DRAFT ADVISORY REPORT

Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making

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1.0 EXECUTIVE SUMMARY

This report is the product of an original study conducted by the EPA Science Advisory Board Ecological Processes and Effects Committee (EPEC) to provide advice to EPA on advancing the science and application of ecological risk assessment in environmental decision making. In developing this report, EPEC considered the advantages and potential shortcomings of EPA's current ecological risk assessment approach and its effectiveness in various decision-making contexts. To develop this report EPEC drew upon the wealth of risk assessment expertise within the academic, regulatory, and regulated communities. The following specific findings and recommendations are provided to strengthen EPA's application of ecological risk assessment in Agency decision making.

EPA's Ecological Risk Assessment Framework and Guidelines

- EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992; 1998) have improved the state of the practice of ecological risk assessment by establishing a phased multidisciplinary risk assessment approach. The strength of ecological risk assessment for use in decision making is its value as a process. It provides a consistent approach for integrating laboratory and field data, analytical tools, and assessment methods and a consistent format for reporting risks and uncertainties.

- The *Framework and Guidelines* provide a robust and useful foundation upon which to build the information needed to support EPA decision making. However, the sheer range of applications of the *Framework and Guidelines* has made it difficult to develop Agency-wide policy and guidance that define what ecological attributes the EPA is striving to protect and how to apply risk assessment findings in decisions. EPEC finds that such guidance would bring consistency to the overall risk assessment process.

- EPEC notes that ecological risk assessments have been most effective when clear management goals were included in the problem formulation, translated into information needs, articulated using data quality objectives (DQOs) and most importantly, developed in collaboration with decision makers, assessors, scientists, and stakeholders.

- Non chemical stressors should be considered in developing ecological risk assessment guidance, models, and endpoints. In addition, outcomes of ecological risk assessments should consistently report risks and uncertainties.

Risk Assessor and Risk Manager Dialogue in Planning and Problem Formulation

- A risk assessor and risk manager dialogue is necessary during problem formulation to integrate ecological risk assessment into the environmental management decision process. EPEC therefore recommends that EPA take steps to encourage and promote,

if not require, problem formulation dialogue between risk assessors and risk managers.

- There is a need to engage risk managers and risk assessors in bringing greater specificity to problem formulation and "risk question" or hypothesis setting in ecological risk assessments. During problem formulation, explicit connections should be established between risk measures, data quality needs, data collection activities, and risk management decisions. The gap between risk management and risk assessment can be bridged by developing guidelines and examples to: 1) connect risk management with risk questions or testable hypotheses and, 2) address scientific and technical issues such as the appropriate spatial and temporal scale of the risk assessment and communication of uncertainty.

- EPEC finds that the EPA Science Advisory Board's *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002) provides a useful reference checklist for ensuring that appropriate levels of temporal and spatial scale and biological organization are considered in ecological risk assessments.

- For large complex risk assessments, peer review at the problem formulation stage and again at risk assessment completion would help assure that the assessment study design and implementation are appropriate for the risk management goals. EPEC recommends that for high priority (i.e., high risk, high cost) assessments, problem formulation and study design be peer reviewed by an independent scientific panel prior to study implementation. For smaller risk assessments, checklists could be developed to ensure that management goals are adequately considered in problem formulation and translated into information needs using data quality objectives (DQOs).

- To promote a dialogue between risk assessors and risk managers and improve problem formulation, EPEC recommends that EPA compile and develop ecological risk assessment case studies that can provide information for developing standards of practice to determine ecological condition.

Decision Making in the Presence of Uncertainty

- EPEC finds that ecological risk assessments often fail to identify and prioritize uncertainties that may affect the quality of risk management decisions. The problem formulation process in ecological risk assessment could be improved by explicitly identifying uncertainties, the consequences of those uncertainties, and the additional information needed to reduce those uncertainties

- Adaptive management is an option for dealing with uncertainties. EPEC suggests that EPA explore how adaptive management can be applied in the context of ecological risk assessment and risk management.

- EPEC finds that problem formulation in ecological risk assessment 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.

- Probabilistic ecological risk assessment is a useful tool for considering uncertainty in the risk management process. However, probabilistic risk assessments can be difficult to explain to non scientific managers. EPEC finds that the results of probabilistic risk assessments could be more effectively communicated by articulating, during problem formulation, 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 management decisions.

- EPEC finds that it is important that EPA initiate post-decision audit programs to evaluate the environmental outcomes of risk management decisions relative to those effects predicted and used to formulate the management decision. Specifically, EPEC recommends that EPA more fully describe the beneficial ecological consequences resulting from risk management decisions in terms that the public can understand, and then follow the risk management decision with a post-decision audit program.

Linking Natural and Social Sciences in Environmental Decision Making

- EPA risk management decisions focus on the application of ecological risk science within a legal and regulatory context. EPEC notes, however, that Agency decisions are conditioned by community values and economic objectives as well as ecological conditions. Therefore, EPEC finds that cost/benefit and ecosystem valuation methods must be further developed in order to communicate risk management alternatives at multiple scales to different stakeholder groups. In this regard, EPEC advises EPA to develop guidance for comparing risk management costs to the benefits associated with short-term risk reduction metrics (such as reduction in hazard quotients), while also maintaining a long-term focus on research to develop methods for valuation of ecosystem services.

- EPEC finds that there is a critical need to develop a consensus approach to interpreting lines of evidence, or weight of the evidence in complex ecological risk assessments, or a process for evaluating competing technical assessments in environmental decision making. It is recommended that EPA develop case studies and/or standards of practice for interpreting lines of evidence, with an emphasis on application in decision making.

- Product life cycle analysis is not typically used in ecological risk assessments but it can provide useful information for investigation of the risks of emerging technologies such as nanotechnology. EPEC therefore finds that additional guidance on the application of life cycle analysis would be helpful to risk assessment practitioners.

Spatial, Temporal, and Biological Scales

- EPEC recommends that during the problem formulation phase of ecological risk assessments, EPA explicitly define the extent and resolution of the pertinent spatial, temporal and biological scales of concern.

- It would be useful to develop standard techniques for assessing risks at specific levels of biological organization. The SAB *Framework for Assessing and Reporting on Ecological Condition* can be used to guide the choice of scale.

- EPEC recommends that EPA promote the evaluation and use of modern tools for data collection and analysis (such as time series and spatial data analysis) in identifying the appropriate spatial and temporal scales to be considered in ecological risk assessments.

Improving Ecological Risk Assessments for Product Health and Safety

To improve ecological risk assessments for product health and safety, EPEC recommends that EPA:

- Move away from generic problem formulation that is focused on levels of concern and risk quotients toward broader consideration of the appropriate spatial, temporal, and biological scales in the context of the decisions being made.

- Develop tools for cumulative risk assessments because contaminants are often released into stressed environments.

- Continue to conduct research to determine how biomarker and mechanistic data might best be used in exposure and risk assessments.

- Conduct multigenerational analysis or other retrospective ground-truthing analyses for prospective risk estimates and re-evaluate and validate levels of concern with monitoring studies.

- Use currently available tools for rapid screening level assessments, such as EPA's Estimation Programs Interface (EPI) Suite, to assist in determining whether chemicals are biodegradable, toxic, or bioaccumulative.

Improving Ecological Risk Assessments for Contaminated Site Management

To improve ecological risk assessments for contaminated site management, EPEC recommends that EPA:

- Evaluate how large scale spatial, temporal, or population-level effects (and the cumulative effects of several sites within a small area) could be investigated in the context of legal and regulatory requirements that may limit the focus of contaminated site assessments.

- To increase efficiency and reduce uncertainty in risk assessments, develop "programmatic-level" assessments for contaminants commonly found at contaminated sites.

- Develop guidance on the application of adaptive management of ecological resources in contaminated site decision making.

Improving Ecological Risk Assessment for Natural Resources Protection

To improve ecological risk assessments for natural resources protection, EPEC recommends that EPA:

- Explicitly identify in the problem formulation phase of the risk assessment specific ecological resources to be protected and options for their protection.

- Implement an independent, scientific peer review process to evaluate endpoints, scale, levels of biological organization, uncertainties, and study design outcomes of problem formulation prior to initiating the analysis phase of the risk assessment.

- Consider ongoing change processes (such as global climate change) as part of the risk assessment.

- Identify during problem formulation those spatial and temporal scales of concern that are large enough to capture emerging patterns across a landscape.

- Consider indirect effects that are often revealed at different levels of biological organization (i.e., individual, species, community, or ecosystem).

- Develop standard techniques for assessing risks at specific scales and levels of biological organization (e.g., common definitions of habitat types and communities).

- Explore ways to focus hypothesis development on causal relationships and weight of evidence instead of traditional hypothesis testing with null models.

- Categorize uncertainties in the ecological risk assessment, and in the final assessment identify and acknowledge those that profoundly affect results and outcomes.

- Develop a process to provide an interface between risk assessment and monitoring programs so that monitoring data can improve risk assessments.

The EPEC notes that these and other changes discussed in this report would accelerate the evolving practice of ecological risk assessment. They would also enable more effective use of the *Framework for Ecological Risk Assessment* to address the challenges of dealing with uncertainties and high variability, linking assessment endpoints to

realistic temporal and spatial scales, and addressing legal and regulatory requirements of policy precedence.

2.0 INTRODUCTION

This report was prepared by the Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC). The report is the product of an original study conducted by the Committee to provide advice to the U.S. Environmental Protection Agency (EPA) on advancing the science and application of ecological risk assessment in environmental decision making. In conducting the study and developing this report, EPEC considered the advantages and potential shortcomings of EPA's current ecological risk assessment approach, drawing on the wealth of risk assessment experience within the academic, regulatory and regulated communities. EPEC considered the effectiveness of EPA's ecological risk assessment approach and its application in various decision-making contexts. In this regard, the following key cross-cutting ecological risk assessment issues were considered: the effects of spatial and temporal scale, assessing risks at different biological scales, problem formulation and the adequacy of testable hypotheses, and decision making in the presence of uncertainty.

To gather information for this advisory report, EPEC convened a public workshop on the role and conduct of ecological risk assessments for environmental decision making. Titled *Ecological Risk Assessment – An Evaluation of the State of the Practice*, the workshop was held on February 7-8, 2006 in Washington, D.C. 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 experience and suggested steps for improving ecological risk assessment in three decision-making contexts: product health and safety, management of contaminated sites, and natural resource protection. The primary objective of the workshop was to provide information for EPEC by initiating a broad dialogue on the current state of the practice of ecological risk assessment as applied in environmental risk management and decision making. A workshop summary document containing key discussion points supporting this advisory may be found at http://www.epa.gov/sab/sab_epec_wkshp_eco_risk_02_7-9_2006.htm. The workshop agenda and other supporting material are also available on that website.

3.0 BACKGROUND ON EPA'S *ECOLOGICAL RISK ASSESSMENT FRAMEWORK AND GUIDELINES*

EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992; 1998) have improved the state of the practice by stressing the importance of conducting assessments using 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 helps 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.

The strengths of ecological risk assessment for use in decision making include its value as a process, not just a technique. In this regard, ecological risk assessment provides a consistent approach for using diverse types of laboratory and field data, a source of analytical tools applicable to address a wide array of environmental problems, a means to integrate assessment methods (e.g., species sensitivity distributions, and weight-of-evidence approaches), and a consistent format for reporting risks and uncertainties.

Both scientific and non-scientific limitations occur in implementing ecological risk assessment. Scientific and technical challenges in the risk assessment process 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 (e.g., variability in dietary exposure to contaminants), and dealing with variations in toxicological profiles for different taxa. Non-scientific limitations to the use of ecological risk assessment in decision-making processes 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 elements to be part of risk assessment or establish inappropriate endpoints. For example, questions often arise about the validity of policy or precedent-based point estimates of effects used in risk assessments (e.g., No Observed Effects Concentrations), the quality of data obtained from peer reviewed literature (e.g., poor study design and reporting standards), common failures to connect risk assessments to management issues, and exclusion of some key stakeholders from the ecological risk assessment process. Social challenges include the need to engage stakeholders, risk assessors, and risk managers early and often in the process in order to understand communities' positions on potential management decisions.

4.0 FINDINGS AND RECOMMENDATIONS

4.1 EPA's *Ecological Risk Assessment Framework and Guidelines*

EPEC finds that EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. EPA, 1992; 1998), which have been used to conduct assessments for nearly 20 years, 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. Participants at the EPEC Ecological Risk Assessment Workshop described the Framework 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. The ecological risk assessment paradigm has been emulated in Canada, various European countries, the European Union, and other countries, which further attests to the utility of the Framework.

Risk assessment and risk management are closely linked by design, necessity and law. Consistent with the National Research Council's finding (National Research Council, 1994), 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. EPEC finds that ecological risk assessments have been most effective when clear management goals were included in the problem formulation, translated into information needs, articulated using data quality objectives (DQOs), and, most importantly, developed in collaboration with the decision makers, assessors, scientists, and stakeholders.

Many participants at the EPEC Ecological Risk Assessment Workshop stated that EPA's Ecological Risk Assessment Framework has utility, but they noted major differences in ecological risk assessments among EPA Program Offices and EPA Regional Offices. Furthermore, the application of ecological risk assessments in decision making has been inconsistent. Most EPA offices have, or are in the process of, updating program specific ecological risk assessment guidance to reflect the *Ecological Risk Assessment Framework and Guidelines* principles. Although 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, EPEC finds that such guidance would bring consistency to the overall risk assessment process. EPEC also finds that models and endpoints to be used in ecological risk assessments should include consideration of non-chemical stressors. In addition, outcomes of assessments should consistently report risks and uncertainties. If the *Framework and Guidelines* are carefully followed, risk assessment results will be used more frequently in EPA risk management decisions.

4.2 Risk Assessor and Risk Manager Dialogue in Planning and Problem Formulation

While recognizing the considerable utility of the Framework and Guidelines, EPEC finds that there are scientific and technical challenges to be addressed in using ecological risk assessment for decision making. Foremost is to foster increased awareness and use of ecological risk assessment in the management decision process. EPEC finds that the integration of ecological risk assessment into the environmental management decision process should be promoted.

EPEC finds that there is a need to bring more specificity to problem formulation in ecological risk assessment. There is also is a need for guidelines and examples describing how to bridge the gap between risk management and risk assessment. While no single clear consensus on how to best bridge this gap resulted from the workshop, patterns of ideas emerged on how to address risk and risk management for different objectives, on the need to consider the role of spatial and temporal scales, and on appropriate tools for considering and communicating uncertainty in risk assessments during the problem formulation step. Broadly, these ideas can be grouped into four central themes:

1. Managers, assessors, and stakeholders should be engaged early and iteratively throughout the risk assessment process.

2. Specificity and direct consideration of management alternatives are needed during problem formulation.

3. Incorporation of specific testable hypotheses, questions, or site assumptions should be tied directly to management information needs and data collection and analysis.

4. Uncertainty should be addressed in a manner that allows trade-offs in risk management alternatives to be evaluated in a manner that can be communicated and understood by the public.

Risk assessor and risk manager dialogue 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 EPA and stakeholders earlier in the process. Some participants at the EPEC Ecological Risk Assessment Workshop noted that it is difficult to get the Agency risk managers to engage in a dialogue. A consistent approach for encouraging such a dialogue is needed, and EPEC recommends that EPA take steps to encourage and promote, if not require, problem formulation dialogue.

EPEC notes that the *EcoUpdate Bulletin* published by EPA's Office of Solid Waste and Emergency Response remains an excellent means of communicating important aspects of the ecological risk assessment process both within and outside of the Agency. While the most recent edition of *EcoUpdate Bulletin* is June 2001, EPEC encourages EPA to consider using the *EcoUpdate Bulletin* and developing similar publications so that other EPA program offices can address the issue of problem formulation dialogue, as well as communicate elements and recommendations included in this advisory report.

As noted above, EPEC finds that there is a need to explore how to bring more specificity into problem formulation and "risk question" or hypothesis setting. Explicit connections between risk measures, data quality needs, data collection, and risk management decisions are needed during problem formulation. However, such connections are not consistently achieved. Additional guidance or examples of how to formulate and scientifically test such connections would be helpful. Formulation of specific problems incorporating testable hypotheses or risk questions has not been effective or consistent in ecological risk assessments across EPA. While the ecological risk assessment 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 (e.g., "protection of avian populations" or "no adverse effects to benthic macroinvertebrates"). Generalized questions are difficult to interpret, do not result in measurable endpoints, and are not explicitly linked to risk management

decisions. EPEC recommends that EPA develop examples and/or guidance to help connect risk management with risk questions or testable hypotheses.

EPEC finds that EPA should focus more attention on ensuring that selected measures of risk for which data will be collected are appropriate for their intended use in decision making. Often a large amount of field data are collected for risk assessments without first focusing on how those data will be used in the risk management context. It is recommended that EPA explicitly tie data collection to risk management questions through the data quality objectives (DQO) process. As noted above, often EPA does not clearly identify the ecological attributes or resources the Agency is striving to protect. EPEC notes that the EPA Science Advisory Board's *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002) provides a useful reference checklist for ensuring that appropriate levels of temporal and spatial scale and biological organization are considered in ecological risk assessments.

EPEC finds that, 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. EPEC recommends that for high priority (i.e., high risk, high cost) assessments, problem formulation and study design be peer reviewed by an independent scientific panel prior to study implementation. Peer review early in the process will strengthen ecological risk assessments whether or not there is a conflict about the study design. The identification of assessments where early peer review would be triggered could be based on a recommendation or predetermined criterion or based on evaluation of prior risk assessments. EPEC notes that the composition of a panel convened for problem formulation review may be different from the composition of a panel formed for a study design review.

Recognizing that a peer review process could be unnecessarily cumbersome for smaller risk assessments, the EPEC notes that 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 directly considering management alternatives. The goal of providing such checklists would be to ensure that various important points (e.g., adequacy of problem formulation, consideration of possible management strategies in problem formulation, connections between assessment and measurement endpoints, and consideration of data quality objectives) are adequately addressed at all sites. Checklists could be adopted from existing EPA documents such as Chapter 9 of the *Risk Assessment Guidance for Superfund, Part A* (U.S. Environmental Protection Agency, 1989).

An additional means of assisting the dialogue between risk assessors and managers and improving the problem formulation process is to compile and present case studies that evaluate how ecological data have been used in decision making. Case studies presented at the EPEC Ecological Risk Assessment Workshop highlighted the strengths and weaknesses of risk assessments. EPEC recommends that EPA compile and develop such ecological risk assessment case studies. The case studies would provide useful

information for developing standards of practice to determine ecological condition. They would also be useful to risk assessors considering how to address issues of spatial and temporal scale, levels of biological organization, and cumulative risk.

4.3 Decision Making in the Presence of Uncertainty

EPEC notes that it is important to consider uncertainty and probability in ecological risk assessment. Ecological risk 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. EPEC finds that the problem formulation process in ecological risk assessment 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 of regulatory programs. Where uncertainty exists, EPA decision makers often 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. This absence compromises the decision-making process.

For decision making in the face of uncertainty, there are three options that should be explored during the problem formulation phase:

- Conducting more study to reduce uncertainty;
- Making a decision with an understanding of the existing uncertainties; or
- Making a decision with monitoring and triggers for further action, if needed.

Additional study data may reduce the uncertainty associated with a decision. However, there is a financial tradeoff between study costs and a management decision under consideration. For example, in a system where the main impacts are expected to be risks associated with bioaccumulated contaminants in fish and the consumers of those fish, spending additional funds to reduce uncertainty associated with risks to benthic macroinvertebrates may not be justified.

Adaptive management is an option for dealing with uncertainties. Adaptive management allows a decision to be implemented and requires long-term monitoring with clear performance triggers to account for uncertainty in the management decision. An adaptive management approach would address a concern raised by some representatives of both industry and the environmental and conservation community who attended the EPEC Ecological Risk Assessment Workshop. These individuals viewed the ecological risk assessment process is too long, too expensive, and at times encumbered with extensive and unnecessary investigations that do little to protect the exposed ecological resources. EPEC notes that EPA currently has no guidance on planning for, or application of, adaptive management in ecological risk assessment. Adaptive

management with iterative triggers for action should be planned as part of the problem formulation step. EPEC therefore suggests that EPA explore how adaptive management can be applied in the context of ecological risk and risk management.

At the EPEC Ecological Risk Assessment Workshop, there was considerable discussion, but no consensus, on the use of rigorous "hypothesis-testing" versus "risk questions" in problem formulation. Some participants expressed the opinion that it is difficult to link hypothesis statements in ecological risk assessments to explicitly stated process goals. They noted that when such hypothesis statements are used in ecological risk assessments, risk managers may not have the information needed to make decisions. Others thought that well-defined statistically testable exploratory hypotheses with defined Type I and II error rates were necessary in ecological risk assessments. EPEC finds that problem formulation could be improved by exploring the use of methods, such as Bayesian analysis and causal argumentation, to develop hypotheses or "risk questions" focused on causal relationships and weight-of-evidence. Likelihood statements or estimation methods could be incorporated into problem formulation rather than binary (yes/no) statements.

Probabilistic ecological risk assessment is another means for understanding uncertainties and implications regarding the degree of protectiveness of various management options. However, EPEC notes that probabilistic assessments can be difficult to explain and communicate to non-scientific 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. EPEC finds that 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. Uncertainties must be clearly identified during problem formulation so that risk managers can evaluate the need for conservative or risk tolerant decisions.

A considerable amount of work has been done on the mechanics of conducting quantitative uncertainty analyses. However, good examples showing how such information could be used in risk management decisions are lacking. Throughout this advisory report, EPEC has noted that one way to reduce the uncertainty in future risk assessments is to understand what past risk assessments revealed. EPEC recommends that EPA develop a national compendium, inventory, and/or database containing information from past ecological risk assessments that can be used to improve the certainty of future risk assessments. Case examples developed for such a compendium would provide useful information on the strengths and weaknesses of various risk assessment approaches and aid in the development standards of practice for future risk assessments.

EPEC believes it is important that EPA initiate post-decision audit programs to evaluate the environmental outcomes of risk management decisions relative to those

effects predicted and used to formulate the management decision. Specifically, EPEC recommends that EPA more fully describe the beneficial ecological consequences resulting from risk management decisions in terms that the public can understand, and then follow the risk management decision with a post-decision audit program. This process may be equally applied to contaminated site, natural resource and product health and safety decisions. This recommendation is consistent with recent findings of the recent SAB Advisory on EPA's Superfund Benefits Analysis (U.S. EPA Science Advisory Board, 2006).

4.4 Linking Natural and Social Science in Environmental Decision Making

EPA's *Ecological Risk Assessment Framework and Guidelines* focus on the application of ecological risk science within a legal and or regulatory decision-making context. In reality, however, Agency decisions occur within a broader context that is conditioned by a community's values and economic objectives, as well as ecological conditions. In order for ecological risk assessment 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, EPA 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 what valued ecological services 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 optimize social costs and benefits of any EPA decision.

EPEC recognizes that EPA, through its *Ecological Benefit Assessment Strategic Plan* is wrestling with the integration, or at least the alignment, of ecological risk assessment and economic benefit analysis. However, EPEC finds that there has been little elaboration of how ecological risk estimates might be considered or weighed in these broader decision-making contexts. So from EPEC's perspective, the path to identifying how social attributes of an ecosystem are translated into assessment endpoints that meet decision makers' needs is as yet uncharted waters, and additional guidance is needed. EPEC strongly encourages the Agency to test these waters through field demonstrations and then develop guidance as needed.

EPEC finds that cost/benefit and valuation methods need to be further developed in order to communicate risk management alternatives at multiple scales to different stakeholder groups. Net benefit analysis may be a useful cross-cutting approach for linking uncertainty analysis and risk management decisions. In this regard, EPEC notes that some type of net benefit analysis would be beneficial, but it should not be used to avoid risk assessment. EPA has begun to explore the use of cost/benefit and ecosystem valuation methodologies as summarized in the recent review of the Agency's draft document, *Ecological Benefit Assessment Strategic Plan* conducted by the SAB Committee on Valuing the Protection of Ecological Systems and Services (CVPESS)

(U.S. EPA Science Advisory Board, 2005). The CVPESS report notes that methods are needed for valuation of ecological resources and attributes. EPEC encourages EPA to continue developing these holistic ecosystem valuation methods. However, EPEC notes that simpler cost/benefit metrics can be applied in the problem formulation phase of ecological risk assessments. Costs can be compared 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. While these types of cost-benefit comparisons are clearly in the domain of the risk managers, identifying the data needs for articulating not only the baseline risk, but also the mechanisms and measures for incremental risk reduction to ecological resources, should be addressed in the problem formulation and risk assessment. EPEC advises EPA to develop guidance for application of short-term risk-reduction metrics, while also maintaining a long-term focus on research to develop methods for valuation of ecosystem services. This approach will provide the knowledge needed for comprehensive benefit assessments.

EPEC finds that there is a critical need to develop a consensus approach to interpreting lines of evidence, or weight of the evidence in complex ecological risk assessments, or 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 weighing evidence to be too subjective. EPEC, therefore, recommends that EPA develop case studies and/or standards of practice for interpreting lines of evidence or weight-of-evidence with an emphasis on application in decision making.

Product life cycle analysis (LCA), while not typically used for ecological risk assessments, was viewed by participants at the EPEC Ecological Risk Assessment Workshop as potentially providing useful information for future-oriented investigative questions and emerging areas (e.g., nanotechnology). EPEC finds that additional guidance on application of LCA would be helpful to risk assessment practitioners.

4.5 Spatial, Temporal and Biological Scales

As noted previously, spatial, temporal and biological scales are not often explicitly considered in the problem formulation phase of ecological risk assessments, even though they should be. Risk assessments may range from local to global applications, from immediate to long-term effects, and across a number of levels of biological organization. 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 EPEC recommends explicit definition of the extent and resolution of the pertinent spatial, temporal and biological scale of concern 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 ecological risk assessment depends upon such factors as the stressors and media being evaluated, episodic events considered, specific ecological receptors, and the recovery time of systems. The SAB *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002) can be used to guide choice of scale.

EPEC notes that it would be useful to develop standard techniques 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 organizations (i.e., community, habitat, and landscape scales). Guidance is also needed on the use of population models in ecological effects assessments.

Multi-generational 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 such as geographic information systems, continuous monitors, habitat models and other models, and species life history information may be used to incorporate spatial and temporal scales in ecological risk assessments. Therefore, EPEC recommends that EPA promote the evaluation and use of modern tools for data collection and analysis (e.g., time series and spatial analyses).

5.0 IMPROVING ECOLOGICAL RISK ASSESSMENT IN SPECIFIC DECISION-MAKING CONTEXTS

Participants at the EPEC Ecological Risk Assessment Workshop discussed opportunities for advancing ecological risk assessment in three decision-making contexts: product health and safety, management of contaminated sites, and natural resource protection. EPEC provides the following specific findings and recommendations to improve ecological risk assessment in these specific decision-making contexts.

5.1 Ecological Risk Assessments for Product Health and Safety Evaluation

Ecological risk assessments for product health and safety evaluation are conducted to meet varying requirements of different statutes (e.g., Federal Insecticide, Fungicide, and Rodenticide Act, Toxic Substances Control Act). EPEC finds that in product health and safety risk 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. In order to optimize appropriate assessment and

measurement endpoints, it is important to consider relevant contaminant release pathways, fate and transport, and sensitivity of receptors during problem formulation. To improve ecological risk assessments for product health and safety evaluations, EPEC recommends that EPA:

1. Explicitly consider during problem formulation the appropriate spatial, temporal, and biological scale of the risk assessment in the context of decisions to be made. This approach will require broader consideration of receptors and stressors. Again, the *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002) may be useful in this regard.

2. Develop tools for cumulative risk assessment because contaminants are often released into stressed environments

3. Continue to conduct research to determine how biomarker and mechanistic data might best be used in exposure and risk assessments.

4. Conduct multigenerational analyses or other retrospective ground-truthing analyses for prospective risk estimates and re-evaluate and validate levels of concern with monitoring studies.

5. Use currently available tools for rapid screening level assessments, such as the Agency's Estimation Programs Interface (EPI) Suite, to assist in determining whether chemicals are biodegradable, toxic, or bioaccumulative.

5.2 Ecological Risk Assessments for Contaminated Site Management

While there is sufficient flexibility built into EPA's *Ecological Risk Assessment Framework and Guidelines* to evaluate large scale spatial, temporal, or even population-level effects at contaminated sites, many of these sites are relatively small (e.g., 2 to 10 acres). Under the requirements of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), a contaminated site remedy must be protective of human health and the environment within the site boundaries. CERCLA requires that the site investigation, including the ecological risk assessment and the remedy, focus on the site. An investigation with broader focus may not be a legal expenditure of resources under the law. This situation can preclude considering effects that would occur beyond the boundaries of a site. While acknowledging the regulatory constraints imposed, EPEC encourages EPA to further evaluate how large scale spatial, temporal, or population-level effects (and the cumulative effects of several sites within a small area) could be investigated in the context of legal and regulatory requirements that may limit the focus of assessments.

Contaminated site management decisions are often made using a weight-of-evidence approach, but as noted above the ecological risk assessment process lacks a common understanding of what is meant by weight of evidence. The result is inconsistency in contaminated site decision making. This problem is not unique to contaminated sites or

even to ecological risk assessment in general. The National Research Council recently advocated the use of weight of evidence (National Research Council, 1996), without providing context for what that means. As discussed above, EPEC recommends that EPA, or alternatively the EPA Science Advisory Board, develop a common definition and application methodology addressing what constitutes weight of evidence.

The issue of uncertainty in the decision process encumbers the ecological risk assessment process with many lengthy and costly studies. Additional studies often are unable to resolve those uncertainties, and during the time taken to conduct the studies the ecological resources continue to be exposed. As noted previously, in the face of those uncertainties EPA resource managers often choose to make the most conservative (protective) decisions, or more often make site decisions based on human health concerns, rendering the ecological risk assessment moot. To increase efficiency in the process of assessing contaminated sites and to help address the uncertainty issue, EPEC recommends that EPA develop:

1. Programmatic-level risk assessments for contaminants commonly found at contaminated sites.

2. An evaluation of post-remedial monitoring of ecological resources as compared to risks identified as part of remedial decisions.

3. Guidance on the application of adaptive management of ecological resources in contaminated site decision making.

5.3 Ecological Risk Assessments for Natural Resource Protection

In a fundamental way, ecological risk assessments for natural resource protection are different from risk assessments conducted in other decision-making contexts. 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. 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.

Ecological risk assessments for natural resource protection can be large and complex. Therefore EPEC finds that early peer review of the risk assessment study designs may be needed 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.

EPEC finds that natural change processes should be considered as part of ecological risk assessments 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.

EPEC finds that it is particularly important to identify the scale of concern during the problem formulation phase of a risk assessment for natural resource protection. It is important to look at broad scales but to answer specific questions on local or 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 a landscape. If additional spatial resolution is needed to describe species abundance and distribution, this need should be considered in the uncertainty analysis. In addition, spatial and temporal scale analysis may help later integration of a risk assessment into a meta-analysis or larger scale analysis. Such analyses may assist development of a larger body of knowledge for assessment projects. Although tools are available for spatial and temporal analyses in risk assessment, it is unclear whether there are enough risk assessment practitioners with specialized expertise to meet the current need. Resolving this need is another concern in which it may be useful to build from the *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002). Standards of practice are needed for ecological risk assessors and risk managers. These standards of practice should address methods to assure that spatial and temporal scale issues are appropriately addressed.

EPEC notes that 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 (e.g., chemical stress predisposing trees to disease). EPEC finds that it would be useful to develop standard techniques for assessing risks at specific levels of biological organization. The utility of community level information is demonstrated by the sediment quality triad of benthic community measures, sediment toxicity tests, and sediment chemistry.

As in risk assessments conducted and applied in other decision-making contexts, elements of uncertainty should be identified and incorporated into problem formulation and built into the design of a risk assessment for natural resources protection. Uncertainties in the ecological risk assessment should be categorized, and those that profoundly affect results and outcomes should be identified and acknowledged in the final assessment. As noted previously, systematic data collection, organization and cataloging from past risk assessments could provide information that could reduce the uncertainty of future risk assessments. Such efforts could provide better metadata and a centralized data repository for ecological risk assessment data, endangered species information, program specific risk assessment information, and peer reviewed literature.

To improve ecological risk assessments for natural resource protection, EPEC recommends that ecological risk assessors rethink how hypotheses are formulated and consider how to move away from traditional hypothesis testing with null models. Such hypothesis testing can result in null models that are developed without considering how

to balance Type I and Type II errors. Hypotheses should focus on causal relationships and weights of evidence.

EPEC recommends that EPA develop a better interface between risk assessment and monitoring programs so that monitoring data can be used to improve risk assessments. Specific monitoring projects could be designed to provide data that could reduce uncertainty in risk future assessments. Monitoring programs need better direction and redesign to provide information useful for testing hypotheses and reducing uncertainty in risk assessments.

EPEC also recommends that EPA integrate work in different disciplines (e.g., biology, chemistry, toxicology, ecology) to prevent fragmentary risk analyses. In this regard, expert systems could be developed to enable the integration of specific chemical and biological endpoints and identify classes of chemicals to be assessed.

To improve ecological risk assessments for natural resource protection, EPEC recommends that EPA:

1. Explicitly identify discrete ecological resources to be protected and options for their protection in the problem formulation phase.

2. Implement an independent, scientific peer review process to evaluate endpoints, scale, levels of biological organization, uncertainties, and study design outcomes of problem formulation prior to initiating the analysis phase.

3. Consider the development of standards of practice for risk assessors and managers.

4. Explore ways to focus hypothesis development on causal relationships and weights of evidence instead of traditional hypothesis testing on null models.

5. Develop a process to interface risk assessment and monitoring programs.

6.0 CONCLUSION

In developing this report, EPEC considered the current state of the practice of ecological risk assessment and opportunities to connect the early roots of this approach in comparative toxicology with recent advances in ecology. The *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992; 1998) have improved the state of the practice of ecological risk assessment and provided a robust and useful foundation upon which to build. A number of specific opportunities for advancing the risk assessment process have emerged. Peer review of proposed risk assessments before execution would likely improve many assessments. 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 landscape scales). More systematic, post-assessment monitoring would enhance the risk assessment process in the long run. A national compendium of past ecological risk assessment 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. Moreover, communication between risk managers and assessors should be a part of all aspects of the process. The risk assessment framework should be viewed in an adaptive management context whereby, as new understanding is attained, it is incorporated into the analysis process.

Together, these and other changes discussed in this report would accelerate the evolving practice of ecological risk assessment. They would also enable a more effective use of the framework for ecological risk assessment 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 the adaptive management approach will allow consideration of validity of data and its scale of reference, connection to major management problems, and involvement of stakeholders. The development and application of the consistent approach of ecological risk assessment has greatly enhanced the integration of laboratory and field data, analytical tools, and assessment methods and provided a consistent format for reporting risks and uncertainties. There are clearly big challenges ahead in applying and using the framework for ecological risk assessment; yet there are also opportunities to address current limitations and advance the state of the practice.

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