.

Table 5-5

Anticipated Scientific Developments in The Existing Risk Assessment Process
Step 4: Risk Characterization

Risk Assessment Process	Purpose	Methods	Requirements
Risk Characterization	Risk characterization links risk assessment and risk management. The results of this step are critical for site related remedial efforts. Information from exposure and toxicity assessments are suitably combined to estimate health risks[1]	Characterize potential non-carcinogenic (or systemic) risks. Derive hazard quotients.	• Methods for deriving hazard quotients are described in RAGS[3]
		Characterize excess lifetime cancer risks	• Methods for deriving excess lifetime cancer risks are described in RAGS[3]
		Describe uncertainties in the estimation of risks[2]	Uncertainties in Steps 1-4 are described to qualify the estimated risks

RAGS = Risk Assessment Guidance for Superfund (EPA, 1989a).

[1] Efforts to address the gaps between risk assessment methods and risk management objectives are expected in the future.

[2] Development of quantitative methods to characterize uncertainties in the risks is anticipated to greatly influence future risk assessment.

[3] Probability methods involving a density distribution of risks for various exposure parameters may substitute the existing single point estimate method.

Conventional risk assessment methods are expected to become more sophisticated in the following areas:

- Development of realistic approaches to the problems of hazard identification and exposure assessment;

- Advancement of methods to accurately derive exposure dose estimates as probable measures, with realistic assumptions of human activity patterns;

- Development of mechanistic considerations for toxic effects, and better approaches to account for their variations at molecular, cellular, and physiological levels;

- Reduction of uncertainties in the use of animal bioassay data, and uncertainties in the extrapolation models used in the derivation of cancer slope factors;

- Recognition of threshold dose models in the derivation of cancer slope factors for epigenetic carcinogens*. Co-carcinogens may be included under this category except for PCBs, dioxins (as epigenetic carcinogens), and chemical agents which act as promoters;

- Incorporation of qualitative considerations into the analysis of chemical mixtures;

- Development of a weight-of-evidence method similar to carcinogen classification for addressing cancer and non-cancer endpoints;

- Formation of specific methodologies to derive toxicity parameters for assessing neurotoxic risks (for neurotoxic agents);

- Development of specific methodologies to assess toxicity parameters for developmental and reproductive end effects. Reference doses for reproductive and developmental toxicity and risk characterization for these effects may be modified;

- Application of quantitative uncertainty analysis as the acceptable method to perform risk characterization;

- Description of risks as a range function based on probability methods.

The potential scientific areas for research and developments cited above are listed in Tables 5-2 through 5-5 to depict the input of more sophisticated analytical methods for various stages of risk assessment in the future.

5.2 PROGRAMMATIC PERSPECTIVE

The regulatory community is expected to translate the results of scientific investigations into feasible environmental programs. In this process, the regulatory community has the dual challenge of maintaining the scientific credibility of the evolving program and suitably accounting for policy considerations. In the absence of a sound scientific framework, the regulatory agencies are likely to overbear to ensure the maximum protection of human health and the environment protection. Tendencies in this direction are already observable.

The limitations in the existing scientific methods used in the risk assessment process, and its implications in risk mitigation have been described earlier (see, Chapter 2). This will be a major growth area in the coming years (EPA, 1990d). Another important trend area from a programmatic point of view is the rapid growth of environmental programs geared to protect ecosystem health and reduce the global impact of pollutants generated by human activities (Kraft, 1991).

In response to a request from the U.S. Congress, the EPA, ORD submitted a comprehensive five-year plan for environmental research and development (EPA, 1990d). According to the ORD estimates, the key future growth areas in the environmental program areas are:

- Programs to enhance support for developing core scientific areas for ecological and human health risk assessment;

- Methods to improving existing human health risk assessment;

- Programs to improve monitoring and assessment of human exposure to pollutants.

- Programs on long-term pollution prevention and waste reduction;

- Programs dealing with CO_2 and global climate change;

Tables 5-6 through 5-8 list the trends in several environmental program areas with a focus on the approach taken in each program to improve human health and ecological risk assessment and monitoring efforts. The program focus on health effects and studies on monitoring listed under the EPA air program (Table 5-6) indicates the broad framework of scientific development affecting risk characterization. Most of the program focus listed in the table directly contributes to improving risk assessment and risk mitigation methodologies.

Table 5-7 lists the trends in water programs with a special emphasis on the human health effects and groundwater monitoring projects underway. For the purposes of brevity, Drinking Water, Marine, Estuary, and Great Lakes Programs were selected as representative of ongoing major water programs. The anticipated changes and program approach indicate a need for strengthening the scientific methods used in risk assessment, and a need for efficient methods for monitoring water resources for contamination.

A summary of anticipated trends in the hazardous waste and pesticides programs are presented in Table 5-8. From the Table, it is evident that the pesticide programs have placed special emphasis on the long-term toxic impact of pesticides to wildlife, and ecosystem health. Development of alternative toxicity test models to assess neurotoxic, immunotoxic, developmental toxicity, and genotoxicity have been adequately considered for future improvement and there are plans to develop new methods to monitor pesticide residues in human and biotic samples.

Like the pesticide program, the Solid Waste program is expected to place a high priority on improving the approaches to hazard characterization. Advances are expected in the future toward; analytical methods to deduce the structure and functional relationships

Table 5-6

Trends in The Air Programs With Special Emphasis on Program Approach to Health Effects and Monitoring*

Air Programs	Human Health Effects	Monitoring
Criteria Pollutants	• Health effects testing of criteria pollutants in animal and human subjected will continue; • Health effects will focus on respiratory, metabolic and immune system effects; • Effects of very short exposures to high levels of particulates and SO_2 will support reevaluation of emergency standards; • A major assessment of acid aerosol will be undertaken;	• Evaluation of National Ambient Air Quality Standards for lead will continue; • Development of new methods to monitor criteria pollutants;
Hazardous Air Pollutants	• Experimental models to develop animal bioassay models are expected to continue; • Animal models for neurotoxic, respiratory, reproductive, and developmental effects will be undertaken; • New inhalation study models are expected;	• New sampling and analytical systems are expected to accelerate; • The toxic air monitoring system (TAMS) will continue to characterize urban atmosphere;
Mobile Sources	• Studies on the cardiovascular and neurotoxic effects will continue; • New risk assessment methods for diesel exhaust, CO, NO_2, O_3, and aldehyde exposure are expected;	• Improved exposure activity pattern models will be developed; • Improvements in simulation of human activity and pollutant exposure (SHAPE) are expected;
Indoor Air	• Studies to better understand neurobehavioral effects of mixtures of volatile organic compounds in humans are expected to continue; • Studies on the genotoxicity of volatile organic compounds are expected to begin;	• Development of low cost monitoring devices for indoor air pollutants concentrations will progress;

Based on EPA (1987, 1990d).

Table 5-7

Trends in The Water Programs With Special Emphasis on Program Approach to Health Effects and Monitoring*

Water Programs	Human Health Effects	Monitoring
Drinking Water	• Maximum contaminant levels (MCL), maximum contaminant level goals (MCLG) for disinfectant and disinfectant byproducts, radionuclides, organic and inorganic compounds will continue; • Methods to extrapolate toxicological data from high-dose to low-dose and from animals to humans will continue; • Microbiological methods to identify infectious diseases organism in drinking water are expected;	• Efforts will continue to improve methods, geophysical techniques and interpretation analysis of groundwater monitoring data; • Fiber optics technology will be studied as inexpensive and reliable monitoring option;
Marine, Estuaries and Great Lakes	• Develop information bases for mitigating risk through sewage sludge treatment and disposal options; • Toxicity assessment with incineration and ocean disposal of sludge; • Health hazards from exposure to sludge where sludge is composted and used as fertilizer;	• Methods to identify and characterize unlisted chemicals in industrial waste waters will continue; • Evaluations will continue on the fate and transport of toxic pollutants in municipal waste water treatment system.

* Based on EPA (1987, 1990d).

Table 5-8

Trends in The Solid Waste and Pesticide Programs With Special Emphasis Program Approach to Health Effects and Monitoring*

Program	Health Effects	Monitoring
Pesticides/toxics	• Health effects studies will be directed toward developing and validating reliable cost-effective in vitro and in vivo test systems; • Test methods for reproductive, developmental, neurotoxic, immunotoxic, and genotoxic effects; • Structure-activity relationship (SAR) methods for premanufacture notification (PMN) chemicals; • Pesticide effects on aquatic and terrestrial wildlife will progress; • Methods and models for determining the fate and effects of these chemicals for ecosystem risk assessment;	• New methods to monitor pesticide residues in humans, human tissues and body fluids; • Application of geographic information system (GIS) technology to risk assessment will be developed; • Statistical survey procedures will be developed and tested for use in micro-environmental studies;
Hazardous Waste	• Methods to characterize potential exposure an effects of hazardous chemicals is a significant growth area; • Development of alternatives to land disposal of waste will be a top priority area; • Groundwater research will focus on the transport and fate of contaminants in groundwater as it relates to risk assessment;	• Innovative approach to pollution prevention and tools for assessment and decision making for pollution prevention measures. This will be a major growth area; • Identification of pollutant types from municipal waste combustion and new monitor and control technologies are expected;

* Based on EPA (1987, 1990d).

of hazardous chemicals in municipal and industrial waste sites, environmental fate and transport characteristics, and methods to determine risks based on doses delivered at the target tissues (EPA, 1990d). There will also be program efforts in groundwater monitoring as it relates to hazardous waste site contaminant/transport, and innovative pollution prevention methods for risk mitigation at waste sites which will gain increasing momentum in the coming years (Kraft, 1991).

5.3 POLICY PERSPECTIVES

The EPA SAB in its review on *"Unfinished Business"* made recommendations that have far reaching policy implications on the future trends in risk prioritization (EPA, 1990c). The environmental policy community is grappling with crucial problems. First, the existing policy structure for environmental regulation is a piecemeal approach, partly due to the organization of environmental problems around single media and single classes of pollutants. This approach does not follow the recommendations of academic and policy study groups to develop a single agency-wide consistent environmental policy. Second, policy considerations based on inadequate scientific data often compel the policy makers to resort to over protective standards to safeguard public health in some areas (Lave, 1982). Public perception on risk is a major factor that influences the policy-making process. Third, the existing policy considerations are inclined more towards protecting human health. This position has been getting increasing attention recently. The ongoing debate on risk prioritization is geared to address issues concerning ecosystem risks on an equal basis with human health, and greater emphasis is being placed on pollution prevention rather than risk mitigation approaches. The EPA SAB report on the relative risk reduction project (EPA, 1990c), clearly states that:

- great emphasis should be placed on establishing priorities based on the potential for risk reduction;

- pollution prevention should be the most important approach for reducing environmental risks over the long term;

- in order to reduce risk and prevent pollution in a significant way, EPA must substantially broaden its kit of environmental protection tools, especially in the areas of economic incentives and information transfer;

- environmental protection must be integrated into other policy areas, just as fundamentally as are economic concerns;

- in order to integrate environmental policy into other policies, a special governmental mechanism should be created in the Executive Branch;

- analyses similar to the risk reduction strategies project (EPA, 1987) should continue in order to integrate the results into all EPA strategic planning processes;

- the Agency annual budget should more directly reflect risk-based priorities;

- the Agency should develop an enhanced environmental education and training program for both professionals and the general public.

For the purposes of determining the policy options for critical environmental problems, the EPA SAB selected a set of critical problem areas from the 31 major environmental problems described in *"Unfinished Business"* (EPA, 1990c; see Table 3-1 for the list of problem areas). Prior to recommending policy options, the subcommittee considered all the pertinent issues such as; availability of background information on human and ecological risks, conventional risk assessment methods, data requirements, scientific issues and limitations, and existing and potential future policies (EPA, 1990c). Table 5-9 lists the anticipated trends in optional risk prioritization strategies for these critical environmental problems. It is evident from the Table that risk reduction and pollution prevention approaches are the basis for suggested future policy options in a majority of the environmental problem areas.

5.4 Summary

This chapter has presented a brief review of future perspectives for environmental risk prioritization. The topic was presented from the scientific, programmatic and policy

Table 5-9

Anticipated Trends in Optional Strategies For Risk Prioritization of Some Major Environmental Problems*

Problem Area	Suggested Policy Option For Future	Influence on Risk Mitigation
Criteria Air Pollutants	• Reduce sources of SO_x and NO_x that lead to acid deposition; • Reduce emission of volatile organic compounds that are considered major contributors to ozone depletion;	• Focus on risk reduction
Toxic Air Pollutants	• Reduce the amount of fuel consumed in transportation; • Demonstrate uses and feasibility of clean fuels as alternative fuels; • Reduce the use of solvents in consumer products;	• Focus on risk reduction
Indoor Air Pollution	• Educate State and Local governments about existing technical information on indoor air pollution; • Establish ventilation standards;	• Focus on risk reduction
Hazardous Waste	• Reduce generation of hazardous wastes by using EPA's authorities; • Add new facilities to achieve adequate treatment and disposal capacity;	• Focus on risk reduction and mitigation
Pesticides	• Encourage use of integrated pest management; • Change use patterns of pesticides; • Create right-to-know programs;	• Focus on risk reduction and mitigation
Habitat Alterations	• Develop national inventory of important ecological areas; • Preservation of ecological areas by federal acquisition;	• Focus on risk reduction and mitigation
Estuaries, Coastal Waters, and Oceans	• Develop integrated systems and avoid focussing only on water quality; • Manage contamination by developing ecologically protective cost-effective technology	• Focus on risk reduction, assessment, and mitigation

Based on the EPA SAB review of relative risk reduction project (EPA, 1990).

standpoint. In conclusion, the following highlights may be drawn from the previous discussion:

- Conventional risk assessment is expected to become more sophisticated due to the introduction of advanced methods for exposure and toxicity assessment and the long-term EPA(ORD) research and development agenda for risk assessment (EPA, 1990d). Four core areas comprising ecological risk assessment, health risk assessment, risk reduction, and basic research and development are expected to receive considerable funding in the coming years (EPA, 1990d). Section 5.1 presented a list of scientific areas that are anticipated to grow significantly under ORD activities.

- The risk management approaches for environmental programs are expected to improve in future. In particular, programmatic trends are placing greater emphasis on environmental monitoring, inventory of environmental pollutants, and development of a programmatic approach for gathering data on exposure and toxicity of environmental pollutants. More program emphasis is expected towards establishing the nature and extent of human health and ecological risks due to exposure to environmental contaminants.

The interaction of science and program management has not been discussed in this paper other than a brief mention in Section 1.2 concerning the need for better communication and understanding among those involved and their contribution to the risk prioritization process. Pollution prevention is expected to be the centerpiece of long-term environmental policy for reducing risk to human health and the environment, while effective management of current environmental problems will remain be the daunting challenge for the scientific, policy, and programmatic community. Improvements in the sciences underlying risk assessment, and collection of data on exposure and toxic effects, are expected to bring steady improvement in risk prioritization methodologies. A cooperative, integrated effort is required by all players to effectively move forward at the pace that is needed to achieve national environmental goals. As the Army considers a risk based methodology for prioritizing environmental problems, it should expect to encounter some of the same scientific, policy, and program limitations that are occurring on the national level. The next chapter will discuss the significance of scientific and programmatic issues as they relate to risk prioritization.

CHAPTER 6

SIGNIFICANCE OF RISK PRIORITIZATION TO THE ARMY

6.0 OVERVIEW

The Army employs risk assessment in the RI/FS process under CERCLA (for clean-up of Superfund sites) and in its protocols for environmental baseline studies (EBS), as described in AR 200-1. In some respects, one might consider that Army policies implementing NEPA as described in AR 200-2, Environmental Effects of Army Actions, are analogous to the risk assessment process when used as a management tool for deciding the significance of environmental impacts. Although this is true in a qualitative comparison of risk assessment and the NEPA process, risk assessment in the context of ranking human health and ecological problems is more complex, involving elaborate steps for collecting data on exposures, conducting dose-response assessments, and characterizing human health and environmental impacts. The NEPA process is primarily used to compare environmental data with a set of environmental criteria to estimate the significance of environmental impacts without any inference about the nature of risks and associated uncertainties. Unlike Environmental Impact Statements (EISs), which contain a large portion of qualitative data and professional judgement, the uncertainties in the risk assessment process are more amenable to quantitative analysis. However, inclusion of quantitative data from risk assessments in EISs would strengthen them.

Apart from these instances, existing Army policy as described in Chapter 2, indicates that risk assessment and risk prioritization are not currently being used as management tools for allocating resources or ranking the importance of environmental programs. The Army, like other federal agencies, is vulnerable to public and regulatory pressures and must comply with increasingly complex regulations at ever increasing cost. Effective tools are needed to prioritize resources for the most serious environmental problems, which may not be the problems receiving the most attention from regulatory agencies.

"Unfinished Business" (EPA, 1987), and the comprehensive SAB review of the strategies and selection criteria for ranking of environmental problems, affords the Army a guide for formulating future environmental policies and programs based on the concept of relative risk and risk prioritization. This may be a particularly attractive strategy option for the Army because its activities contribute to many of the pollutant categories which generate the problem areas identified in Table 3-2.

6.1 SCIENTIFIC SIGNIFICANCE

In considering the significance of relative risk concepts for managing Army environmental programs, one should recall the limitations of current risk prioritization methods as discussed in Chapters 2 and 3. First, uncertainties in the data sets used for ranking, and the ambiguities in categorizing complex environmental problems may pose limitations on the value of risk prioritization schemes for formulating long-term environmental policies and programs (EPA, 1990a-c). As a federal agency required to comply with environmental laws, the Army may be concerned about using very restrictive risk assessment processes and applying very technical risk assessment results to mitigate environmental problems. The relative risk ranking scheme and the evolving research and development strategies within the EPA are a clear indication of the Agency's recognition of the deficiencies in the existing risk assessment methods. The EPA, ORD has placed top priority on improving the techniques and methods for hazard identification, exposure, and toxicity analysis to enhance the usability of risk assessment methods (EPA, 1990d). As improvements are made, there will be continuing modifications in the risk assessment approach to environmental mitigation. The Army should be ready to apply these new methods as they are developed.

Second, ammunition production, materiel procurement and acquisition, weapons development and testing, depot level maintenance, and research and development activities, to name a few, pose unique environmental compliance challenges for the Army. Problems associated with the procurement, storage, and transportation of hazardous materials, and the disposal of hazardous wastes are complex. Some chemical byproducts, intermediates, and chemical wastes have unknown toxicity and may present formidable problems for the Army in identifying effective mitigation methodologies. In the absence of adequate chemical and toxicity information, the full nature and extent of the hazards posed by these activities is not clearly known.

Table 6-1

Scientific Trends Significant to Army Environmental Problems

Anticipated Scientific Developments in Public Health and Ecological Risk Assessment	Significance to Army Environmental Problems*
Health Effects R&D	
• Experimental models to develop new bioassay methods. Animal models for testing neurotoxic, reproductive, developmental, and inhalation toxicity;	• Useful toxicological assessment methods and toxicity parameters to characterize risks for neurotoxic and developmental effects for the unique chemicals agents likely to be disposed;
• Studies to better understand neurobehavioral effects of mixture of volatile organic compounds in humans;	• Potentially usable neurobehavioral effects data from humans for evaluating risks with limited uncertainty;
• Structure-activity relationship (SAR) methods for premanufacture notification (PMN) chemicals;	• Useful in hazard identification and characterization for wastes containing unique chemical agents with limited toxicity information;
• Methods to characterize potential exposure and effects of hazardous chemicals;	• Could provide useful clues to assess exposure scenarios involving exposure to hazardous chemicals unique to the Army activities;
• Use of physiologically-based pharmacokinetic analysis for estimating risks based on dose levels at the target tissues;	• A valuable tool to more specifically define risks for potent chemical wastes unique to the Army based on dose estimates at target tissue;
Research on Environmental Monitoring	
• The toxic air monitoring system (TAMS) development;	• A potentially useful tool for monitoring air toxics characteristic of the Army waste type;
• Improvements in simulation of human activity and pollutant exposure (SHAPE) system;	• Is expected to be particularly useful for better estimates of exposure doses;
• Methods to identify and characterize unlisted chemicals;	• A valuable tool for hazard characterization process for chemical agents unique to the Army waste sites;
• Application of geographic information system (GIS) technology;	• Unique tool to study contaminant distribution characteristics for the Army storage and waste sites, and locating areas for remedial actions;
• Innovative pollution prevention approaches;	• A potentially useful set of risk reduction methods for application in occupational exposure scenarios unique to the Army activities.

Significance applicable only for instances with unique waste chemical composition.

Table 6-2

Proposed Ranking Scheme for Prioritizing Human Health and Ecological Risks for Army Environmental Programs[1]

Combined Ranking for Human and Ecological Risks from a Programmatic Standpoint for the Army	*Relative Ranking Descriptor*		
	Cancer Risks	*Non-cancer Risks*	*Ecological Risks*
Air			
Criteria Air Pollutants	High	High	High
Hazardous/toxic Air Pollutants[2]	High	High	Medium
Other Air Pollutants[2]	-NA-	-NA-	-NA-
Radon (indoor)	High	Medium	-NA-
Other Indoor Air Pollution (other than radon)[2]	High	High	-NA-
Substances depleting stratospheric ozone	High	Medium	High
CO_2 and Global Warming	Low	-NA-	High
Water (ground- and surface water)			
Direct, point source discharge to surface waters[2]	-NA-	Low	High
Indirect, point source discharges to surface water	-NA-	Medium	High
Nonpoint source discharge to surface waters	-NA-	Medium	High
Discharge to estuaries, coastal waters, and oceans[2]	-NA-	Medium	-NA-
Drinking water as it arrives at the tap[2]	Low	High	-NA-
Other groundwater contamination[2]	-NA-	-NA-	Medium
Multimedia			
To wetlands from all sources	-NA-	Low	-NA-
Hazardous waste-sites (active)[2]	Medium	Low	Low
Hazardous Superfund sites (inactive)[2]	Medium	Low	Medium
Nonhazardous waste sites (municipal)	-NA-	Medium	Medium
Nonhazardous waste sites (industrial)	-NA-	Medium	Medium
Mining waste	High	Low	High
Accidental release of toxics[2]	-NA-	High	Medium
Accidental release (oil spills)[2]	Low	-NA-	Medium
Release from storage tanks[2]	Low	Low	Low
Other pesticide risks	Medium	Medium	High
Radiation			
Radiation (from source other than indoor radon)[2]	High	Medium	Low
Solid Waste			
Contaminated sludge[2]	-NA-	Low	Medium
Food			
Pesticide residues on food	High	High	High
Exposure to consumer products	High	High	-NA-
Occupational Related			
Workers exposure to chemicals[2]	High	High	-NA-
Applications of pesticides	High	High	Medium
Miscellaneous			
New toxic chemicals[2]	-NA-	-NA-	-NA-
Biotechnology[2]	-NA-	-NA-	-NA-

[1] The combined ranking for carcinogenic and non-carcinogenic (humans) and ecological effects is based on earlier EPA study (EPA, 1987).

[2] Program areas of significance for the Army's risk-based prioritization efforts.

In Table 6-2, relative ranking descriptors were not assigned for environmental problem categories such as new toxic chemicals and biotechnology. The major difficulties in the ranking of these problem categories is due to limitations in the available data on potential human health and ecological risks from exposure to new classes of chemical compounds or biological products originating from biotechnological research and manufacture processes. The problem categories associated with exposure to consumer products, and mining waste problems, may not directly apply to the Army environmental program. Further, the origin and scope of problem categories such as substance depleting stratospheric ozone, CO_2, and global warming are extremely broad and complex. However, for long-term planning strategies based on risk-based priorities, the Army environmental program must be cognizant of other problem categories and consider the possibility of potential interactions resulting in altered risk scenarios.

6.3 POLICY SIGNIFICANCE

The increase in environmental laws and the growing public awareness of environmental problems, has beset federal agencies with numerous environmental policy issues (Johnson, 1992). For example, under existing Superfund laws, contaminants purported to be migrating across the boundaries of federal hazardous waste sites are to be included in the feasibility study for clean-up. Further, authority has been granted to federal, state, and local regulatory agencies to inspect federal facilities. Pressure is being felt at many federal agencies to "get on" with the clean up process. Costs for environmental clean-up continue to escalate forcing major policy decisions about the priority of resources for environmental programs.

Even as political and administrative changes continue in Washington, concern for the environment is expected to be a long term trend. There is also a growing trend among regulators and the regulated to replace the existing reactive approach to environmental problem management with innovative and rational approaches for environmental policy and long-term planning. The use of risk as an objective criteria for setting long-term environmental policy goals is being increasingly recognized as an effective alternative approach (EPA, 1990c). This approach is attractive because it is possible to determine the progress of risk based policies and programs by using scientific risk measurement and risk

management techniques. Without scientific evidence on health and/or ecological effects, policy decisions may shift to the realm of attitude and perception (Lave, 1982).

Although, the concepts of risk assessment and risk prioritization are relatively new, the underlying goal of reducing risk is not new to the Army policy community. For instance, the most recent revision to Army Regulation 200-1, Environmental Protection and Enhancement, clearly recognizes the importance of waste minimization as a viable option for reducing long-term liability in terms of costs, environmental damage, and mission performance (Army, 1990). The goals stated for HAZMIN are to: (a) achieve 50% reduction in hazardous waste generation by 31 December 1992, (b) incorporate techniques to institute "front-end" reduction of hazardous waste, (c) pursue on-site recycling and treatment methods, and (d) promote research and development towards new and improved techniques. These goals exemplify pollution prevention (a form of risk reduction) as a long-term environmental policy of the Army (Army, 1990).

Although the HAZMIN goals appear feasible, implementation methods may suffer crucial deficiencies. One problem may be in identifying a consistent and rational parameter to use as a basis for future planning. Risk prioritization may be an answer. Other federal agencies have been attracted to the use of risk assessment and risk prioritization methods (NRC, 1983; EPA, 1987 and 1991; Machino, 1990). Likewise, the Army may find these concepts useful for determining priorities, allocating resources, measuring progress, and managing the Army environmental program.

The trends in risk prioritization are toward risk reduction strategies, risk communication techniques, and improvement of existing human and ecological risk assessment methods (See Table 5-9). Although risk reduction is anticipated to be the basis for long term environmental policies, the practical trend in policy development is expected to involve a blend of risk communication and risk assessment methods as equally important to environmental mitigation. In addition, the importance of ecosystem risk is expected to approach a par with human health risk considerations.

6.4 Summary of Risk Prioritization

Risk prioritization provides the Army with a strategic option for developing a long-term environmental policy based on the concept of relative risk. Risk prioritization is a

relatively new idea emerging as a policy alternative aimed at risk reduction through pollution prevention. The Army should examine the subject further to develop a risk-based approach to long-term policy and program decisions for mitigating environmental problems. Significant areas for further study and consideration might include:

- Strengthening the application of relative risk by following scientific developments in risk assessment methods and by collecting data on environmental exposure and toxicity to improve the application of relative risk ranking for Army environmental problems. In addition, scientific developments in the area of contaminant monitoring, hazard identification, and exposure assessments would provide useful insights into unique environmental management problems for specialized military programs within the Army.

- The EPA, Science Advisory Board reclassification of 31 problem areas (EPA, 1990). This report indicates that air pollutants may be the major human health problem for cancer, and non-cancer risks. Under the EPA reclassification, occupational exposures are another high risk category for cancer and non-cancer affects on humans. Ground water and surface water contaminants are anticipated to be the major factor for ecological risks, while multimedia pollution (originating from hazardous waste sites) is a complex category with limited information on the nature of human and ecological risks. The Army may want to re-evaluate its policies and programs for air pollution control, occupational health, and cross-media pollution prevention based on these findings.

- The increasing importance of a long-term approach for risk minimization through prevention of toxic emissions to the environment (EPA, 1990, 1990 a-d). Federal and state environmental programs should integrate appropriate societal, economic and technological considerations to achieve risk reduction. However, these efforts are not expected to reap immediate economic and social benefits. Realistically, there are no short term solutions to many environmental problems. The EPA is expected to initiate a national risk reduction strategy involving the scientific community, the private sector, and the public as equal participants in developing criteria for ranking environmental and human health problems.

CHAPTER 7

OBSERVATIONS AND OPTIONS

Existing Army regulations on environmental protection encompass four basic program areas: environmental restoration, compliance, pollution prevention, and conservation. These program areas are the basis for developing future environmental strategies and for allocation of environmental resources. The Army has initiated efforts to examine alternative methods for prioritization of Army environmental problems in these basic program areas. The objective of this paper was to provide an initial investigation into the complex subject of risk prioritization and to assess current trends in risk assessment with a special focus on relative risk ranking methods. In addition, this paper attempted to review current Army policies for risk prioritization and determine the significance of this method for improved management of Army environmental programs. The following observations are based on this initial investigation and a review of the most current literature on relative risks and risk prioritization:

- Although risk assessment methods can serve as tools in the decision-making process for risk mitigation, most often the assumptions used in conventional risk assessment are unrealistic, yielding distorted risk estimates. This could seriously jeopardize efforts to distinguish serious hazards from trivial ones, and could hamper the efforts of federal agencies to prioritize risks. Scientific limitations in the use of toxicity parameters, exposure assumptions, and extrapolation models have contributed to uncertainties in estimating human health and environmental risks. Scientific trends in these areas will continue to improve the existing risk assessment methods.

- The concept of relative risk may offer a useful alternative for long-term environmental planning and policy implementation. In a pioneering study, EPA commissioned a task force in 1987 to investigate current environmental problems and prioritize them on the basis of relative risks. The outcome of the EPA study, and the subsequent EPA science advisory board review has set

the stage for national dialogue on risk-based prioritization and relative risk ranking methods.

- The Army applies the results of site-specific quantitative risk assessment in the decision process for waste-site remediation efforts. However, the Army does not clearly identify a conceptual basis for risk assessment in its existing regulation on environmental protection and enhancement. As an agency required to comply with "Superfund" regulations, the Army is confronted with the inconsistencies and shortcomings of the imposed risk assessment methods. However, environmental planning based on human health and environmental risks does offer a unique opportunity to develop a broad environmental policy and program strategy based on the objective criteria of risk.

- Within Federal agencies, risk reduction is a major focus of future environmental programs relating to human health and ecological risk assessment, and monitoring efforts. For instance, the EPA Office of Research and Development (ORD) predicts the following key future growth areas: (a) programs to enhance support to develop core scientific areas for ecological risk assessment, (b) programs dealing with CO_2 and global climate change (c) programs for improving existing human health risk assessment methods, (d) programs on long-term pollution prevention and waste reduction, and (e) programs to monitor and improve assessment of human exposure to pollutants. These are the scientific trends and the research focus for the next decade.

- The possible impact of recent developments in relative risk methods for prioritizing Army environmental problems are two fold. First, the concept of relative risks and the anticipated trends in risk prioritization described in this paper are expected to advance the existing risk assessment methodologies. This is expected to significantly alter the risk assessment approach in the future, and enhance the efficiency of risk mitigation. Second, military mission activities and operations pose unique problems for the Army with regard to environmental compliance. Problems associated with the development, manufacture, storage, transportation, use, and disposal of chemical and radioactive wastes are complex. The anticipated trends in basic research

relating to hazard identification, contaminant monitoring, and toxicity estimates based on structural and functional considerations, may provide the Army with sophisticated methods and scientific data to more effectively assess occupational and environmental risks.

The concept of relative risk is new and there are several problems that must be overcome before it can be recommended as a reliable basis for long term planning and program development. Army initiatives on risk-based prioritization have to critically consider the merits and deficiencies of all components of the risk prioritization approach, and their applicability to Army specific environmental problems. These issues should be kept in mind as the following options are presented.

Option 1 Risk assessment and risk management are interrelated processes with the results of risk assessment serving as technical input for risk management decisions. The Army should look into risk management techniques as a complement to risk assessment and risk prioritization. Risk management deals with the regulation of risks, and takes into account, economic, engineering and political considerations in the decision-making process. Therefore an examination of the factors that comprise risk management is necessary to develop a consistent environmental policy framework.

Option 2 The long-term objectives of the Army for adopting risk-based methods have to be identified. Within the Army, issues concerning environmental compliance and protection are broadly diversified and complex. Apart from routine compliance-related problems, specialized programs such as materiel development and acquisition, and production of propellants, explosives, and pyrotechnics (PEP), pose unique environmental problems for the Army. Based on these considerations, the Army should develop appropriate criteria for ranking the human health and environmental risks associated with routine and specialized programs. For this purpose, the EPA Regional study described in this paper may be used as a possible model (EPA, 1989c). In the EPA project, regional offices ranked the major regional environmental problems according to the relative ranking methods described in *"Unfinished Business"*, and correlated the problem ranking trends with national and other regional trends. Instead of a geo-administrative regional approach, the Army could investigate a design for general and specialized programs involving significantly different hazard characteristics. The ranking for these program types could be used for devising long term strategies and program options. This has the dual advantage of

categorizing hazards on the basis of data availability while approaching the individual hazard categories using relative risk ranking methods.

Option 3 It may be beneficial to develop a long-term environmental research and development strategy based on risk-based prioritization. A weighted-approach could be adopted to identify the critical research and development areas and then distribute the research dollars based on the long-term advantages and cost effectiveness of the environmental programs. Risk reduction could be used as the guiding principle for funding allocation. Also, it might be prudent to rank Army environmental research programs into near-term, mid-term, and long-term time frames.

Option 4 The Army might consider entering into co-operative agreements with other military services, other federal agencies, states, industry, and academia to investigate the application of risk assessment and risk prioritization methods for identifying the most important environmental problems from a national, or global perspective.

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