

## Enhancing the Ecological Risk Assessment Process

Virginia H Dale,\*† Gregory R Biddinger,‡ Michael C Newman,§ James T Oris,/ Glenn W Suter,#  
 Timothy Thompson,†† Thomas M Armitage,‡‡ Judith L Meyer,§§ Richelle M Allen-King,|| G Allen Burton,†††  
 Peter M Chapman,‡‡‡ Loveday L Conquest,§§§ Ivan J Fernandez,||| Wayne G Landis,###  
 Lawrence L Master,†††† William J Mitsch,‡‡‡‡ Thomas C Mueller,§§§§ Charles F Rabeni,||||  
 Amanda D Rodewald,#### James G Sanders,††††† and Ivor L van Heerden†††††

†Environmental Sciences Division, Oak Ridge National Laboratory, Oak Ridge, Tennessee 37831-6036, USA

‡ExxonMobil Biomedical Sciences, 800 Bell Street, Houston, Texas 77005, USA

§School of Marine Sciences, Virginia Institute of Marine Science, College of William and Mary, Gloucester Point, Virginia 23062, USA

/Department of Zoology, Miami University, Oxford, Ohio 45056, USA

#National Center for Environmental Assessment, US Environmental Protection Agency, MS 117, Cincinnati, Ohio 45268

††Science, Engineering, and the Environment, Seattle, Washington 98105, USA

†††US Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Washington, DC 20460

§§Odum School of Ecology, University of Georgia, Athens, Georgia 30602-2202, USA

||Department of Geology, University at Buffalo, SUNY, Buffalo, New York 14260-3050, USA

|||Department of Earth and Environmental Science, Brehm Laboratory 064, Wright State University, Dayton, Ohio 45435, USA

‡‡‡Environmental Sciences Group, Golder Associates, North Vancouver, British Columbia V7P 2R4, Canada

§§§School of Aquatic and Fishery Sciences, University of Washington, Seattle, Washington 98195-5020, USA

||||Department of Plant, Soil, and Environmental Sciences, University of Maine, Orono, Maine 04469-5722, USA

####Institute of Environmental Toxicology, Huxley College of the Environment, Western Washington University, Bellingham, Washington 98225-9180, USA

††††Retired from NatureServe, currently at Box 310, Lake Placid, New York 12946, USA

‡‡‡‡Oletangy River Wetland Research Park, The Ohio State University, Columbus, Ohio 43202, USA

§§§§Department of Plant Sciences, The University of Tennessee, Knoxville, Tennessee 37996-4563, USA

|||||Missouri Cooperative Fish and Wildlife Research Unit, US Geological Survey, University of Missouri, Columbia, Missouri 65211-7240

#####School of Environment and Natural Resources, The Ohio State University, Columbus, Ohio 43210, USA

†††††Skidaway Institute of Oceanography, Savannah, Georgia 31411, USA

‡‡‡‡‡Department of Civil and Environment Engineering, LSU Hurricane Public Health Research Center, Louisiana State University, Baton Rouge, Louisiana 70803, USA

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### EDITOR'S NOTE:

This is 1 of 4 papers from the US Environmental Protection Agency Science Advisory Board's Ecological Processes and Effects Committee workshop on the current and future practice of ecological risk assessment. The workshop was held in Washington, DC in February 2006.

### ABSTRACT

The Ecological Processes and Effects Committee of the US Environmental Protection Agency Science Advisory Board conducted a self-initiated study and convened a public workshop to characterize the state of the ecological risk assessment (ERA), with a view toward advancing the science and application of the process. That survey and analysis of ERA in decision making shows that such assessments have been most effective when clear management goals were included in the problem formulation; translated into information needs; and developed in collaboration with decision makers, assessors, scientists, and stakeholders. This process is best facilitated when risk managers, risk assessors, and stakeholders are engaged in an ongoing dialogue about problem formulation. Identification and acknowledgment of uncertainties that have the potential to profoundly affect the results and outcome of risk assessments also improves assessment effectiveness. Thus we suggest 1) thorough peer review of ERAs be conducted at the problem formulation stage and 2) the predictive power of risk-based decision making be expanded to reduce uncertainties through analytical and methodological approaches like life cycle analysis. Risk assessment and monitoring programs need better integration to reduce uncertainty and to evaluate risk management decision outcomes. Postdecision audit programs should be initiated to evaluate the environmental outcomes of risk-based decisions. In addition, a process should be developed to demonstrate how monitoring data can be used to reduce uncertainties. Ecological risk assessments should include the effects of chemical and nonchemical stressors at multiple levels of biological organization and spatial scale, and the extent and resolution of the pertinent scales and levels of organization should be explicitly considered during problem formulation. An approach to interpreting lines of evidence and weight of evidence is critically needed for complex assessments, and it would be useful to develop case studies and/or standards of practice for interpreting lines of evidence. In addition, tools for cumulative risk assessment should be developed because contaminants are often released into stressed environments.

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\* To whom correspondence may be addressed: dalevh@ornl.gov

## INTRODUCTION

Ecological risk assessments (ERAs) are conducted to provide information about the potential diverse effects of management decisions. The US Environmental Protection Agency (USEPA) published a Framework for Ecological Risk Assessment (Framework) and Guidelines for Ecological Risk Assessment (Guidelines; USEPA 1992, 1998) that greatly improved the state of the practice of ERA in jurisdictions around the world, by establishing a phased, multidisciplinary approach. The Framework and Guidelines provide a robust and useful foundation upon which to build the information needed to support the decision-making process. Yet, the range of applications has made it difficult to develop general policy and guidance that characterize ecological attributes being targeted for protection and that can be used to apply risk assessment findings to decisions. Other papers in this issue of *Integrated Environmental Assessment and Management* explore the history (Suter 2008), limitations (Kapustka 2008), and strengths (Barnhouse 2008) of ERA. This paper addresses ways to enhance the ERA process and to advance the state of the practice. The study draws upon recent advances in ERA science in 3 decision-making contexts: 1) product health and safety, 2) management of contaminated sites, and 3) natural resources protection.

To gather information, the Ecological Processes and Effects Committee (EPEC) of the USEPA Science Advisory Board convened a public workshop on the role and conduct of ERAs for environmental decision making on 7–8 February 2006 in Washington, DC. The workshop brought together more than 120 ecological risk assessors from academia, government, industry, trade associations, and environmental organizations. The invited speakers, panelists, subject matter experts, and participants discussed their experiences and suggested steps for improving ERA. Our findings and recommendations are based on the workshop discussions, our subsequent analysis, examples discussed in the literature, and our expertise and experiences. Some of these recommendations are largely hypotheses, for they have yet to be tested.

The following key cross-cutting ecological risk assessment issues were considered: The effects of spatial and temporal scale, assessing risks at different levels of biological organization, problem formulation and the adequacy of testable hypotheses, and decision making in the presence of uncertainty. The resulting findings and recommendations presented below are intended to guide the development of policies and strengthen program-specific risk assessment guidance.

## USEPA'S ERA FRAMEWORK AND GUIDELINES

The USEPA's Framework and Guidelines have greatly improved the state of the practice by stressing the importance of conducting assessments with a phased approach in a multidisciplinary setting. A key aspect of the Framework is the problem formulation phase. Early interaction and discussion among risk assessors, risk managers, and stakeholders help ensure relevance of risk assessment results to risk management questions. The development of conceptual models and assessment endpoints during the problem formulation phase of a risk assessment is critical to guiding the establishment of a valid analysis plan.

One strength of ERA is its value as a process, not just as a result. It provides a consistent approach for integrating laboratory and field data, analytical tools, and integrative assessment methods (e.g., species sensitivity distributions and

weight-of-evidence approaches) as well as a consistent format for reporting risks and uncertainties.

Its strengths notwithstanding, both scientific and non-scientific limitations occur in implementing ERA. Scientific limitations include characterizing and incorporating uncertainties associated with the stochastic nature of ecological systems and the effects of multiple stressors, linking assessment endpoints to realistic time and space scales, establishing ecological baselines, predicting exposure to toxic contaminants or other stressors (e.g., variability in dietary exposure to contaminants), and dealing with variations in toxicological profiles for different taxa. Nonscientific limitations include legal and regulatory requirements. For example, potential liability can promote avoidance of risk assessment, and requirements to assess individual rather than cumulative risks may limit the utility of a risk assessment. Furthermore, policies and precedents may require specific components to be part of a risk assessment or may establish inappropriate endpoints. Social challenges include the need to engage stakeholders, risk assessors, and risk managers early and often in the process to understand communities' positions on potential management decisions.

## FINDINGS AND RECOMMENDATIONS

### *USEPA's Ecological Risk Assessment Framework and Guidelines*

The USEPA's Framework and Guidelines, used to conduct assessments over the past 2 decades, have been and continue to be a robust and useful foundation upon which to build the information needed to support decision making for ecological resources. Workshop participants described the Framework and Guidelines as "standing the test of time." The value of the Framework is further evidenced by its incorporation into many federal and state guidelines and a large body of references in the scientific literature, and it has been emulated in Canada, the European Union, and other countries.

Risk assessment and risk management are closely linked by design, necessity, and law. The National Research Council has stated that the role of risk assessments is to provide the information to distinguish between important and trivial threats and, when coupled with political, social, economic, and engineering considerations, to enable decisions about the need and methods for risk reduction (NRC 1994). The ERAs have been most effective when clear management goals were developed in a collaboration between decision makers, assessors, scientists, and stakeholders; included in the problem formulation; translated into information needs; and then articulated with data-quality objectives. The USEPA has developed guidance for designing a data collection plan to support study goals (USEPA 2000a, 2000b, 2006b). This guidance should be consulted during the problem formulation phase of ERAs.

Many workshop participants stated that USEPA's Framework has utility, but noted major differences in ERAs conducted by various USEPA program and regional offices. The application of ERAs in decision making has been inconsistent. Most USEPA offices have, or are in the process of, providing updated, program-specific ERA guidance to reflect the principles established in the Framework and Guidelines. However, the sheer range of applications of the Framework and Guidelines has made it difficult to develop recognizable Agency-wide policy or guidance that defines

what ecological attributes the Agency is striving to protect and how to apply those findings in risk decisions. Wherever possible, general guidance would bring consistency to the overall risk assessment process. Furthermore, models and endpoints used in ERAs should consider relevant nonchemical stressors as well as mixtures of chemical and nonchemical stressors (e.g., biological invasion, habitat disruption, and altering hydrography), and assessments should report both risks and uncertainties.

#### *Risk assessor and risk manager dialogue in planning and problem formulation*

Although USEPA's Framework provides for interaction between risk managers and risk assessors, the integration of ERA into the environmental management decision process should be further promoted.

In addition, more specificity is needed in problem formulation during ERA, and guidelines and examples describing how to bridge the gap between risk management and risk assessment are needed. While the workshop developed no clear consensus on how best to bridge this gap, some ideas emerged on how to address risk and risk management for different objectives. These ideas can be grouped into 4 central themes:

- Managers, assessors, and stakeholders should be engaged early and iteratively throughout the risk assessment process.
- Specificity and direct consideration of management alternatives are needed during problem formulation.
- Incorporation of specific, testable hypotheses, risk questions, or site assumptions should be tied directly to management information needs and to data collection and analysis.
- Uncertainty should be addressed in a manner that allows tradeoffs in risk management alternatives to be evaluated with approaches that can be communicated and understood by the public.

Dialogue between risk assessors and risk managers is necessary during the planning and problem formulation phase of a risk assessment to develop focused risk assessment questions or hypotheses that inform specific risk management options. Problem formulation is currently receiving greater attention than in the past and involves the USEPA and stakeholders earlier in the process. Some workshop participants noted that it is difficult to get the Agency risk managers to engage in a dialogue; therefore, a consistent approach for encouraging such a dialogue is needed, and dialogue during problem formulation should be encouraged and promoted if not required.

Risk managers and risk assessors should be encouraged to bring greater specificity to problem formulation and "risk question" or hypothesis formulation in ERAs. While the ERA paradigm does provide that risk management questions should be addressed in the problem formulation phase, often the "testable hypotheses" or "risk questions" are too generic, are difficult to interpret, do not result in measurable endpoints, and are not explicitly linked to risk management decisions. Broad questions (e.g., risks to avian populations) must be broken down into smaller ones (e.g., testing for a 10% decrease in the abundance of a particular species of bird in a specified period of time). At the same time, testable hypotheses are not useful unless they are very closely tied

to management goals; correct problem formulation will result in decisions to collect field data that are meaningful to decision making. Explicit connections among risk measures, data quality needs, data collection, and risk management decisions are therefore needed during problem formulation. However, such connections have not been consistently achieved. Additional guidance or examples of how to formulate and scientifically test such connections would be helpful. Furthermore, formulation of specific problems incorporating testable hypotheses or risk questions has not been effective or consistent in ERAs across the USEPA. Examples and/or guidance should be developed to help connect risk management with risk questions or testable hypotheses.

More attention should be focused on ensuring that selected measures of risk for which data will be collected are appropriate for their intended use in decision making. Often large amounts of field data are collected for risk assessments without first focusing on how those data will be used in the risk management context. Furthermore, data collection processes will be somewhat different between retrospective and prospective ERAs. Data collection should be explicitly tied to risk management questions through the data-quality objectives process. The ecological attributes or resources to be protected are not always clearly identified. The USEPA Science Advisory Board's Framework for Assessing and Reporting on Ecological Condition (USEPA SAB 2002) provides a useful reference checklist for ensuring that appropriate levels of temporal and spatial scale and biological organization are considered in ERAs.

For large, complex risk assessments, peer review at the problem formulation phase and again at risk assessment completion would help assure that the assessment study design and implementation are appropriate for the risk management goals. For high-priority assessments (i.e., high-risk, high-cost risk assessment like those that are very large and deal with imminent concerns), problem formulation and study design should be reviewed through an independent scientific peer review process prior to study implementation. Peer review early in the process will strengthen ERAs even if there are no conflicts associated with the study design. Such a peer review process could be unnecessarily cumbersome for smaller risk assessments; for such cases, checklists could be developed to assist risk assessors and risk managers in planning and problem formulation. These checklists could identify key points to be addressed in developing specific risk questions and considering management alternatives. Checklists could be adopted from existing documents, such as Chapter 9 of the Risk Assessment Guidance for Superfund, Part A (USEPA 1989).

As an additional means of assisting the dialogue between risk assessors and managers, ERA case studies should be compiled and developed to provide useful information for developing standards of practice to determine ecological condition. Case studies would also be useful to risk assessors considering how to address issues of spatial and temporal scale, levels of biological organization, and cumulative risk.

#### *Decision making in the presence of uncertainty*

It is important to consider uncertainty and probability in ERA. Assessments often fail to identify and prioritize uncertainties that could affect the quality of remedy decisions and additional information that would be needed to reduce

the uncertainty of the assessment. This gap leads to an over-reliance on conservative point value estimates of risk. The problem formulation process in ERA could be improved by explicitly identifying uncertainties, the consequences of those uncertainties, and the additional information needed to reduce those uncertainties.

Decision making in the presence of uncertainty is constrained by statutory and regulatory requirements (for example, when a decision must be made before all pertinent background about a situation is known). Where uncertainty exists, the USEPA decision makers sometimes select the most conservative (protective) risk management measures. Although some statutes require consideration of risks and benefits, ecological risk can be relegated to a “nonfactor” in decision making where there is great uncertainty in identifying risks. The absence of ecological risk considerations compromises the decision-making process.

For decision making in the face of uncertainty, 3 options should be explored:

- Defer making a decision until more study is conducted to reduce uncertainty;
- Make a decision with an understanding of the existing uncertainties; or
- Make a decision with monitoring and triggers for further action, if needed.

Additional study data can reduce the uncertainty associated with a decision. However, there is a financial tradeoff between study costs and a management decision under consideration.

Adaptive management is a process for decision making in the presence of uncertainty that could be a part of ERAs. It allows a decision to be implemented and requires long-term monitoring with clear performance triggers to account for uncertainty in the management decision. It also addresses concerns that the ERA process is too long, too expensive, and involves extensive and unnecessary investigations that do little to protect the exposed ecological resources. The USEPA currently has no guidance on planning for, or application of, adaptive management in ERA and should explore how adaptive management can be applied in the context of ERA and risk management.

Some workshop participants expressed the opinion that it is difficult to link hypothesis statements in ERAs to explicitly stated process goals. When hypothesis statements are not clearly linked to risk assessment goals, risk managers may not have the information needed to make decisions. Well-defined, statistically testable exploratory hypotheses with defined type I and II error rates are necessary in ERAs. In fact, problem formulation could be improved by exploring the use of such methods as Bayesian analysis and causal argumentation to develop hypotheses or “risk questions” focused on causal relationships and weight of evidence. The use of Bayesian approaches would allow risk assessors to obtain a “posterior likelihood” for a parameter, along with the uncertainty associated with the parameter estimate. Posterior likelihoods can be presented to the public in an informative and understandable manner. However, if practitioners prefer to use inferential statistics, they should explicitly test the power of their statistical tests to avoid type II error and thus prevent incorrect conclusions.

Probabilistic ERA is another means for understanding uncertainties and implications regarding the degree of protectiveness of various management options. However,

probabilistic assessments can be difficult to explain and communicate to risk managers and the general public. It is often easier but less precise to communicate a deterministic hazard quotient used in a risk assessment than a probabilistically derived hazard quotient. The results of probabilistic risk assessments could be communicated more effectively by articulating, during the problem formulation phase, a summary of the sources and sizes of major uncertainties and how probabilistic approaches would be applied to understand the implications of uncertainty to the degree of protectiveness of the management decisions. For example, the risk quotient is the ratio of predicted environmental concentration to predicted no effect concentration; yet reliable estimates of no effect are typically not available for assessing the risks of particular stressors, and surrogate values are often used that may involve various levels of extrapolation. Both of these estimates lead to inflation of uncertainties in ERA.

A considerable amount of work has been done on the mechanics of conducting quantitative uncertainty analyses. However, good examples are not available to demonstrate how such information could be used in risk management decisions. One way to reduce the uncertainty in future risk assessments is to understand what past risk assessments revealed. A national compendium, inventory, and/or database containing information from past ERAs should be developed for use in improving the certainty of future risk assessments. Case examples developed for such a compendium should illustrate how ecological data have been used in decision making. Such case examples would provide useful information on the strengths and weaknesses of various risk assessment approaches, aid in the development of standards of practice for future risk assessments, and assist in maintaining consistent use of risk assessment procedures. Establishment of an online archive could provide executive summaries of previous ERAs that would serve as both case studies and precedents for prospective assessments. To reduce uncertainty in future risk assessments, it is critically important that the USEPA initiate postdecision audit programs to evaluate the environmental outcomes of risk management decisions relative to those effects predicted and used to formulate the management decisions. Specifically, the beneficial ecological consequences resulting from risk management decisions should be more fully described in terms that the public can understand, and risk management decisions should be followed with postdecision audit programs. This process may be equally applied to contaminated site, natural resource, and product health and safety decisions. This recommendation is consistent with findings in the recent Science Advisory Board Advisory on the USEPA’s Superfund Benefits Analysis (USEPA SAB 2006).

Uncertainty in ERAs could be reduced by undertaking critically needed work to develop a consistent approach to interpreting lines of evidence and weight of evidence in complex ERAs or via a process for evaluating competing technical assessments in environmental decision making. Weight-of-evidence approaches enable ecologists to evaluate multiple types of evidence and multiple lines of evidence within a type. While many risk assessment practitioners prefer to consider all available relevant evidence, some consider the process of weighting evidence to be too subjective. Case studies and/or standards of practice for interpreting lines of evidence and weight of evidence should be developed with an emphasis on application to decision making.

### *Linking natural and social science in environmental decision making*

The USEPA's Framework and Guidelines focus on the application of ecological risk science within a legal and or regulatory decision-making context. In reality, however, decisions occur within a broader context that is conditioned by a community's values and economic objectives, as well as ecological conditions. For ERA applications to be optimized in the broad context, they need to be aligned with the social-economic conditions in which decisions are to be made. To accomplish such alignment, the USEPA must identify what ecological services delivered by the environment being protected matter to relevant community stakeholders. The involvement of stakeholders early and iteratively with the technical experts and decision makers is needed to identify the valued ecological services that are at risk. Once those service flows have been identified, they can inform the selection of relevant assessment endpoints and associated data. Such a coupling will result in a risk assessment that is linked to quantifiable services and will allow testing of alternative management strategies to maximize social net benefits (benefits minus costs) of any USEPA decision.

Currently, steps are being taken to integrate ERA and economic benefit analysis (e.g., as in the Ecological Benefit Assessment Strategic Plan; USEPA 2006a). However, there has been little elaboration of how ecological risk estimates might be considered or weighted in these broader decision-making contexts, and additional guidance is needed and encouraged.

Benefit-cost and valuation methods need to be further developed to provide mechanisms for conducting risk assessments in the context of policy decisions regarding risk reduction. Net benefit analysis may be a useful cross-cutting approach for linking uncertainty analysis and risk management decisions (as has been done in predicting risks and benefits of biological control of invasive plants; Raghua et al. 2007) and place-based analyses undertaken to develop total maximum daily loads (Serveiss et al. 2005). Although some type of net benefit analysis could be beneficial, it should not be used to avoid risk assessment. Rather, development of these holistic ecosystem valuation methods should be continued. During the problem formulation phase of ERAs, screening can be conducted by simple comparisons of costs to benefits, such as reduction in area-weighted average concentrations of contaminants, reduction in hazard quotients or other measures of risk to identified receptors, or even probability distributions of risk. Data requirements for articulating baseline risks and the mechanisms and measures for incremental risk reduction to ecological resources should be identified in the problem formulation and risk assessment. Guidance should be developed for application of risk reduction metrics while maintaining a long-term focus on research to develop methods for valuation of ecosystem services.

Product life-cycle analysis, while not typically used for ERAs, was viewed by workshop participants as potentially valuable in providing useful information for future-oriented investigative questions and emerging areas (e.g., nanotechnology). Issues like inputs required for production and maintenance activities, product use and reuse options, and disposal and recycling alternatives can be considered in a systems approach. Additional guidance on application of life-cycle analysis would be helpful to risk assessment practitioners.

### *Spatial, temporal, and biological scales*

Pertinent spatial and temporal scales and levels of biological organization are not often explicitly considered in the problem formulation phase of ERAs, even though they should be. It is critical that both the decision makers and the risk assessors be cognizant of the extent and resolution of scales being considered in addressing any particular issues. Therefore, the extent and resolution of the pertinent spatial and temporal scales and levels of biological organization of concern should be explicitly defined at the problem formulation phase of a risk assessment.

Scales must be appropriate to each problem in order to identify emerging patterns across space, time, and levels of biological organization. The appropriate scale of an ERA depends upon such factors as the stressors and resources being evaluated, episodic events considered, specific ecological receptors, and the response time of the systems. Specifically, the appropriate scale needs to explicitly include the relevant scale of the endpoints being considered and the range of the disturbances.

It would be useful to develop standard approaches for assessing risks at specific levels of biological organization (e.g., based on common definitions of habitat types and communities). Indirect ecological effects are often revealed at levels of biological organization above populations, and there is a need for techniques for assessing risks at all levels of biological organization (i.e., community, habitat, and ecosystem scales).

Multigenerational analyses or estimates of past conditions are rarely used for prospective risk estimates but should be considered when the time of concern precedes current information. These tools may include analysis of archaeological structures, witness-tree data, historical journals, and other place-based information.

In addition, tools like geographic information systems, continuous monitors, habitat and other models, and species life history information may be used to incorporate spatial and temporal scales in ERAs. The evaluation and use of statistical, geospatial, and other tools for data collection and analysis (e.g., time series and spatial analyses) should be promoted.

### **IMPROVING ECOLOGICAL RISK ASSESSMENT IN SPECIFIC DECISION-MAKING CONTEXTS**

Opportunities for advancing ERA are considered in the context of decision making regarding product health and safety, management of contaminated sites, and natural resource protection.

#### *Ecological risk assessments for product health and safety evaluation*

Ecological risk assessments for product health and safety evaluation are conducted to meet the requirements of particular statutes (e.g., the Federal Insecticide, Fungicide, and Rodenticide Act and the Toxic Substances Control Act). In such assessments, levels of concern and risk quotients often drive the problem formulation phase of the risk assessment, but these measurement endpoints may not provide realistic ecosystem protection goals. Such generic problem formulation does not focus on why particular risk assessments are being conducted or what ecological resources should be protected. Problem formulation should focus on relevant contaminant release pathways, fate and transport of contaminants, sensitivity of receptors, and optimization of appro-

appropriate assessment and measurement endpoints during problem formulation. This focus can be attained by

- Explicitly considering the appropriate spatial and temporal scales and level of biological organization to be taken into account in the risk assessment in the context of decisions to be made;
- Developing tools for cumulative risk assessment because contaminants are often released into stressed environments;
- Conducting research to determine how biomarker and mechanistic data might best be used in exposure and risk assessments;
- Conducting multigenerational analyses or other retrospective ground-truthing analyses for prospective risk estimates and re-evaluating and validating levels of concern with monitoring studies; and
- Using currently available tools (e.g., the Estimation Programs Interface [EPI] Suite; USEPA 2004) to assist in determining whether chemicals are biodegradable, toxic, or bioaccumulative.

#### *Ecological risk assessments for contaminated site management*

Many contaminated sites are relatively small (e.g., 2–10 acres). Under statutory requirements (such as those of the Comprehensive Environmental Response, Compensation, and Liability Act), a contaminated site remedy must be protective of human health and the environment. Such statutes typically result in site investigation, including the ERA and the remedy that often focus on the site. Exceptions are risks to surface or groundwater contamination. An investigation with broader focus may not be interpreted as a legal expenditure of resources under the law; however, issues of how large-scale spatial, temporal, or population-level effects (and the cumulative effects of several sites within a small area) could be investigated within legal and regulatory requirements.

Contaminated site management decisions are often made using a weight-of-evidence approach; however, the ERA process lacks a common understanding of what is meant by weight of evidence. The result is inconsistency in contaminated site risk assessment decision-making process. A common definition and application methodology addressing what constitutes weight of evidence should be developed.

Guidance is needed in the area of risk calculation and application. Too often ERAs are designed and executed solely with a comparison of measured exposure concentrations to toxicological reference values, the “hazard quotient.” At the workshop, much of the discussion in this area focused on the need to better understand the appropriate use of hazard quotients to assess and subsequently manage risk, the issues of uncertainty in calculating risk, and the need for full exploration and disclosure of uncertainty. The hope was that efforts to address the appropriate use of hazard quotients and the reduction of uncertainty will prompt the exploration of a range of risk calculation methods that represent better and more certain approaches to estimating risk. Guidance on the appropriate and acceptable use of such screening tools as hazard quotients, hazard indices, and other environmental benchmarks should be developed, especially with regard to their utility in setting actionable environmental protection goals. The USEPA is also advised to take stronger leadership in

training Agency personnel, and those of state regulators, on the appropriate use of ERA methods and data, and to explicitly make regulators aware of how such data and methods can be misused. The USEPA should also consider how to effectively integrate and weigh the importance of modeled estimates of risk in the presence of ecological observations from the field that provide assessments of ecological integrity or biological performance.

Data needs are a particular concern. For example, the science of ecotoxicology needs to catch up with the data needs for an ERA process that relies on concentration-dependent benchmarks as its primary assessment of risk. Real links between observed effects at a population level and toxicity data (i.e., dose–response, biomarker, bioassay, etc.) are missing for most chemicals and species. As such, most of the current ERAs utilize toxicity data that are questionable in terms of the reality of application to the species or endpoints being assessed. This is a key limitation of the ERA process to contaminated sites.

Some have suggested the need to balance the risks from contamination with the risks and expected benefits from removal of contaminated media. Net environmental benefit tools (Efroymson et al. 2004) may be a useful approaches for specific processes, such as the remediation of chemically contaminated sites.

The efficiency of assessing contaminated sites can be increased and the uncertainty issue can be addressed by

- Programmatic-level risk assessments for contaminants, such as polychlorinated biphenyls, commonly found at many contaminated sites. Such assessments would be similar to programmatic environmental impact statements that are described in the National Environmental Policy Act and are typically prepared with the intention of describing the impacts of actions that are repeated over time. This would decrease the number of redundant risk assessments for contaminants commonly found at contaminated sites;
- An evaluation of postremedial monitoring of ecological resources as compared to risks identified as part of remedial decisions;
- Guidance on the application of adaptive management of ecological resources in contaminated-site decision making;
- Guidance on the appropriate and acceptable use of screening tools such as hazard quotients, hazard indices, and other environmental benchmarks, especially with regard to their utility in setting actionable environmental protection goals;
- Training of personnel on the appropriate use of ERA methods and data and how such data and tools can be misused; and
- Research on tools that balance the risks from contamination with the risks and expected benefits from removal of contaminated media.

#### *Ecological risk assessments for natural resource protection*

Natural resources include clean water, clean air, and habitats for native species, and their protection recognizes the ecological services they provide. In general, risk assessments for natural resource protection are more closely tied to an ecological attributes “values” perspective rather than the stressor perspective that is typical of chemical-specific risk assessments. When viewed from an economic perspective,

such assessments must take into consideration the use and nonuse values people may place on natural resources and healthy ecosystems. Because these types of risk assessments typically focus on the ecological attributes to be protected, rather than responses to specific stressors, the discrete ecological resources to be protected and options for their protection should be explicitly identified in the problem formulation phase.

The ERAs for natural resource protection can be large and complex. Therefore, early scientific peer review of the risk assessment study designs should be encouraged for many of these risk assessments. This review should occur between problem formulation and analysis stages of risk assessments. Peer review of study designs prior to initiating work plans will enhance the quality and efficiency of such risk assessments and will help assure that the assessment study design and implementation are appropriate for the risk management goals.

Natural-change processes should be considered as part of ERAs for natural resource protection. Protecting natural resources requires consideration of natural, ongoing, and global process change (e.g., global climate change) and how such change influences anthropogenic changes in the system under study. In addition, cumulative risks may include nonchemical stresses (e.g., over-fishing, bottom trawling) and climate changes. Finding ways to differentiate between noise and signal is a central challenge of ERAs.

Identification of the scale of concern during the problem formulation phase of a risk assessment for natural resource protection is a critical stage. It is important to look at broad scales but also to answer specific questions on local to global scales. Decisions can be made at very small scales, but they should be considered in the context of a broader scale. For natural resource protection, spatial scales should be large enough to identify emerging patterns across an ecosystem. If additional spatial resolution is needed to describe species abundance and distribution, this need should be considered in the uncertainty analysis. Standards of practice are needed to ensure that spatial- and temporal-scale issues are appropriately addressed. To resolve this need, it may be useful to build from the Science Advisory Board Framework for Assessing and Reporting on Ecological Condition (USEPA SAB 2002).

Indirect effects can be particularly important in risk assessments for natural resource protection, and such effects are often revealed at specific levels of biological organization. Risk assessors should consider effects at the individual, species, community, and ecosystem scales. Developing standard techniques for assessing risks at specific levels of biological organization is a particularly useful step in the assessment process.

Elements of uncertainty should be identified and incorporated into problem formulation and built into the design of a risk assessment for natural resources protection. Those uncertainties that profoundly affect results and outcomes should be identified and acknowledged in the final assessment. Systematic collection, organization, and cataloging of data from past risk assessments could provide information to reduce the uncertainty of future risk assessments. Such efforts could provide better metadata and a centralized repository for ERA data, endangered species information, program-specific risk assessment information, and peer-reviewed literature.

Ecological risk assessors should rethink how hypotheses are formulated and consider how to move away from traditional

hypothesis testing with null models, which might not consider how to balance type I and type II errors. Hypotheses should focus on causal relationships and weights of evidence.

A better interface between risk assessment and environmental monitoring programs should be developed so that monitoring data can be used to improve risk assessments because data collection and analysis procedures developed by monitoring programs can also be useful to risk assessors.

In addition, work in different disciplines (e.g., biology, chemistry, toxicology, and ecology) should be integrated to prevent fragmentary risk analyses. Expert systems could be developed to enable the integration of specific chemical and biological endpoints and to identify classes of chemicals and nonchemical stressors to be assessed.

## CONCLUSION

The current state of the practice of ERA was evaluated to connect the early roots of this approach in comparative toxicology with recent advances in ecology. The Framework and Guidelines have improved the state of the practice of ERA and provided a robust and useful foundation upon which to build. A number of specific opportunities for advancing the risk assessment process have emerged. ERAs have been most effective when clear management goals were included in the problem formulation and developed in collaboration with decision makers, assessors, scientists, and stakeholders. Dialogue among ecological risk managers, risk assessors, and stakeholders (including both ecologists and the lay public) should be encouraged, if not required, during problem formulation. Moreover, communication between risk managers and assessors should be a part of all aspects of the assessment process. The practice of ERA can also be advanced by developing methods and tools that assist risk assessors in designing analyses that appropriately consider the chemical, physical, biological, and socioeconomic contexts of decisions. Many risk assessments could be enhanced by the creation of more innovative techniques for framing and testing risk hypotheses and use of multiple lines of evidence to assess risk at higher levels of biological organization (population, community, and ecosystem scales). Ecosystem valuation methods should be developed and used in conjunction with risk management decisions. Peer review of proposed risk assessments before execution would likely improve many large and complex assessments. More systematic, postassessment monitoring would enhance the risk assessment process in the long run. A national compendium of past ERA and remediation projects would provide a foundation for enhancing future assessments and would allow the benefits and weaknesses of the various risk assessment, management, and remediation approaches to be more readily identified. The risk assessment framework should be viewed in an adaptive management context whereby, as new understanding is attained, new insights are incorporated into the analysis process.

Together, these and other changes would advance the evolving practice of ERA. They would also enable more effective use of the Framework to address the challenges of dealing with uncertainties and high variability; linking assessments' endpoints to realistic temporal and spatial scales; and addressing legal and regulatory requirements or policy precedence. Furthermore, an adaptive management approach to ERA would allow consideration of the validity of data and

its scale of reference, connection to major management problems, and involvement of stakeholders.

A substantial research effort is needed to develop the methodology required to address many of the complex issues discussed here. However, governmental funding for ecological research has decreased by approximately 40% since fiscal year 2003, and research and monitoring programs that assess the status and health of ecological resources have been eliminated. The declining budget trend for ecological research and monitoring must be reversed to address many of the complex issues faced by risk assessors. Additional resources are also needed to provide an interface between risk assessment and monitoring programs so that monitoring data can be used to improve future risk assessments.

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