A Multi-Stakeholder Framework for Ecological Risk Management: Summary of a SETAC Technical Workshop

Edited by C.A. Pittinger on behalf of the SETAC Workshop Steering Team:
R. Bachman, Fisheries Service, Maryland Department of Natural Resources
A.L. Barton, USEPA Science Advisory Board
J.R. Clark, Exxon Biomedical Sciences
P.L. deFur, Virginia Commonwealth University
S.J. Ells, USEPA Superfund Program
C.A. Pittinger, The Procter & Gamble Company
M.W. Slimak, USEPA National Center for Environmental Assessment
R.G. Stahl, Jr., E.I. DuPont de Nemours & Company
R.S. Wentsel, USEPA National Center for Environmental Assessment

This summary outlines the Framework for Ecological Risk Management workshop sponsored by SETAC and administered by the SETAC Foundation for Environmental Education on 23–25 June 1997. This consensus framework describes a participative, decision-making, multi-stakeholder process, which closely complements the USEPA's (1992) model for ecological risk assessment by offering guidance on the substantive nature of interactions between risk assessors and risk managers, both preceding and following an ecological risk assessment. Workshop participants emphasized that ecological risk management (ERM) concerns should represent the diversity of stakeholder inputs, be considered early in the design of an ecological risk assessment (ERA), and optimally support sound decision-making. It was further recognized that sound and acceptable ERM decisions are supported by a process that effectively integrates social, political, economic, and technical interests and concerns.

Keywords: risk management; framework; stakeholders; ecological

Ecological risk management decisions surrounding the use of chemicals, the remediation of contaminated sites, and the protection of natural resources are highly complex and often contentious, as they typically involve an array of stakeholders with very distinct values and concerns. On 23–25 June 1997, a technical workshop, “A Framework for Ecological Risk Management,” was held in Williamsburg, Virginia, to develop a multi-stakeholder consensus framework for ecological risk management (ERM). It was envisioned that such a framework would describe the fundamental elements of the process through which public and private risk managers should determine what natural resources are to be protected from a given risk and the degree to which those resources should be protected.

This summary outlines the results and conclusions of that technical workshop. Chief among them was the development of a 7-element framework for ERM, closely complementing the framework for ecological risk assessment (ERA).
first proposed by the USEPA in 1992 and recently published in the USEPA’s Guidelines for Ecological Risk Assessment (1998). Specifically, the risk management framework described here embellishes those elements of the USEPA’s risk assessment process pertaining to pre- and post-assessment “discussions between the risk assessor and risk manager” around “planning” and “results.” As such, the framework supports what was perhaps the major consensus of workshop participants: that ERM concerns should represent the diversity of stakeholder inputs, be considered early in the design of an ERA, and optimally support sound decision-making.

**Workshop purpose and goals**

The workshop concept grew from discussions among an ad hoc group of public and private sector risk scientists representing the American Industrial Health Council, the Chemical Manufacturers Association, and the USEPA. The group was loosely formed in early 1996 to provide a forum for discussion on ERM. This Multi-stakeholder Ecological Risk Management Dialogue Group (MERMD) met periodically for more than 1 year to outline issues and common problems in ERM. At a pivotal meeting involving risk managers from government, industry, and the environmental community, an urgent need was identified for a clear framework or decision-making process that could be used to understand how to manage risks to ecological receptors. Such a framework would provide risk managers with guidance for deciding what natural resources to protect, to what degree to protect them, and the means to achieve that protection. Recognizing SETAC’s leadership in advancing ERA and the organization’s experience in promoting balanced technical dialogues, the MERMD approached SETAC and ultimately served as the workshop steering team in developing the proposal, planning the format, and gaining financial support.

The goal of the workshop was to work toward consensus in developing general guidance on the ERM process. Questions posed to the workshop participants were

1) what process is used to determine how we decide what to protect?
2) what criteria are applied?
3) what tools are available to help make decisions?

Participants were tasked with developing a consensus ERM framework, with appropriate breadth to address all major applications of ecological risk assessment/risk management, e.g., chemical evaluations, site evaluations, natural resources management, and exotic species introductions.

In addition to the questions above, workshop participants were asked to consider the following:

- What are the common elements of the processes through which public and private risk managers determine which natural resources to protect?
and the degree of protection? What are the major drivers in the process (e.g., statutory requirements, regulatory precedents, public perceptions of acceptability, economic feasibility)?

- How do existing frameworks for general risk management (e.g., those proposed by the National Research Council [1983]; the Presidential/ Congressional Commission on Risk Assessment and Risk Management [1997]; ASTM [1997]) suit the unique needs, goals, and constraints of ERM?

- Can a single framework encompass the risk management processes used by public and private managers to manage risks associated with chemicals, sites, and natural resources?

- What additional elements (e.g., ecological resource valuation and priority-setting) might be needed to adapt existing risk management frameworks for ecological risks in particular? How do these elements fit together?

**Participation and format**

The workshop included participation from a broad array of ecological risk assessors, risk managers, and stakeholders across the public and private sectors. Criteria for selecting participants included expertise in the assessment and management of chemicals, waste sites, and natural resources; representation across public and private stakeholder groups; and a balance across government, industry, and academia. Ultimately, 41 professionals participated, representing risk managers and natural resource managers from federal, state, and local government; from corporations representing chemicals, consumer products, mining, and agricultural interests; from academia; and from national, regional, and local public interest groups (see Participants List, p. 23).

Because the issues and questions to be discussed were perceived as having a distinct cultural basis and a dependence upon legal and regulatory infrastructure, the workshop primarily involved North American managers and stakeholders. It was hoped that a successful workshop would inspire similar initiatives in other geographies. The acceptability of a given ecological risk was viewed as being highly contextual and heavily dependent upon a diversity of social and cultural values; therefore the framework developed at the technical workshop was not intended to prescribe standards or numerical criteria for protection of ecological resources.

Participants were divided among 4 workgroups according to the 3 principle application areas identified in USEPA’s Framework for Ecological Risk Assessment (USEPA 1992): new products or chemicals; waste sites; and natural resources. A fourth group with diversified expertise from each of the 3 applica-
tion areas was also convened. The format alternated workgroup and plenary sessions by focusing on particular questions related to ERM. Key points from the discussions are presented below.

**Defining ecological risk management**

A comprehensive definition of “ecological risk management” proposed at the workshop was, “Ecological risk management is the process of identifying, evaluating, selecting, and implementing cost-effective, integrated actions that manage risks to environmental systems while emphasizing scientific, social, economic, cultural, technological feasibility, political, and legal considerations.” By this definition, ERM is synonymous with the decision-making process.

The goal of ERM is to manage one or both of the 2 components of ecological risk, exposure and stress (hazard), so that risks to ecological resources are controlled at acceptable levels or avoided altogether. The early stages of risk management are aimed at setting goals and identifying options, both of which serve to guide the subsequent risk assessment. The product of an ERA is evaluated by the ecological risk manager on the basis of multiple factors, including the severity of the ecological risk; the ecological significance, uniqueness, and integrity of the natural resources at risk; the ability of the system to compensate or recover; the availability of mitigation measures; the technologies available to mitigate the risk; the practicality in terms of cost and other resources to mitigate; and the public’s perception of the risk and the value dedicated to the resource. Key drivers include

- Economics: Cost-effectiveness of various risk reduction or mitigation alternatives and the benefits derived from each.
- Societal factors: Public perceptions, risk communication, stakeholder involvement, environmental justice, and competing economic concerns (e.g., jobs, crime, education).
- Policy and politics: Environmental laws and regulations; federal, state, and municipal policies; and associated processes by which they are developed.
- Technology: Availability of engineering capability to support various risk management options.
- Public values: Regulations, case law, market analyses, public influence, quality of life, clean environment, good health, good jobs, and public perceptions, etc.
- Science: The state of knowledge pertaining to the risk and its attendant uncertainty and variability.

Sound risk management decisions should reflect in large part the wide diversity
A Multi-Stakeholder Framework for Ecological Risk Management

of inputs to the decision (Figure 1). The vital policy/science interface requires that the process integrates social, political, economic, and technical interests and concerns. It was proposed that scientific advances can shape or even dictate the development of public values and vice versa. An example given was the accelerated public debate and interest in policy development surrounding human genetic manipulation, which became a controversial public issue only after the recent development of animal cloning technology.

It was noted by all workgroups that some risk management decisions are at times not wholly consistent with purely technical considerations of ecological safety or natural resource protection. Such decisions are often made when social, economic, or policy considerations are judged to take precedence. An example offered by a natural resource manager was the public outrage that accompanied and ultimately defeated a proposal for a hunting restriction on an endangered wildlife population in Tennessee. In this case, the hunting tradition was valued and protected as a public “right,” despite technical data predicting the eventual demise of the population. While such decisions may be particularly disconcerting or misunderstood by the technical risk assessment community, it was recognized that ERM decisions often hinge upon prevailing public values or concerns. Likewise, risk management decisions based solely on technical considerations may fail to appease stakeholders with unique values or concerns.

Parallels to human-health risk management

In developing a framework for ERM, participants frequently compared and contrasted human-health and ecological risk assessment and management goals. Ecological risk management decisions are rarely independent of considerations of human health yet are not always in parallel. In an increasing number
of cases, such as Superfund assessments of mining sites in the western U.S., ecological considerations may be a major driver. In instances in which ecological consequences may be severe, such as remediation efforts involving extensive soil removal and decontamination, balanced consideration must be given to both human-health and ecological goals.

In theory, it was noted that there are few fundamental differences in making risk management decisions for humans as compared to ecological resources. Ecological risk assessment, however, is complicated by the diversity of species, the complex scales of biological organization, and the numbers of endpoints and criteria that might be relevant. While many human-health risks center on the individual, the majority of ecological risks concern populations and ecological communities. Furthermore, society has historically evolved extensive practices and information resources for managing human-health risks in concert with the medical community and public health concerns. Historical knowledge of ecological issues is far more limited and anecdotal. At least until recently, there has not been an analogous effort for managing risks to ecological resources.

Human-health concerns have historically driven major environmental policies with respect to chemical usages and industrial operations. There appears to be broader consensus on “benchmarks” for human safety endpoints (e.g., 1 in 1,000,000 increased lifetime risk of contracting cancer), which are at times even embedded in statutory requirements. In contrast, ecological risks require consideration of many more endpoints for which there are fewer established benchmarks, and hence more decisions are made on a case-by-case basis. In ERM, there is often greater reliance placed upon site-specific considerations and the professional judgment of the assessors. Invariably, this often gives rise to significant controversy in ERM decisions.

**Complementary roles of ecological risk managers and stakeholders**

For the purposes of the workshop discussions, ecological risk managers were broadly defined as individuals, groups, or organizations that apply the results of an ERA or other resource assessment tool, along with economic, social, political, technological, and engineering inputs, to determine a course of action to resolve an environmental issue. Ecological risk managers encompass both public (e.g., federal, state, or municipal regulatory officials or legislators) and private (e.g., corporate) affiliations. Beyond the management of anthropogenic risks, there was consensus that the ERM concept equally applies to natural resource managers with responsibility for conserving, protecting, or nurturing important commercial or recreational plants, animals, and ecosystems. While natural resource managers (e.g., federal and state wildlife conservation officials) may not traditionally identify themselves and their work with “ecologi-
cal risk assessment” per se, it was recognized that resource management goals and criteria are often identical to those of conventional “risk scientists.” The resource managers at the workshop were thus able to contribute a valuable and practical perspective to discussions on decision-making criteria.

The National Research Council (NRC) describes the importance of interested and affected parties in the risk assessment process (NRC 1996). The report stresses that risk assessment should be a “decision-driven activity” directed toward informing choices and solving problems. It is the outcome of an “analytic-deliberative process,” in which “analysis” uses methods to arrive at answers to factual questions, and “deliberation” is the process of communication and collective consideration of values and issues. To begin to answer the “what to protect?” question that has plagued ERAs, analytic-deliberative methods must be developed and used at all stages of a risk assessment, not only by risk managers but by stakeholders as well.

Selection of appropriate stakeholders can be problematic: Who should have a say? Are important perspectives not represented at the table? Stakeholder input is important because value judgments must be taken into account by risk managers. The socio-economic relationship of stakeholder groups to the risk assessment issues and to each other is critical to the outcome. Deliberate consideration of stakeholder involvement will lead to better risk management decisions. The appropriate blend of stakeholders and the extent and type of their involvement will vary from step to step as well as from setting to setting. In addition, ecological risk decisions frequently deal with significant uncertainties that should be conveyed in meaningful terms. Workshop participants emphasized the need for better risk communication to the lay public, recognizing that the more localized the issue, the greater the need for transparency.

**Risk management decision criteria**

While separate breakout sessions were convened to address the questions of “how to decide what to protect” and “how to decide the degree of protection,” there was consensus that the drivers, criteria, and decision processes for addressing both questions are often synonymous. Identification of “what to protect” is typically accomplished at an early stage, while the “degree of protection” is determined through collective consideration of the drivers mentioned above. It was noted that the context of the ecological risk often determines, to a large part, what to protect and the degree of protection deemed acceptable. A distinction was made between “crisis risk management” (e.g., a derailment spill) from “systematic risk management” (e.g., a new chemical or pesticide evaluation, a natural resource management plan). Workshop participants viewed different processes and criteria to be operational in each case.

Equally important in deciding the degree of protection can be the affiliation...
of the risk manager, whether in a public (regulatory) or private (corporate) capacity. Both must satisfy multiple stakeholder groups, albeit differing in composition. As such, criteria and procedures for determining “acceptable risk” typically vary. The regulatory risk manager must serve the expectations and concerns of the public, the regulated community, and elected legislative bodies in a highly visible fashion often dictated by prescriptive statutes. Divergent concerns and sometimes inconsistent demands surrounding the regulatory manager favor a cautious approach, with few incentives and little reward for innovation and flexibility. Legislative edicts may require agencies to adopt a “tunnel vision approach” to risk management. For example, “single media statutes” (e.g., the Clean Water Act) may at times restrict considerations of potential risks in other media.

Routine environmental risk management decisions by corporations (e.g., in the formulation of new products, the development of manufacturing processes, and the management of industrial sites) are usually less subject to exhaustive public scrutiny than decisions made by public officials. Nevertheless, the private risk manager also answers to an array of stakeholders. Unique demands are placed upon private risk managers by internal management lines that ultimately reflect stockholders’ expectations of financial success and sound business practices. National and international regulatory conventions and standards impose criteria for decision-making. Equally important is how the corporation’s risk management decisions are viewed by the consuming public. Hence, private sector risk managers are challenged to satisfy a set of fundamental environmental management needs, including human and environmental safety, regulatory compliance, efficient resource use and waste management, and satisfaction of public (societal) concerns. The first 2 elements are obligatory prerequisites for corporations to remain in operation and ideally should not be compromised by commercial or other objectives. The latter 2 elements are less tangibly related to conventional risk assessment than to corporate profitability and the long-term success of the business but must nevertheless be weighed in management decisions. Innovative solutions that simultaneously accomplish each of these goals are encouraged, particularly in an increasingly global and visible business environment.

Risk management approaches in the U.S. have historically focused on the protection of individual species, and even individual animals, threatened by isolated risks. There is recent attention being given to consideration of higher levels of biological organization, including populations, communities, and ecosystems (e.g., the Florida Everglades), although current assessment methods to assess these higher scales of complexity with the same level of precision are seen as lacking. Similarly, greater emphasis needs to be placed on assessment of multiple stressors acting interdependently (e.g., the net effects of physical,
chemical, and/or biological stressors) and on more holistic perspectives (e.g., on community and ecosystem level endpoints) in risk management decisions.

Statutory criteria and discretionary regulatory policies of federal agencies in some cases narrowly define the natural resources to be protected. The Endangered Species Act and the Marine Mammal Protection Act are among the more prescriptive environmental statues that explicitly dictate protection measures for individual species. The Toxic Substances Control Act and The Comprehensive Environmental Response, Compensation, and Liability Act (Superfund Law) tend to be less prescriptive in this regard but can be equally contentious. Statutory and regulatory risk management policies or standards are viewed as either discretionary (e.g., the aesthetic or recreational value of a natural resource) or non-discretionary (e.g., under Superfund, any applicable, relevant, and appropriate requirements [ARARs] invoked in a particular decision). In either case, even statutory criteria were seen as the expression of a public value at a point in time (i.e., the passage of the enabling legislation) and are subject to change as a result of evolving political considerations and public sentiments.

In a majority of statutes, protection goals for key natural resources (e.g., the habitat of an endangered species versus the organism itself) are not explicitly stated, providing ample room for interpretation by agencies with enforcement authority. This, too, has amplified the controversy of environmental management decisions, often resulting in civil or criminal litigation in the U.S. The degree of protection to be afforded is also vaguely defined in qualitative terms that leave considerable discretion to authorities. Current and reasonably foreseeable land-use scenarios were identified as frequent drivers in decisions involving waste site remediation.

Some participants at the workshop voiced concern that natural resource attributes traditionally valued by the general public (e.g., abundant fishing and hunting, recreational opportunities, scenic views) do not sufficiently reflect the requirements of well-functioning ecosystems. At times the public may appreciate the value of the natural resource as a whole, yet people may overlook the ecological significance of a given species or community. In other cases there was concern that the public may genuinely value a particular ecological resource (e.g., wetlands) yet be unable to articulate its value in quantitative measures meaningful to scientists or actionable by policy-makers. It was noted that contingent valuation techniques (to estimate economic worth through comparisons with known commodities) and other procedures increasingly are being developed and applied by natural resource economists to ascertain the public values placed upon natural resources, aesthetic and recreational qualities of the environment, etc. Needs for more research and validation in these areas were emphasized.
A challenge for the ecological risk manager is to understand public values and communicate them to the ecological risk assessor. The risk assessor is then challenged to select ecologically meaningful endpoints and to collect and evaluate information relevant to those values. Ecological risk management goals may be viewed as representing operationalized public values expressed in measurable and, hence, manageable terms. Communication with the lay public by risk assessors and risk managers was seen as critical to gaining support for protecting little known species, ecological communities, or potentially undervalued habitats.

A multi-stakeholder ecological risk management framework

A multi-stakeholder framework for ERM emerged from the workshop’s plenary discussions. Seven discrete elements to ERM were identified at the workshop and subsequently organized by the steering team into 3 stages (Figure 2). Each stage contains elements that are fundamentally linked and that are often conducted in parallel. An aspect common to all elements underscored at the workshop was the need for broad communication among risk managers, risk assessors, and stakeholders.

Figure 2 Relationship of the Ecological Risk Management Framework to the Ecological Risk Assessment Framework (USEPA 1998).
The ERM framework closely complements the framework for ERA developed by the USEPA (1992) (see Figure 3). The first stage of the management process, consisting of issue identification, goal-setting, and management options development, can be identified as the process occurring prior to and during the “risk assessor/risk manager dialog box” of the risk assessment process. The data compilation element of the management framework essentially represents the conventional ERA process, consisting of problem formulation, effects assessment, exposure assessment, and risk characterization. The last 3 elements of the management framework—option selection, decision implementation, and tracking/evaluation—represent the risk management and risk communication elements represented in the ERA process.

Such a framework builds upon other risk management frameworks that have been proposed, as many of the concepts and processes of these frameworks—primarily derived from consideration of human-health risks—are fundamentally relevant and applicable to ecological risks as well. In 1983, the NRC’s “Red Book” described the distinction between risk assessment and risk management; it did not distinguish human-health and ecological risk applications. In 1997, the Presidential/Congressional Commission on Risk Assessment and
Risk Management published a risk management framework based upon extensive dialogues with various stakeholder groups across the U.S. The American Society for Testing and Materials (ASTM) has also initiated the development of an environmental risk management framework (ASTM 1997). Each has emphasized the role of stakeholder involvement as a means to satisfy the public values paramount in a management decision.

**Framework elements**

**Issue identification**

The 3 elements of issue identification, goal-setting, and management options development typically occur in unison in an ERM process. Issues are generated through a number of mechanisms, including economic or governmental actions, legislative requirements, public concerns raised by the media, advocacy by interest groups, the dissemination of new information, or the availability of new technology. How an issue may arise frequently determines its course of management and the degree of urgency given to its resolution. For example, in natural resource management, the regulator as the resource manager is often the subject of high levels of public and political attention. Environmental legislation creates issues through either or both enforcement and mandated actions. Governmental actions that generate risk management issues stem from major statutory requirements, including oversight for chemical and product registration and commercialization; private, federal, or municipal construction projects; transportation and occupational safety; site remediation or reclamation; and natural resource management. Private sector risk managers have parallel responsibilities for identifying risk management issues associated with product and process development, plant sitings and operations, consumer habits and practices, and product use and disposal. Cost-effective risk management in the private sector is accomplished by the earliest possible identification of risk issues before new commercial activities are fully invested.

**Goal-setting**

During goal-setting, the environmental issue is translated into a series of goals and objectives conducive to systematic analysis and planning by risk assessors, natural resource managers, economists, and planners. Ideally, a concise statement of the issue capturing all stakeholder concerns is accompanied by a statement of general goals, each of which carries specific objectives guiding subsequent actions. Such an approach enables risk assessors to tailor their selection of assessment endpoints to maximize their relevance and utility for decision-making. Paramount to ERM goal-setting is the question of “what to protect,” including consideration of the entity or resource to be protected, the attribute or aspect of that resource to be protected, and a desired state or
outcome of the management actions. Goal-setting must recognize not only ecological goals, but also economic, human-health, political, legal, and social objectives as well.

As an example, a rural farming community concerned about the protection of a rare riverine ecosystem might first develop a succinct statement of the issue that describes the conflicts and challenges between the economic goal of farming and the effects of farming upon the endangered ecosystem. A general goal, or ideal outcome, might be the maintenance of a successful farming economy and the mutual protection of the ecosystem. Specific objectives supporting this goal, e.g., maintaining irrigation water volume or habitat for an endangered species, can be linked to measures for the risk assessors.

Goal-setting requires risk assessors and managers to frame the issue in meaningful, measurable, and achievable terms in order to focus and accommodate specific data compilation objectives. Acknowledgment of the entity or resource to be protected, the attributes of resources essential to its protection, and the values represented by stakeholders should be communicated. Values of diverse parties may often be competing; for example, commercial waterfront property development may compete with needs to maintain an undisturbed wetland habitat to support aquatic communities. Competing interests should be identified and stakeholder representatives brought to the table early to maximize the acceptance of the analysts’ results and acceptability of the ultimate management decision.

**Management options development**

Rarely is a risk assessment conducted without some prior consideration given to the range of potential management options available to the risk managers. Understanding the extent to which management options are known is valuable in helping to tailor empirical studies in order for the ultimate decision to be made. As recognized by the NRC (1983), however, the nature of the interaction between risk assessor and risk manager must be balanced to ensure objectivity in the assessment. Ecological risk assessments should not be “force-fitted” to justify preordained management decisions. If the scope of the assessment is constrained by the prerequisites of given management options, the process may be perceived as biased. At the same time, an uninformed risk assessor with little knowledge of the management decision or purpose of the assessment may fail to produce decisive information. Risk managers should not unduly influence the risk assessor with regard to a particular option; rather, they should inform the assessor of technical feasibilities and stakeholder issues so that meaningful assessment endpoints can be chosen.

The assessment process enables the risk manager to select the option best suited to the technical, regulatory, economic, and political constraints of the
decision. Options may range across a broad spectrum extending from “no action,” to “monitor the situation,” to “limited management,” to “virtual risk avoidance.” Initially the list of options may be extensive and may include those that may not at first glance be deemed feasible or practical. Options may subsequently be sorted into categories based on like properties.

Parallel to the development of a list of practicable management options, and equally dependent upon broad stakeholder input, is the establishment of clear decision criteria. The criteria should reflect the key concerns of stakeholders and the main drivers of the decision. A variety of decision theory methods have been proposed for weighting criteria in risk management decisions. A “gap analysis” (i.e., evaluation of what is and is not known or readily available) may aide in identifying information needs, as shown in the conceptual matrix in Table 1, recognizing that additional information is required in order to distinguish among options.

### Data compilation and analysis

The framework elements of “data compilation and analysis” and “option selection” are typically accomplished through an iterative process in which the data acquired are used to inform the decision-maker’s option selection (Figure 2). Data compilation and analysis for ecological issues typically include the conventional process of ERA but should extend to other analytical tools supporting economic, legal, and technological drivers to the decision. A major topic of discussion during the workshop focused on the relative roles and interactions between risk assessors and risk managers, as emphasized in USEPA’s Framework for Ecological Risk Assessment (1992) and Guidelines for Ecological Risk Assessment (1998). The degree to which effective interaction occurs between risk managers and risk assessors in the earlier elements of the framework process ultimately determines the relevance and utility of the risk assessment in decision-making. Through the first 3 elements of the framework described above, the risk manager ensures that the data compilation and analyses provide
information relevant to decision-making by clearly stating the reason for the analysis, the decisions it may influence, and the expectations of the analyists.

In turn, the risk assessor should clearly convey to the risk manager the scope of the analysis that reasonably can be expected on the basis of the resources and timing at hand. The assessor should be able to relate the assessment endpoints used to the goals and objectives provided by the manager and help the manager understand the limitations of the assessment (i.e., key assumptions, qualifiers, expected precision, and uncertainty). At times, the risk assessment process identifies unique considerations of the risk or the ecological entity to be protected, which may alter the concerns of stakeholders or the options available for consideration. Last, risk assessors provide insights to risk managers about alternative or additional investigations that may supplement stated goals. Data gaps can be prioritized and addressed in an iterative manner, recognizing that complete knowledge is virtually unattainable, and that it is likely some risks have yet to be identified. Criteria should be established for determining when more data are needed (e.g., how much uncertainty in the risk estimate is acceptable?), and when adequate data are available to support a sound decision or risk management option.

The effort and expense of the analytical methods employed should be reasonably commensurate with the decision at hand and are often dictated by needs for accuracy or predictive certainty. Iteration may occur as data are collected, options are characterized, and needs for additional data are identified. While some iteration is appropriate and necessary, it is recognized that at times the iteration process between risk assessors and risk managers can become overly exaggerated. When this process is perceived as circular or redundant, stakeholders may feel disenfranchised with the process and lose interest. Some workshop participants voiced a concern that ERA may serve as a “delay tactic” by risk managers who either fail to comprehend the decision that must be made, or who are unwilling or incapable of making such a decision. For this reason, many agreed that the degree of study, the technical resources allocated, and the duration of the analysis should be commensurate with the priority of the decision at hand. These issues should be recognized and discussed at the start, especially in management decisions involving multiple stakeholders, to promote the understanding that a finite decision or action hinges upon a given outcome in the analysis.

The quantitative and descriptive science used to conduct an ERA does not answer, in a direct way, the question of what should be done to manage the risk. Science determines adversity, whereas the public determines acceptability. The key difference between the risk assessment and its reliance on quantitative empiricism and the normative science used in social decision-making is that risk assessment does not convey the value of natural resources to stakeholders and
decision-makers. To be objective, the risk assessor should strive to minimize the introduction of social values into the assessment. Certain elements of the assessment process such as the selection of assessment endpoints, however, are invariably linked to how natural resources are perceived and valued. In these circumstances, the risk assessor should clearly identify (“make transparent”) the value-laden questions and policy decisions made. The use of normative analysis can never be wholly scientific since it involves values that are rooted in a different domain of human experience. Thus, it is important to recognize the role of both in risk assessment and, in particular, risk management deliberations.

Option selection (“decision-making”)

Option selection is synonymous with decision-making, the ultimate goal of the ERM process. The risk managers must consider and weigh each of the various inputs of stakeholder groups and drivers to the decision in selecting the “most reasonable and acceptable option” under the given set of circumstances. The context of the risk, the attributes of the natural resource, and the stakeholders perception of the resource’s value largely determine what may be deemed acceptable or unacceptable. It was the consensus of the workshop participants that prescriptive criteria for “acceptable” ecological risk could not and should not be offered, as decision criteria and acceptability of a management decision are highly contextual and case-specific.

The “reasonableness” of an ERM decision (i.e., its acceptability or unacceptability) was viewed as a function of the perceived value of the ecological entity or natural resource at risk. The resource’s perceived value is ideally reached through a collective consensus among various stakeholder groups. Other factors, such as the severity and irreversibility of the risk and the stringency, cost,
and equability of the proposed management option, also play important roles in determining acceptability (Cooper 1998). One conceptual relationship developed at the workshop (Figure 4) relates the value given an ecological resource to the acceptability of a risk management option, i.e., risk tolerance. In this relationship, a resource’s value may be expressed by a variety of scales. For example, an attribute of ecological structure or function may reflect its importance in maintaining ecological integrity (e.g., as a primary producer). Other measures of resource value may more closely reflect economic values related to parameters such as scarcity, uniqueness, vulnerability, or inaccessibility. Consistent with the “law of supply and demand,” an ecological entity or natural resource that is considered relatively resilient to harm, in abundant supply, or easily accessed tends to be less valued (either by ecologists or by the public) than those perceived to be relatively more vulnerable, less abundant, or inaccessible.

The conceptual relationship depicted in Figure 4 suggests that risk tolerance, the acceptability of subjecting a natural resource to risk, is inversely related to the resource’s perceived ecological or social value. That is, decisions to undertake or implement more stringent, restrictive, or expensive risk management measures will receive greater acceptance for highly valued resources than for less valued resources. The risk manager should ideally strive to identify and select management options that represent “acceptable and reasonable risk,” i.e., those that would be viewed as neither under-protective of the resource nor overly burdensome to stakeholders. More often than not, however, important risk reduction or avoidance decisions are difficult, and disagreements among stakeholders are inevitable.

With this background, a number of broadly applicable ERM decision criteria were identified, based upon the practical experience of the participants.

- Sound decisions should address the problem at hand without creating worse problems in other media or contexts. “Don’t make things worse” was voiced by participants who noted that some management decisions seem to exacerbate rather than alleviate environmental problems. Site remediation decisions involving widespread topsoil removal or extensive sediment dredging were cited as an example.

- Decisions should be meaningful and relevant to the risk. Across a sometimes bewildering array of inputs and data, some participants felt that common sense was at times set aside in favor of strict legal interpretations of compliance, both those deemed under-protective of resources or overly burdensome to stakeholder groups. Many believed that a “reality check” was needed before finalizing complex risk management decisions.

- Risk management should be innovative and flexible. Consistency with
precedent decisions, i.e., regulatory “traditions” or administrative policy models adopted from other contexts, were seen to strongly influence many management decisions. “Serving the status quo” was viewed as a frequent barrier to innovative risk management and effective natural resource protection.

- Workshop participants from virtually all affiliations expressed dissatisfaction with the domineering role the legal system has played in ERM in the U.S. Particularly in hazardous waste site remediation cases under Superfund, the judicial system was viewed as the single most powerful decision-making influence and final arbitrator of ecological management questions. The displacement of fundamental scientific considerations by due legal processes and litigious confrontation was seen as an obstacle to effective risk management.

- Benefits of risk reduction or avoidance should justify costs to society. Conventional cost-benefit analysis using monetary measures of ecological value was recognized as an emerging environmental management tool that can provide a comparative basis for evaluating benefits and liabilities of certain management options, at least in economic terms. However, a few were skeptical of this process, given the difficulty of “valuing” intangible ecological resource attributes in conventional monetary terms. It was observed that the “currency” used to weigh costs and benefits in ERM cannot be limited to monetary currencies only because economic measures may be unreliable indicators of the inherent ecological significance of a species, population, community, or ecosystem. Development of an “ecological currency” that better reflects the ecological value of a resource was a need identified within the emerging discipline of environmental economics.

The role of the risk manager and stakeholder may differ in “option selection” relative to other elements of the management framework. Most agreed that the authority and accountability for a management decision must be retained by those with ultimate responsibility for the decision. While risk managers should carefully weigh stakeholder input, at some point a decision must be made by the risk managers without undue influence by a single stakeholder group. Examples were cited in which controversy arising from continued stakeholder advocacy, even in the final option selection, was seen as a barrier to effective and definitive decision-making. It was noted that the failure to make a definitive or timely risk management decision may result in ecological and economic consequences as serious as a poorly informed or hasty decision. Concerns were raised that some regulatory managers seemed to seek highly compromised solutions reflecting an impractical marriage of all options, leading to ineffective or unsatisfactory management. The need for practical training in decision ana-
lytical techniques and risk management was broadly supported by workshop participants.

**Decision implementation**

Implementation of the management decision sets in motion the regulatory, legal, and economic processes necessary to satisfy the option selected. It requires that the risk managers have adequate authority not only to make but also to enforce the decision, whether enforcement responsibility remains under the risk manager or passes from the risk managers to other parties. An implementation plan for each option should be developed, documented, and made available to the interested parties prior to the decision (i.e., during options development) to ensure that stakeholders are reasonably aware of what each option will entail. Problems in implementation cited by participants included Superfund site remediation decisions in which costs to implement the management decision far exceeded anticipated levels. Other cases were cited in which management plans failed to deliver the degree of resource protection originally envisioned.

**Tracking and evaluation**

The uncertainties and variabilities in ecological risk assessment and management set limits to predicting the effectiveness of management decisions, triggering the need for follow-up evaluation after a decision is implemented. Evaluations may range in complexity, extending even to sophisticated ecological monitoring programs, but should be dictated by criteria similar to those used in selecting the option, including the severity and extent of the risk, the reasonableness of the measures taken for evaluation, and the need for certainty.

**Applying the ecological risk management framework: a Superfund site case study**

Following the conclusion of the workshop, the following hypothetical case study was developed from a realistic scenario by the workshop steering team to demonstrate the framework process.

**Issue identification**

During a routine stream survey by the State Fish and Game Department in a suburban setting, an apparent decrease in the number of trout was identified. Further investigation revealed that the types of benthic invertebrates in the stream bottom were not typical of healthy trout streams. Local anglers had been complaining about a decrease in trout abundance, discolored sediments, and increased algal growth in parts of the stream. Some community members reported an apparent increase in childhood health problems and believed that this was caused by pollution from a metal finishing company located adjacent to the stream. The metal finishing company employed many of the town residents.
Goal-setting
The community wanted the federal and/or state regulatory agencies to take whatever actions were necessary to return the stream to a premium trout fishery and to make sure there was no danger from eating fish caught in the stream and from their children playing in the stream. The community expected this to be done quickly and with minimal cost to be borne by themselves.

Management options analysis
The source of the apparent contamination was unknown, but the town’s landfill bordered the stream, as did the metal finishing company. The landfill currently received only household waste, but its prior history was unknown. Water sampling identified several metals and organics in the stream, but all at levels that are lower than the State’s Ambient Water Quality Standards. Sediment samples also revealed the presence of elevated metals, especially near the landfill and the metal finishing plant. Several leachate seeps, many of them colored, were found between the landfill and the stream. Records showed that the metal finishing plant had been out of compliance with its National Pollutant Discharge Elimination System (NPDES) discharge permit only once in the last 3 years.

Possible management options were to
· change the permit requirements of the metal finishing plant,
· stop the leachate seeps from the landfill,
· remove or treat the hot spots of sediment contamination, or
· perform habitat improvement work to increase the trout holding capacity of the stream.

Decision criteria identified were
· cost of each option,
· party to bear the costs,
· likelihood that stream could be restored to previous condition,
· length of time to additional degradation if no action were taken, and
· likelihood that existing levels of contamination could cause human-health problems.

Data compilation
The human-health risk assessment identified 2 major contaminants, one a known human carcinogen and the other a suspected carcinogen. One chemical had also been shown to cause birth defects in laboratory studies. Based upon the levels found in the stream water and sediment and the expected rates of exposure to users of the stream, predicted exposures were not expected to result in significant human-health risks.
The ERA indicated that contamination came from both the landfill and the metal finishing company; the relative amount from each source could not be accurately determined but was expected to be approximately equal. The study also revealed elevated amounts of nitrogen and phosphorus and elevated stream temperatures during the summer. These increases were attributed to the relatively large population increase in the town over the last 10 years, especially the increased number of homes bordering the stream. The use of lawn fertilizers, septic tank leachates, loss of stream tree cover, and possible reductions in ground water discharges to the stream from increases in well water use were thought to contribute to the degradation of the stream habitat.

Toxicity tests showed that the landfill leachate was toxic to young trout, but the effluent from the metal plating company was not. Sediment toxicity tests near the landfill were negative, while sediment tests near the effluent discharge were inconclusive; minimal increased toxicity was observed near the effluent as well as upstream from the effluent. The majority of the vocal community (those that attended public meetings) did not want to install and operate an expensive leachate collection and treatment system for the landfill because its cost would be born solely by the town. The State did not believe the company’s discharge permit required revision, as the company had a good compliance record and the new tests did not demonstrate unacceptable toxicity. If the company were required to upgrade its treatment system or to eliminate its discharge, it claimed it would be forced to relocate, causing job losses.

**Option selection**

The State decided not to change the discharge requirements of the metal finishing company and concluded that the degradation of the trout fishery was due mostly to increases in stream temperature and nutrient loading (chemical contamination). Elimination of all contaminant inputs from the landfill and plant were not seen as effective in restoring the fishery. The decision was made to work with the community and the metal finishing company to perform long-term habitat restoration work along the stream corridor.

**Decision implementation**

The town decided to fund the cost of regrading the current landfill to minimize the amount of leachate reaching the river. The town supported the initiation of a community group to monitor the health of the stream and to work with the stream landowners on an education program to reduce fertilizer runoff and to voluntarily minimize tree-cutting near the stream.

The metal finishing company agreed to sponsor local civic groups to perform stream habitat improvements. The State agreed to increase the trout-stocking program in the stream until a self-sustaining trout population could be maintained.
Tracking and evaluation
The State increased the frequency of point-source and non-point-source loadings to the stream and performs an annual stream survey.

Summary and conclusions
The ERM technical workshop culminated nearly 2 years of discussion and interaction among risk assessors and managers in the public and private sectors. There was clear consensus at the workshop that the topic of ERM was timely, if not overdue. The major accomplishment of the workshop was the drafting of a framework for ERM outlining a participative, decision-making process stressing input from multiple stakeholders. The risk management framework closely complements the USEPA’s (1992) model for ERA by offering guidance on the substantive nature of interactions between risk assessors and risk managers, both preceding and following an ERA.

Workshop participants felt strongly that ERM concerns representing the diversity of stakeholder inputs needed to be considered early in the design of an ERA to ensure that the assessment optimally supports sound decision-making. In addition to the risk assessment itself, workshop participants identified a number of other key considerations for ERM decisions. It was recognized that sound and acceptable ERM decisions are supported by a process that effectively integrates social, political, economic, and technical interests and concerns. In this regard similarities to human-health risk management were apparent, despite the greater complexity of ecological risks resulting from species diversity, scales of biological organization, and numbers of endpoints.

It was the consensus of the workshop participants that narrow and prescriptive criteria for “acceptable” ecological risk could not be offered, as decision criteria and acceptability of management decisions were seen as highly contextual and case-specific. However, workshop participants articulated a number of broadly applicable recommendations based upon their practical experience. They viewed sound decisions as those which are meaningful and relevant to the issue at hand, while at the same time avoiding equal or worse problems in other
SETAC Technical Workshop Participants†
Workshop Moderator:  Peter deFur,* Virginia Commonwealth University

Chemicals Group
Charles Auer, USEPA
Richard Belzer, Office of Management & Budget, Office of Information & Regulatory Affairs
Walt Buchholtz, Exxon Chemical Company
James Donald, California EPA Office of Environmental Health Hazard Assessment
Stephen Ells,* USEPA Superfund Program (Facilitator)
Robert Graney, Bayer Corporation Environmental Research
Susan Lewis, USEPA Chief, Insecticide Branch Registration Division
Janis McFarland, Novartis, Agricultural Stewardship Program
Reo Menning,* American Industrial Health Council (Recorder)
Charles Pittinger,* The Procter & Gamble Company (Facilitator)
Deanna Sampson, Virginia Conservation Network

Waste Site Group
Mike Blum, Washington State Department of Ecology Toxics Cleanup Program
Peter Brussock, Environmental Liability Management, Inc.
David Clarke, The Risk Policy Report
Mark Davis, Coalition to Restore Coastal Louisiana
Nancy Finley, U.S. Fish and Wildlife Service
Eva Hoffman, USEPA, Region 8
Eugene Mancini, ARCO Company, Environmental Protection Division
Greg Schiefer, SETAC/SETAC Foundation (Recorder and ex officio Steering Team Member)
Michael Slimak,* USEPA National Center for Environmental Assessment, (Facilitator)
Ralph Stahl, Jr.,* E.I. DuPont de Nemours & Co., Corporate Remediation, (Facilitator)
James Wilen, University of California at Davis, Department of Agriculture & Resource Economics

SETAC Press
Natural Resources Group
Elaine Dorward-King, Kennecott Utah Copper Corporation
Thomas Eagle, National Oceanic & Atmospheric Administration, National Marine Fisheries Service
Drew Fillingame, USEPA Gulf of Mexico Program
Patricia King, King Research & Law
Mark Kraus, National Audubon Society, Everglades System Restoration
Robert Lackey, USEPA Western Ecology Division
Gary Myers, Tennessee Wildlife Resource Agency
Lee Salamone,* The Chemical Manufacturers Association
Randall Wentsel,* USEPA

Combined Applications Group
Robert Bachman,* Fisheries Service, Maryland Department of Natural Resources, (Facilitator)
Anne Barton,* USEPA Office of Pesticide Programs, (Facilitator)
Larry Champagne, Texas Natural Resource Conservation Commission, Pollution Cleanup Division
Sue Ferenc, USDA Office of Risk Assessment & Cost-Benefit Analysis
Jessica Glicken, ecological planning and toxicology, inc.
Mark Huff, Virginia Commonwealth University (Recorder)
U. Gale Hutton, USEPA, Region 7, Water, Wetlands, Pesticides Division
Lynn McCarty, LS McCarty Scientific Research and Consulting
Paul Mehrle, ENTRIX, Inc.
Warner North, Decision Focus, Inc.

*Steering Team members
†Affiliations were accurate at the time of the workshop
SETAC

A Professional Society for Environmental Scientists and Engineers and Related Disciplines Concerned with Environmental Quality

The Society of Environmental Toxicology and Chemistry (SETAC), with offices in North America and Europe, is a nonprofit, professional society that provides a forum for individuals and institutions engaged in the study of environmental problems, management and regulation of natural resources, education, research and development, and manufacturing and distribution.

Goals

· Promote research, education, and training in the environmental sciences
· Promote systematic application of all relevant scientific disciplines to the evaluation of chemical hazards
· Participate in scientific interpretation of issues concerned with hazard assessment and risk analysis
· Support development of ecologically acceptable practices and principles
· Provide a forum for communication among professionals in government, business, academia, and other segments of society involved in the use, protection, and management of our environment

Activities

· Annual meetings with study and workshop sessions, platform and poster papers, and achievement and merit awards
· Monthly scientific journal, Environmental Toxicology and Chemistry; bi-monthly SETAC GLOBE; and special technical publications
· Funds for education and training through the SETAC Scholarship/Fellowship Program
· Chapter forums for the presentation of scientific data and for the interchange and study of information about local concerns
· Advice and counsel to technical and nontechnical persons through a number of standing and ad hoc committees

Membership

SETAC’s growing membership includes more than 5,000 individuals from government, academia, business, and public-interest groups with technical backgrounds in chemistry, toxicology, biology, ecology, atmospheric sciences, health sciences, earth sciences, and engineering.

If you have training in these or related disciplines and are engaged in the study, use, or management of environmental resources, SETAC can fulfill your professional affiliation needs. Membership categories include Associate, Student, Senior Active, and Emeritus.
Other SETAC Risk Assessment and Management Publications

Natural Remediation of Environmental Contaminants: Its Role in Ecological Risk Assessment and Risk Management
Edited by Michael Swindoll, Ralph Stahl Jr, Stephen Ells, 480 pp., 2000

Multiple Stressors in Ecological Risk and Impact Assessment
Edited by Jefferey A. Foran and Susan A. Ferenc, 115 pp., 1999

Multiple Stressors in Ecological Risk and Impact Assessment: Approaches to Risk Estimation
Edited by Susan A. Ferenc and Jefferey A. Foran

Restoration of Lost Human Uses of the Environment
Edited by Grayson Cecil

Ecological Risk Assessment: A Meeting of Policy and Science
Edited by Ann de Peyster and Kristin Day, 225 pp., 1998

Ecological Risk Assessment Decision-Support System: A Conceptual Design
Edited by Kevin Reinert, Steve Bartell, Greg Biddinger, 120 pp., 1998

Ecological Risk Assessment of Contaminated Sediments
Edited by Christopher Ingersoll, Tom Dillion, and Gregory Biddinger, 390 pp., 1997

Ecotoxicological Risk Assessment of the Chlorinated Organic Chemicals
Edited by Carey, Cook, Giesy, Hodson, Muir, Owens, Solomon, 314 pp., 1998

Research Priorities in Environmental Risk Assessment
Edited by Fava, Adams, Larson, Dickson, Dickson, Bishop, 103 pp., 1987

Sustainable Environmental Management
Edited by Barnthouse, Biddinger, Cooper, Fava, Gillett, Holland, Yosie, 114 pp., 1998

For more information, contact:

SETAC North America
1010 N 12th Avenue
Pensacola, FL 32501-3367
T 850 469 1500
F 850 469 9778
E setac@setac.org

SETAC Europe
Avenue de la Toison d’Or 67
B-1060 Brussels, Belgium
T 32 2 772 72 81
F 32 2 770 53 83
E setac@setaceu.org

http://www.setac.org