UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

October 17, 2007

EPA-SAB-08-002

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision Making: A Report of the U.S. EPA Science Advisory Board

Dear Administrator Johnson:

The Environmental Protection Agency (EPA) conducts ecological risk assessments to implement programs required by a number of key environmental statutes. EPA published a *Framework for Ecological Risk Assessment* (1992) and *Guidelines for Ecological Risk Assessment* (1998) that greatly improved the state of the practice of ecological risk assessment, not only in the United States but around the world, by establishing a phased multidisciplinary approach that has withstood the test of time. The Science Advisory Board's (SAB) Ecological Processes and Effects Committee (EPEC) has conducted a self-initiated study to enhance the Agency's risk assessment guidelines (Guidelines) and advance the state of the practice. The study was initiated to draw upon recent advances in ecological risk assessment science in three decision-making contexts: 1) product health and safety, 2) management of contaminated sites, and 3) natural resources protection. To gather information for the study, EPEC convened a public workshop attended by ecological risk assessors representing academia, government, industry, and various environmental organizations.

Overall, the SAB commends the Agency's previous efforts to advance ecological risk assessment science and encourages further integration of ecological risk assessment into environmental management decision processes. Generally, the SAB finds that a strength of ecological risk assessment is its value as a process to formulate problems, to use analytical tools to evaluate diverse types of environmental data, and to characterize risks. Moreover, ecological risk 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. Many of the SAB's specific recommendations focus on steps that can be taken to improve problem formulation.

The enclosed report provides the SAB's specific findings and recommendations. The report is based on, but not limited to, information received by EPEC at the public workshop. The SAB notes that implementing many of the recommendations in the report would make the process of ecological risk assessment more efficient. Some of the recommendations can be implemented in a relatively short period of time (less than three years), while others will require the development of extensive guidance or completion of research over a longer period of time. The executive summary of the report identifies recommended actions as short or long term efforts.

- The SAB finds that the Agency can advance the practice of ecological risk assessment by developing methods and tools that assist risk assessors in designing analyses that appropriately consider the physical, biological, and socio-economic contexts of decisions. In particular, the SAB believes there is value in advancing methods and tools to aid the proper consideration of temporal and spatial scale, biological complexity, and the environmental influences that amplify or detract from the level of risk associated with any single or multiple stressors in play.

- Developing risk management goals involves making informed normative judgments on behalf of the public, not just scientists. EPA is therefore urged to encourage, if not require, problem formulation dialogue between ecological risk managers, risk assessors, and stakeholders (including both ecologists and the lay public). Managers, assessors, and stakeholders should be engaged early and iteratively throughout the risk assessment process.

- Local and regional regulatory processes are conditioned by community values and economic objectives as well as by ecological conditions. Therefore, aligning the decision and the supporting risk and economic analyses with "what matters to people" is essential to achieve acceptable risk solutions that can be easily and effectively communicated to the public. To achieve such alignment, EPA should increase its understanding of and capacity to utilize ecosystem valuation methods in conjunction with such decisions.

- There is a need to bring more specificity to problem formulation in ecological risk assessments. To accomplish this, the SAB recommends that 1) specific management alternatives be directly considered during problem formulation, 2) specific testable hypotheses and questions be tied to management information needs and data collection and analysis, and 3) uncertainty be addressed in a manner that allows trade-offs in risk management alternatives to be evaluated and communicated to the public.

- For large, complex ecological risk assessments, EPA is strongly urged to conduct scientific peer review of proposed risk assessment study designs at the problem formulation stage to assure that studies can provide the information needed by risk managers.

- Because ecological risk assessments often fail to identify and prioritize uncertainties that may affect the quality of risk management decisions, uncertainties that profoundly affect the results and outcome of risk assessments should be identified and acknowledged during problem formulation. Furthermore, the use of adaptive management with iterative triggers for action offers promise as a way of dealing with uncertainties in ecological risk assessments.

- The SAB recommends that EPA initiate post-decision audit programs to evaluate the environmental outcomes of risk-based decisions. EPA should also use monitoring data to reduce uncertainties in future ecological risk assessments.

In summary, the SAB has identified opportunities to improve the application of ecological risk assessment in environmental decision making and encourages EPA to provide the resources and research support needed to make these improvements. The SAB notes that EPA's budget for ecological research has decreased by approximately 40% since fiscal year 2003. The Agency has eliminated research in monitoring programs to assess the status and health of ecological resources. The declining trend in the EPA budget for ecological research must be reversed in order to address many of the complex issues discussed in this report. 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. We look forward to receiving your response.

Sincerely,

/Signed/

Dr. Virginia Dale, Former Chair
Ecological Processes and
Effects Committee
EPA Science Advisory Board

/Signed/

Dr. Judith Meyer, Chair
Ecological Processes and
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Dr. M. Granger Morgan, Chair
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Table of Contents

ADVICE TO EPA ON ADVANCING THE SCIENCE AND APPLICATION OF ECOLOGICAL RISK ASSESSMENT IN ENVIRONMENTAL DECISION MAKING: A REPORT OF THE U.S. EPA SCIENCE ADVISORY BOARD

1.0 EXECUTIVE SUMMARY

This report presents results from an original study of the Environmental Protection Agency (EPA) Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) and provides advice to EPA on advancing the science and application of ecological risk assessment in environmental decision making. The following specific findings and recommendations are provided to guide the development of EPA policies and to strengthen the Agency's program-specific ecological risk assessment guidance. Cross-cutting recommendations are presented first. These are followed by recommendations pertaining to ecological risk assessments in three decision-making contexts: product health and safety, contaminated site management, and natural resources protection. Implementing many of the recommendations would make the process of ecological risk assessment more streamlined and efficient. EPEC notes that some of the recommendations, identified within each of the headings below as "short term," can be implemented in a relatively short period of time (less than three years). Other recommendations identified as "long term" will require the development of extensive guidance or completion of research over a longer period of time.

EPA's Ecological Risk Assessment Framework and Guidelines

EPA's *Framework for Ecological Risk Assessment* (Framework) *and Guidelines for Ecological Risk Assessment* (Guidelines) have improved 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 as well as 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. Yet, the range of applications 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 to decisions. Such guidance would enhance the consistency of the risk assessment process. 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 developed in collaboration with decision makers, assessors, scientists, and stakeholders.

Short term recommendations

- Guidance should be developed to better define what ecological attributes EPA is striving to protect and how to apply risk assessment findings to decisions. In the short term, EPA could make progress toward incorporating such guidance into decision-making processes. Non chemical stressors alone and in combination with chemical stressors should be considered in developing ecological risk assessment guidance, models, and endpoints. Endpoints should reflect elements of ecological condition such as ecological processes and various levels of biological organization including landscape composition and pattern.

- Ecological risk assessment methodologies are not the exclusive purview of the U.S. EPA. Alternative methodologies have been developed and are being used by other countries (e.g., Canada, Australia, New Zealand, the European Union) and at least one other U.S. government agency (the National Oceanographic and Atmospheric Administration [NOAA]) (Table 1). EPA should be cognizant of these approaches and incorporate valuable aspects of them into the Agency's risk assessment guidance.

Risk Assessor and Risk Manager Dialogue in Planning and Problem Formulation

Risk assessor and risk manager dialogue is necessary during problem formulation to integrate ecological risk assessment into the environmental management decision process. Furthermore, there is a need to engage risk managers and risk assessors in bringing greater specificity to problem formulation and "risk question" or hypothesis formulation in ecological risk assessments. EPEC finds that the EPA Science Advisory Board's *Framework for Assessing and Reporting on Ecological Condition* may provide a useful reference checklist for ensuring that appropriate levels of temporal and spatial scale and biological organization are specifically considered in ecological risk assessments.

Short term recommendations

- EPEC recognizes that EPA's *Framework for Ecological Risk Assessment* provides for interaction between risk managers and risk assessors and recommends that EPA further encourage and promote, if not require, problem formulation dialogue between risk assessors and risk managers.

- EPEC recommends that, during problem formulation, explicit connections 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 scale of the risk assessment and communication of uncertainty.

- 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 assessments, problem formulation and study design be reviewed through an independent scientific peer review process prior to study implementation. For smaller risk assessments, checklists could be used to ensure that management goals are considered in problem formulation and translated into information needs using 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.

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 identifying uncertainties that profoundly affect the results and outcomes of risk assessments and information needed to reduce uncertainties.

Probabilistic ecological risk assessment is a useful tool for considering uncertainty; however, that approach can be difficult to explain to non scientific managers. EPEC finds that the results of probabilistic risk assessments could be more effectively communicated if during problem formulation 1) a summary of the sources and sizes of major uncertainties were provided and 2) risk assessors described how probabilistic approaches would be applied to understand the implications of uncertainty. EPEC finds that 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. EPEC also finds that it would be beneficial for EPA to 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 decisions.

In addition, EPEC finds that uncertainty in ecological risk assessments could be reduced by addressing the critical need to develop either a consistent approach to interpreting lines of evidence and weight of the evidence in complex ecological risk assessments or a process for evaluating competing technical assessments in environmental decision making.

Short term recommendations

- EPEC recommends that EPA explore how adaptive management with iterative triggers for action can be applied in the context of ecological risk assessment and risk management as a way to deal with uncertainties.

- 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 decisions with post-decision audit programs. Post decision audit programs can be implemented in the short term, but a longer period of time would be required to complete and document such audits.

Long term recommendations

- EPEC recommends that EPA develop case studies and/or standards of practice for interpreting lines of evidence, with an emphasis on application in decision making.

- EPEC recommends that EPA explore 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.

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; however, Agency decisions are conditioned by community values and economic objectives as well as ecological conditions. Therefore, EPEC finds that ecosystem valuation methods must be further developed in order to formulate and evaluate risk management alternatives at multiple scales and to communicate them to different stakeholder groups. EPA's *Ecological Benefits Assessment Strategic Plan* (U.S. Environmental Protection Agency, 2006a) highlights the importance of linking natural and social sciences in problem formulation in order to improve decision making. EPEC also notes that product life cycle analysis is not typically used in ecological risk assessment but it could be used to understand the environmental impacts associated with various industrial products, processes, and activities. EPEC therefore finds that additional guidance on the application of life cycle analysis would be helpful to risk assessment practitioners.

Long term recommendations

- EPEC advises EPA to maintain a long-term focus on research to develop methods for valuation of ecosystem services.

- EPEC recommends that EPA develop guidance for risk assessment practitioners on the application of life cycle analysis.

Spatial, Temporal, and Biological Scales

EPEC finds that methods and tools should be further developed and applied to aid the proper consideration of spatial, temporal, and biological scales in ecological risk assessments. A substantial research effort is needed to address the complex issues of evaluating spatial, temporal, and biological scales and their interrelationships

Short term recommendations

- EPEC recommends that during the problem formulation phase of ecological risk assessments, EPA explicitly define the extent and resolution of the pertinent spatial and temporal scales and levels or scales of biological organization (e.g., cellular, organismal, population, and ecosystem).

Long term recommendations

- It would be useful to develop standard techniques for assessing risks at pertinent spatial, temporal, and biological scales. The SAB *Framework for Assessing and Reporting on Ecological Condition* could be used to guide the choice of scale.

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

Improving Ecological Risk Assessments for Product Health and Safety

EPEC provides the following short and long term recommendations to improve ecological risk assessments for product health and safety.

In the short term EPA could:

- 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. The limitations of such tools must be taken into consideration. For example, the EPI Suite tools are generally applicable only to nonpolar organic compounds of relatively low molecular weight. Inorganic compounds, metallo-organic compounds, polar organic compounds, polymers, and surfactants cannot be addressed by most of the EPI Suite tools.

- 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.

In the long term EPA could:

- Develop tools for cumulative risk assessments. Contaminants are often released into stressed environments and risk assessments should consider the combined effects of stressors.

- Continue to investigate 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.

Improving Ecological Risk Assessments for Contaminated Site Management

EPEC provides the following short and long term recommendations to improve ecological risk assessments for contaminated site management.

In the short term EPA could:

- Increase efficiency by developing "programmatic-level" assessments for contaminants, such as polychlorinated biphenyls, commonly found at many contaminated sites. Such assessments would be similar to programmatic environmental impact statements, which 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 approach would decrease the number of redundant risk assessments for contaminants commonly found at contaminated sites.

- Take stronger leadership in training Agency personnel and those of state regulators on the appropriate use of ecological risk assessment methods and data and explicitly make regulators aware of how such methods and data can be misused. The Agency should consider how to effectively integrate and weight the importance of modeled estimates of risk in the presence of ecological observations from the field which are assessing ecological integrity or biological performance

In the long term EPA could:

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

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

- Take the initiative to develop guidance on the appropriate and acceptable use of such screening tools as hazard quotients (HQs), hazard indices (HIs), and similar environmental benchmarks, especially with regard to their utility in setting actionable environmental protection goals. As EPA addresses recommendations related to appropriate use of screening tools such as HQ's and the need to reduce uncertainty, the Agency will need to explore a range of risk calculation methods which represent better and more certain approaches to estimating risk.

- EPEC also finds that advancing net environmental benefit tools may be a useful check to fit a specific process such as the remediation of chemically contaminated sites. These approaches may also be useful to other types of applications (such as natural resource management).

Improving Ecological Risk Assessment for Natural Resources Protection

EPEC provides the following short and long term recommendations to improve ecological risk assessments for natural resources protection

In the short term EPA could:

- 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 for large scale risk assessments 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 (e.g., global climate change) and indirect effects, that are often revealed at different levels or scales of biological organization, as part of the risk assessment. Such processes and indirect effects can be particularly important in ecological risk assessments for natural resources protection.

- Identify, during problem formulation, those spatial and temporal scales and levels of biological organization of concern that are large enough to capture emerging patterns across a landscape such as effects on local watersheds or migratory pathways.

- Categorize uncertainties in the ecological risk assessment according to their sources and sizes, and in the final assessment identify and acknowledge uncertainties that profoundly affect results and outcomes such as the weight-of-evidence decision-making process.

In the long term EPA could:

- Develop standard techniques for assessing risks at specific scales and levels of biological organization and better define associated uncertainties.

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

- Develop guidance for improved weight-of-evidence decision making that decreases "best professional judgment" and increases statistically-based quantification. Guidance should contain examples of typical sites covering major ecoregions, hydrologic types, and stressors (chemical and non-chemical).

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

EPEC notes that these and other changes discussed in this report would advance 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. *EPEC finds that a substantial research effort is needed to develop the methodology required to address many of the complex issues discussed in this report.* However, EPA's budget for ecological research has decreased by approximately 40% since fiscal year 2003. The Agency has eliminated research in monitoring programs to assess the status and health of ecological resources. The declining trend in the EPA budget for ecological research must be reversed in order to address many of the complex issues discussed in this report. 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.

2.0 INTRODUCTION

This report was prepared by the Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC). The report resulted from a 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 levels or scales of biological organization, problem formulation and the adequacy of testable hypotheses, and decision making in the presence of uncertainty. The findings and recommendations in this report are provided to guide the development of EPA-wide policies and strengthen the Agency's program-specific risk assessment guidance. Key findings and recommendations in the report are italicized.

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 describing key points discussed is provided as an attachment to this advisory report. The workshop summary document and supporting material is also available at: http://www.epa.gov/sab/sab_epec_wkshp_eco_risk_02_7-9_2006.htm.

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

EPA's *Framework for Ecological Risk Assessment* (Framework) *and Guidelines for Ecological Risk Assessment* (Guidelines) (U.S. Environmental Protection Agency, 1992, 1998) have greatly 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 or other stressors (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 components to be part of risk assessment or establish inappropriate endpoints. This is exemplified in questions that often arise about: 1) the validity of policy or precedent-based point estimates of effects used in risk assessments (e.g., "No Observed Effects Concentrations" [NOECs] that have been used in some risk assessments are not statistically defensible), 2) the quality of data obtained from peer reviewed literature (e.g., poor study design and reporting standards), 3) common failures to connect risk assessments to management issues, and 4) 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), 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 Framework's underlying ecological risk assessment paradigm has been emulated in

Canada, the European Union, and other countries, and this further attests to the utility of the Framework.

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 (National Research Council, 1994). *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.* EPEC notes that EPA has developed guidance on use of the DQO process to establish performance criteria for designing a data collection plan to support study goals (U.S. Environmental Protection Agency, 2000a,b,c, 2006c). This guidance should be consulted during the problem formulation phase of ecological risk assessments.

Many participants at the EPEC ecological risk assessment workshop stated that EPA's *Framework for Ecological Risk Assessment* has utility, but they noted major differences in ecological risk assessments conducted by various EPA Program and 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 principles established in the Framework and Guidelines. *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 as well as mixtures of chemical and 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. *While recognizing that EPA's Framework for Ecological risk Assessment provides for interaction between risk managers and risk assessors, EPEC finds that the integration of ecological risk assessment into the environmental management decision process should be further 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 EPEC ecological risk assessment 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 using approaches 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 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*. 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. 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, answering a well-defined question is not useful if it does not lead to improvements in managing resources. Testable hypotheses are not useful unless they are very closely tied to management goals, and correct problem formulation will drive decisions to collect field data that are meaningful to decision making. *Explicit connections between 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 ecological risk assessments across EPA. *EPEC therefore 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 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) may provide 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 reviewed through an independent scientific peer review process prior to study implementation. Peer review early in the process will strengthen ecological risk assessments even if there are no conflicts associated with the study design. The identification of assessments requiring early peer review 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, *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 when developing specific risk questions and 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 various risk assessments. *As further discussed below, 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.* For example, Borsuk (2006), in seeking to define a relationship between oxygen conditions and fish kills in the Neuse River estuary, uses expert opinion from people with good knowledge of local conditions (where no good database is available) to construct an influence diagram. Monte Carlo simulation is then used to generate predictions of fish health and fish kills in the estuary under current and improved oxygen conditions. Here, the model for ecological risk must account for both knowledge uncertainty and natural variability.

Decision making in the presence of uncertainty is constrained by statutory and regulatory requirements. 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:

- Defer making a decision until more study is conducted 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 because a decision could be made on the basis of risks to piscivores. Further study of risks to benthic macroinvertebrates would not reduce uncertainty associated with the management decision

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 as 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 assessment 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 rather than binary (yes/no) statements could be incorporated into problem formulation. EPEC notes a number of benefits associated with the use of Bayesian approaches. 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. Bayesian results provide a clearer, more direct interpretation, particularly for nonstatistical scientist. This is because it is easier to grasp the Bayesian notion of "the probability of an event happening, given the data that we have observed," rather than the frequentist's interpretation of "the probability of seeing the observed data, or anything more extreme, given that conditions under an event hold" (the much used, and much abused, P value).

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 are not available to demonstrate how such information could be used in risk management decisions. In 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 therefore 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 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 EPA in maintaining consistent use of risk assessment procedures among various Agency offices. Numerous illustrative examples are available for such a compendium. In one example, Crane et al. (2000) show how the process of ecological risk assessment could be used to assess the effects of a (hypothetical) hazardous substance on fish. Their primary purpose is to illustrate a variety of statistical methods used in ecological risk assessment. However, they also illustrate how to combine estimates of exposure and effects to calculate risk by making specific probability statements about fish mortality given various environmental contaminant concentrations. In another example, Williams et al. (2006) test the assumptions regarding the bioconcentration factor (BCF) for arsenic bioaccumulation. The traditional assumption for bioaccumulation is that it is a linear function of exposure concentration. The authors identify 12 studies (4 laboratory and 8 field investigations, one of which is a study conducted by EPA's Environmental Monitoring and Assessment Program) of arsenic bioaccumulation in freshwater fishes in order to explore differences in laboratory-generated BCFs and field-generated bioaccumulation factors (BAFs), and to assess their relationship to arsenic concentrations in water. Their analysis indicates that arsenic concentrations in tissue and arsenic BAFs may be power functions of arsenic concentration in water. Thus, the assumption of a linear function may be faulty. *To reduce uncertainty in future risk assessments, EPEC also believes it is critically 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 decisions. 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 decisions with post-decision 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 SAB Advisory on EPA's Superfund Benefits Analysis (U.S. EPA Science Advisory Board, 2006).

EPEC also finds that uncertainty in ecological risk assessments could be reduced by undertaking critically needed work to develop a consistent approach to interpreting lines of evidence and weight of 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 and weight of evidence with an emphasis on application in decision making.*

4.4 Linking Natural and Social Science in Environmental Decision Making

EPA's *Framework and Guidelines for Ecological Risk Assessment* 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 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 EPA decision.

EPEC recognizes that EPA, through its draft *Ecological Benefit Assessment Strategic Plan* (U.S. Environmental Protection Agency, 2006a), is wrestling with the integration 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 represents 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 benefit-cost and valuation methods need to be further developed in order to provide mechanisms for conducting risk assessments in the context of policy decisions regarding risk reduction. Because policy decisions might consider costs and benefits (or more generally the values that people attach to specific risk changes), it is important that risk assessments be designed to provide information for estimating costs and/or benefits or the associated values. 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's draft *Ecological Benefit Assessment Strategic Plan* is based on an application of benefit-cost analysis to ecological benefits, following the guidelines for cost benefit analysis contained in U.S. Office of Management and Budget Circular A-4 (U.S. Office of Management and Budget, 2003). EPA's work in this area is summarized in the recent review of the *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 states 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 during the problem formulation phase of ecological risk assessments, 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. While these types of benefit-cost 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 risk-reduction metrics such as those mentioned above, while also maintaining a long-term focus on research to develop methods for valuation of ecosystem services.* Such valuation methods can be applied in the problem formulation phase of a risk assessment to develop a better understanding of appropriate risk questions. This approach will provide the knowledge needed for comprehensive benefit assessments.

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). Issues such as inputs required for production and maintenance activities, product use and reuse options, and disposal and recycling alternatives can be considered in a systems approach. *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, pertinent spatial and temporal scales and levels of biological organization 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. As stated in EPA's *Framework for Ecological Risk Assessment*, the purpose for conducting a risk assessment determines whether it is national, regional, or local in scope. For example, the EPA Office of Pesticide Programs may conduct ecological risk assessments over a range of spatial scales depending upon uses, fate, transport, and effects of pesticides. The spatial scales of risk assessments conducted by EPA's Office of Solid Waste and Emergency Remedial Response may depend upon the boundaries of contaminated sites. Any such exercise necessarily involves numerous trade-offs of site-specificity and accuracy versus general applicability to diverse facilities and locations.

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 and temporal scales and levels of biological organization 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. For example, climate change events of varying scales such as El Nino cycles, the Eastern Pacific Decadal Oscillation, and anthropogenic warming can significantly affect ecosystems and should be considered in ecological risk assessments. 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 organization (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 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 statistical, geospatial, and other tools for data collection and analysis (e.g., time series and spatial analyses).*

4.6 Comparison of Other Protocols for Conducting Ecological Risk Assessments

Ecological risk assessment methodologies are not the exclusive purview of the U.S. EPA. Alternative methodologies have been developed and are being used by other countries (e.g., Canada, Australia, New Zealand, the European Union) and at least one other U.S. government agency (the National Oceanographic and Atmospheric Administration [NOAA]) (Table 1). EPA should be cognizant of these approaches and incorporate valuable aspects of them into the Agency's risk assessment guidance. For example, Environment Canada uses a three-tier approach ranging from (Tier 1) relatively small areas of contamination to (Tier 3) complex, large scale areas of contamination (Canadian Council of Ministers of the Environment, 2007). The British Columbia Ministry of Environment (Canada) has specific guidance for Tier 1 sites including intended land use post remediation (British Columbia Ministry of the Environment, 2007a,b). Incorporation of planned land use is also a feature of Australian guidance, which is focused on natural resource protection (Australia Natural Environmental Protection Council, 2007). New Zealand's guidance is an amalgam of both the Australian and U.S. models, including tiering similar to the Canadian approach (Landcare Research, 2007a,b). The European Union approach is based on comparing predicted environmental concentrations (PECs) to predicted no effects concentrations (PNEC) (European Commission on Health and Consumer Protection Directorate-General, 2003). NOAA's guidance for aquaculture uses a model similar to EPA's but includes non-chemical stressors (Nash et al., 2005). Thus, different approaches to ecological risk assessment exist both outside and within the U.S. Commonalities include an initial data summary (problem formulation, hazard assessment) phase, a conceptual model, considerations of exposure and effects, and a risk calculation process.

Table 1. Links to Various Approaches to Ecological Risk Assessment

Government Unit	Title and/or URL	Short Description
Canadian Council of Ministers of the Environment (CCME)	www.ccme.ca	This site contains the Canadian guidance for ecological risk assessment as well as a wide variety of relevant guideline documents.

BC Ministry of Environment (Canada)	Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia. http://www.env.gov.bc.ca/epd/epdpa/contam_sites/policy_procedure_protocol/protocols/tier_1/index.html	This is the guidance and checklist for smaller scale sites for the province of British Columbia (BC). The approach is based on the Canadian definition of Tiers and the Contaminated Site regulations for BC. Land use is an important and explicit consideration in the risk assessment process.
BC Ministry of Environment (Canada)	Tier 1 Ecological Risk Assessment Policy Decision Summary http://www.env.gov.bc.ca/epd/epdpa/contam_sites/standards_criteria/standards/tier1policy.html	In addition to the guidance document a record of decision making was produced to justify the use of 20% effects concentrations (EC20s), site visits and other features of the above guidance document.
Australia	Australian Schedule B (5) Guideline on Ecological Risk Assessment http://www.ephc.gov.au/pdf/cs/cs_05_era.pdf. Additional documents describing the risk assessment process for contaminated sites can be found at: http://www.ephc.gov.au/nepms/cs/con_sites.html.	Contaminated site risk assessment is the jurisdiction of the National Environment Protection Council that is in turn a part of the Environment Protection and Heritage Council (EPHC). Part of the mandate of EPHC is the preservation of natural resources. Land use is an important and explicit consideration in the guidance, similar to that of British Columbia.
New Zealand	Risk Assessment for Contaminated Sites in New Zealand. http://contamsites.landcareresearch.co.nz/index.htm	New Zealand has an extensive set of risk assessment documents for contaminated sites. Many of the tools are based upon Australian and United States approaches. New Zealand has a tiered system of risk assessments similar to Canada.
European Union	Final Report on the Ecological Risk Assessment of Chemicals Adopted by the Scientific Steering Committee at its Meeting of 6-7 March 2003.	The European Union (EU) document appears significantly different from Canadian or Australian approaches. The risk assessment process is chemical-based, comparing predicted environmental concentrations and predicted no-effect concentrations.

	http://ec.europa.eu/food/fs/sc/ssc/out326_en.pdf	
NOAA	Guidelines for Ecological Risk Assessment of Marine Fish Aquaculture. http://www.nwfsc.noaa.gov/assets/25/6450_01302006_155445_NashFAOFinalTM71.pdf	These guidelines provide information for the evaluation of non-chemical stressors with an approach derived from U.S. EPA but used for a different purpose. Non-chemical stressors included in the assessment include: transmission of disease organisms; interactions between escaped organisms and wild populations; and physical interactions with marine habitat and wildlife.

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. To improve ecological risk assessments for product health and safety evaluations EPEC provides the following specific recommendations. These recommendations focus on actions that can be taken to facilitate consideration of relevant contaminant release pathways, fate and transport of contaminants, sensitivity of receptors, and optimization of appropriate assessment and measurement endpoints during problem formulation.

1. *Explicitly consider, during problem formulation, 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. 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 (U.S. Environmental Protection Agency, 2004), 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 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, 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.

EPEC finds that guidance is needed in the area of risk calculation and application. Too often ecological risk assessments are designed and executed solely with a comparison of measured exposure concentrations to toxicological reference values; the "hazard quotient." Although the area of risk characterization was explored during the EPEC ecological risk assessment workshop, actual discussions around risk calculation and application methods were limited. Much of the workshop discussion in this area focused on the need to better understand the appropriate use of hazard quotients (HQs) to assess and subsequently manage risk, the issues of uncertainty in calculating risk, and the need for full exploration and disclosure of uncertainty. Therefore, in the following discussion and associated recommendations there is an absence of explicit recommendations related to risk calculation methods other than those related to HQs, which some might suggest are not risk calculation methods at all. The Agency and other readers should not take this as a suggestion that the capacity to do better risk calculations could not be improved. Our expectation and hope is that as EPA seeks to address the recommendations related to appropriate use of HQs and the need to understand and reduce uncertainty, the Agency will need to explore a range of risk calculation methods which represent better and more certain approaches to estimating risk.

EPA is most likely aware that there are some scientists (Tannenbaum, 2003, 2005) who challenge the veracity of ecological risk assessment as a tool for effectively informing environmental decisions makers. Although such positions are not widely held, the Agency should not summarily dismiss issues raised by these contrarians. For example, some raise the issue that HQs do not provide estimates of risk (Tannenbaum et al., 2003) and that the use of HQs to set preliminary remediation goals at contaminated sites is mathematically inaccurate. *EPEC recommends that EPA take the initiative on this point and develop guidance on the appropriate and acceptable use of such screening tools such as HQs, hazard indices (HIs), and other environmental benchmarks, especially with regard to their utility in setting actionable environmental protection goals.*

To some degree the concerns raised about ecological risk assessment as a tool for decision making may be more related to how the ecological risk assessment process and its output are utilized in a given management context. For example, in ecological risk assessments of contaminated lands, project managers with limited scientific understanding may give greater weight to modeled estimates of risk than to field observations indicating that no harm is apparent. *To address this point EPA is advised to take stronger leadership in training its personnel, and those of state regulators, on the appropriate use of ecological risk assessment methods and data, and to explicitly make regulators aware of how such data and methods can be misused. EPA should also consider how to effectively integrate and weight the importance of modeled estimates of risk in the presence of ecological observations from the field which provide assessments of ecological integrity or biological performance.* This latter recommendation relates to the stated need for guidance on weight of evidence procedures discussed in section 4.4 of this advisory. **A**lthough these recommendations are presented in the context of contaminated site decision making, EPEC notes that the need for the training and education identified above is a cross-cutting issue that pertaining to ecological risk assessment.

To apply ecological risk assessment in an appropriate decision making context some have suggested the need to balance the risks from contamination with the risks and expected benefits from removal of contaminated media. *Advancing net environmental benefit tools (Efroymson et al., 2004) may be a useful check to fit a specific process such as the remediation of chemically contaminated sites.*

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 such as polychlorinated biphenyls commonly found at many contaminated sites. Such assessments would be similar to programmatic environmental impact statements which 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.*

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.*

4. *Guidance on the appropriate and acceptable use of such screening tools as hazard quotients, hazard indices, and other environmental benchmarks, especially with regard to their utility in setting actionable environmental protection goals.*

5. *Training for Agency personnel and state regulators on the appropriate use of ecological risk assessment methods and data and how such data and tools can be misused.*

6. *Research on tools that balance the risks from contamination with the risks and expected benefits from removal of contaminated media.*

5.3 Ecological Risk Assessments for Natural Resource Protection

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.*

Ecological risk assessments for natural resource protection can be large and complex. *Therefore EPEC finds that early scientific 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 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 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. *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 such standards of practice could be broadly applicable to ecological risk assessments in most decision-making contexts, not just natural resource protection. To resolve this need, it may be useful to build from the *Framework for Assessing and Reporting on Ecological Condition* (U.S. EPA Science Advisory Board, 2002).

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. For example, chemical stress predisposing trees to disease may be revealed at the community level through an assessment of forest condition. 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 in assessing ecological risk is demonstrated by the sediment quality triad of benthic community measures, sediment toxicity tests, and sediment chemistry (Chapman, 2000).

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 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 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 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 also recommends that EPA develop a better interface between risk assessment and environmental monitoring programs so that monitoring data can be used to improve risk assessments. Specific monitoring projects could be designed to provide data to reduce uncertainty in future risk assessments. Monitoring programs need better direction and redesign to provide information useful for testing hypotheses and reducing uncertainty in risk assessments. Data collection and analysis procedures developed by monitoring programs can also be useful to risk assessors. For example, EPA's Environmental Monitoring and Assessment Program (EMAP) has been in operation for more than fifteen years and has addressed scale issues (level of biological organization as well as spatial and temporal scale) in the development of sampling and data analysis procedures (e.g., the General Randomized Tessellation Sampling Program has been used in EMAP to generate estimates of salmon abundance in Oregon Streams, taking into account spatial and temporal correlation, and the fact that sites are sampled at different frequencies).

In addition, EPEC 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 and nonchemical stressors to be assessed.

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

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

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. *Systematically collect, organize and catalog data from past risk assessments that could reduce the uncertainty of future risk assessments. Such an effort could provide better metadata and a centralized repository for ecological risk assessment data, endangered species information, program specific risk assessment information, and peer reviewed literature.*

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 *Framework for Ecological Risk Assessment and Guidelines for Ecological Risk Assessment* (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. Ecological risk assessments 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. EPA is therefore urged to encourage, if not require, problem formulation dialogue between ecological risk managers, risk assessors, and stakeholders (including both ecologists and the lay public). Moreover, communication between risk managers and assessors should be a part of all aspects of the process. The practice of ecological risk assessment can also be advanced by developing methods and tools that assist risk assessors in designing analysis that appropriately consider the physical, biological, and socio-economic 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 landscape scales). EPA should increase its understanding of and capacity to utilize ecosystem valuation methods in conjunction with risk management decisions. Peer review of proposed risk assessments before execution would likely improve many large and complex assessments. 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. 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 advance 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 assessments endpoints to realistic temporal and spatial scales; and addressing legal and regulatory requirements or policy precedence. Furthermore an adaptive management approach to ecological risk assessment would 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. *EPEC finds that a substantial research effort is needed to develop the methodology required to address many of the complex issues discussed in this report.*

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ATTACHMENT - Ecological Risk Assessment in Environmental Decision Making, an Evaluation of the State of the Practice: A Summary of the EPA Science Advisory Board Ecological Processes and Effects Committee Workshop

The attached document describes the key points discussed at the EPA Science Advisory Board Ecological Processes and Effects Committee workshop: *Ecological Risk Assessment in Environmental Decision Making, an Evaluation of the State of the Practice.*

Ecological Risk Assessment in Environmental Decision Making
An Evaluation of the State of the Practice

A Summary of the

EPA Science Advisory Board

Ecological Processes and Effects Committee

Workshop

February 7 - 8, 2006

Washington, D.C.

NOTICE

This workshop summary has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC). EPEC is a standing committee of the chartered SAB which provides extramural scientific information and advice to the Administrator of the EPA. This workshop summary report describes the key points discussed at a public workshop and represents the diverse opinions of workshop participants. The workshop summary does not represent the views and policies of the EPA nor of other agencies in the Executive Branch of the Federal government

Table of Contents

1.0 EXECUTIVE SUMMARY

The U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) is advising the agency on how to advance the science and application of ecological risk assessment in environmental decision making. As part of this advisory activity, the SAB EPEC convened a public workshop on the role and conduct of ecological risk assessments for environmental decision making. 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 background and history of the development of ecological risk assessment were reviewed. A number of opportunities for advancement of the state of the practice were identified by the workshop participants. Key workshop discussion points are briefly summarized in this executive summary and presented in more detail in subsequent sections of this report. *There were many points of view represented at the workshop, and in some cases participants did not agree on points discussed. Consensus findings or recommendations were not developed at the workshop, and this may be reflected in the key points presented below. It should be noted that this document is not an SAB advisory report, but it will be used by the SAB EPEC to develop separate advice to EPA.*

Background

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

  - Problem formulation;
  - Early interaction and discussion among risk assessors and risk managers;
  - Relevance of risk assessment results to risk management questions;
  - Conceptual models and appropriate assessment endpoints;
  - An analysis plan;
  - Consideration of non-chemical stressors;
  - More frequent use of risk assessment results in EPA risk management decisions; and
  - Consistently reporting risks and uncertainties.

- Strengths of ecological risk assessment for use in decision making include:

  - Recognition of its value as process rather than technique;
  - Its value as a consistent approach for using diverse types of laboratory and field data;
  - Its value as a source of analytical tools applicable to a wide array of environmental problems;
  - Opportunities presented for transfer of assessment methods (e.g., species sensitivity distributions and weight-of-evidence approaches); and
  - Its value as a consistent format for reporting risks and uncertainties.

- Challenges to be addressed in using ecological risk assessment for decision making include:

  – Uncertainties associated with
    - the stochastic nature of ecological systems; and
    - the effects of multiple stressors.

  – Difficulties associated with
    - 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
    - variations in toxicological profiles for different taxa.

  – Non-scientific limitations associated with
    - legal/regulatory requirements (examples include potential liability that can promote avoidance of risk assessment, and requirements to assess individual rather than cumulative risks - such as assessing underground storage tanks one tank at a time rather than looking at all in an area – that place limitations on risk assessments); and
    - policy and precedent that may establish inappropriate endpoints.

  – Questions regarding
    - validity of point estimates of effects concentrations used in risk assessments (e.g., No Observed Adverse Effects Concentration);
    - quality of data obtained from peer reviewed literature and used in risk assessments (e.g., as a result of poor study design or reporting standards);
    - failure to connect risk assessments to management problems; and
    - exclusion of some key stakeholders from the ecological risk assessment process.

- Ecological risk assessments for product health and safety are conducted under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Toxic Substances Control Act (TSCA). For ecological risk assessments conducted under these statutes:

  – A tiered iterative process is used;
  – The information used is dependent on the statutory authority;
  – Data requirements are based on hazard quotients (estimated exposure/effects concentration) for a few species;
  – EPA is developing probabilistic risk assessment methods; and
  – New screening and testing methods are being developed and validated for endocrine disruptors.

- Ecological risk assessments for managing contaminated sites are conducted under the Resource Conservation and Recovery Act (RCRA) and Comprehensive Environmental

Response Compensation, and Liability Act (CERCLA). For ecological risk assessments under these statutes:

- EPA has developed useful guidance for risk assessments designed to establish legal action for site-specific remediation goals;
- Statutes may limit assessments to consideration of chemical releases at sites; and
- Legal requirements may constrain evaluation of larger spatial, temporal or biological scale effects.

- Ecological risk assessments for natural resource protection are closely tied to a "value" oriented paradigm focused on ecological attributes to be protected, rather than responses to specific stressors. Ecological risk assessments for natural resource protection should consider:

  - Natural change processes; and
  - The importance of looking at broad scales but answering specific questions on local or global scales.

Key Workshop Discussion Points

Discussion topics were raised across all areas of application and they are summarized below; however several cross-cutting themes emerged. An integrating vision of risk assessment connects its early roots in comparative toxicology with recent advances in quantitative and landscape ecology. Many of the cross-cutting themes discussed at the workshop address challenges associated with these complexities.

A number of common key points emerged from the three focus workgroups (product health and safety, contaminated sites management, and natural resource protection). These key points can be grouped into five general categories: 1) EPA's *Ecological Risk Assessment Framework and Guidelines*; 2) risk assessor and risk manager dialogue in planning and problem formulation; 3) linking natural and social sciences in environmental decision making; 4) spatial, temporal and biological scales; and 5) uncertainty in ecological risk assessment.

EPA's Ecological Risk Assessment Framework and Guidelines

- EPA's *Ecological Risk Assessment Framework and Guidelines* are robust and useful for environmental decision making. They have stood the test of time, as evidenced by a growing scientific literature, and incorporation into various governmental (international, federal, state, and tribal) voluntary and regulatory programs.

- Most EPA offices have, or are in the process of, updating program specific ecological risk assessment guidance to reflect the *Framework and Guidelines* principles. However, the sheer range of applications has made it difficult to develop recognizable Agency-wide policy or guidance that defines what ecological attributes EPA is striving to protect.

Risk Assessor and Risk Manager Dialogue in Planning and Problem Formulation

- Dialogue between risk assessors and risk managers in the planning and problem formulation step is necessary to develop focused risk assessment questions or hypotheses that support specific risk management options. Explicit connections between risk measures, data quality needs, data collection activities, and risk management decisions are needed during the problem formulation step, but these connections have not been consistently achieved. Additional guidance or examples demonstrating how such connections might be formulated and scientifically tested would be helpful.

- Problem formulation for chemical and product risk assessments does not focus on why particular risk assessments are being conducted or what ecological resource should be protected. The EPA Science Advisory Board's *Framework for Assessing and Reporting on Ecological Condition* (2002) can be used as a reference checklist to ensure that appropriate levels of organization are considered in ecological risk assessments.

- For large, complex risk assessments, peer review at the problem formulation stage and again at the completion of the risk assessment would help assure that the assessment study design and implementation are appropriate for the risk management goals. For smaller assessments, checklists could be developed to assist risk assessors and risk managers in planning and problem formulation in order to focus on greater specificity of risk questions and direct consideration of management alternatives.

- Case studies that demonstrate and evaluate how ecological data were used in decisions could be useful to help develop standards of practice for determination of ecological condition, application of appropriate spatial and temporal scales and levels of biological organization, and assessment of cumulative risk.

Linking Natural and Social Science in Environmental Decision Making

- EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992a; 1998) focus on the application of ecological risk science within a socio-economic, legal and political decision-making arena. However, there has been little elaboration of how ecological risk estimates might be considered or weighed in these broader decision-making contexts.

- Benefit-cost and valuation methods are needed 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. Some type of net benefit analysis would be beneficial, but it should not be used to avoid risk assessment.

- There is no consensus approach for interpreting lines of evidence, or weight-of-the-evidence in complex ecological risk assessments, or in evaluating competing technical assessments in environmental decision making.

- Product life cycle analysis (LCA), while not typically used for ecological risk assessments, was viewed as potentially providing useful information for future-oriented investigative questions and emerging areas (e.g., nanotechnology). Additional guidance on application of LCA would be helpful.

Spatial, Temporal, and Biological Scales

- Scales are not often explicitly considered in problem formulation, even though risk assessments may range from local to global applications, from immediate to long-term effects, and across a number of levels of biological organization.

- Scales must be appropriate to see 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, the specific ecological receptors, and the recovery time of systems.

- Multi-generational analyses or other retrospective ground-truthing analyses are rarely conducted for prospective risk estimates, but should be considered.

- Tools such as geographic information systems, continuous monitors, and models, as well as species life history information, may be used to identify and incorporate appropriate spatial and temporal scales in ecological risk assessments.

- Indirect ecological effects are often revealed at levels of biological organization above populations, and there is a need for techniques to assess risks at high levels of biological organization (i.e., community or ecosystem scales).

- Guidance is needed on the use of models for population level effects assessments, particularly for terrestrial population assessment.

- It would be useful to develop standard techniques for assessing risks at specific levels of biological organization (e.g., techniques based on common definitions of habitat types and communities).

Uncertainty in Ecological Risk Assessment

- There was general agreement on the need for explicit consideration of uncertainty and probability during problem formulation. This could be accomplished by explicitly identifying uncertainties, the consequences of the uncertainties, and additional information needed to reduce the uncertainties.

- Probabilistic ecological risk assessment can provide a useful approach for understanding uncertainties and implications regarding the degree of protectiveness of various management options. However, these assessments can be difficult to explain and communicate to non-scientific risk managers and the general public. Uncertainties must be clearly identified so that risk managers can evaluate the need for conservative or risk tolerant decisions.

- Decision making in the face of uncertainty is reduced to three options that should be explored during problem formulation: (1) conduct more study to reduce uncertainty; (2) make a decision acknowledging the uncertainties, and move on; or (3) make a decision with monitoring and triggers for further action if needed.

- Adaptive management was identified as an option for dealing with uncertainties. Adaptive management would allow a decision to be implemented and would require monitoring that could trigger additional work if appropriate risk reduction is not achieved.

- 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 hypothesis statements are not often linked to explicitly stated process goals, leaving risk managers without the information needed to make decisions. Others thought that well-defined statistically testable hypotheses with defined Type I and II error rates were necessary.

- Innovative methods such as Bayesian analysis and causal argumentation could be used 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.

- Reducing uncertainty for future risk assessments could be aided by a better understanding of past risk assessments. It was suggested that EPA develop a national compendium, inventory, and/or database of past ecological risk assessments, and/or case examples to characterize the strengths and weaknesses of various risk assessment approaches. Uncertainty could be further reduced by developing expanded data on phylogenetic responses to stressors (comparative toxicology).

- Post risk assessment ground-truthing and validation should be part of problem formulation for product health and safety decisions, as well as for contaminated site and natural resource management. A better interface between risk assessment and monitoring programs should be developed so that monitoring data could be used to improve risk assessments. Specific monitoring projects could be designed to provide data that could reduce uncertainty in risk assessments.

- EPA was also encouraged to initiate an audit program to evaluate the effects of risk management decisions on ecological receptors and to translate risk reduction into beneficial ecological effects that the public can understand.

The workshop presented an integrating vision of ecological risk assessment that connects its early roots in comparative toxicology with recent advances in quantitative and landscape ecology. In this regard, several potential areas for advancing the risk assessment process emerged from the workshop. 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, or ecosystem scales). More systematic, post-assessment monitoring would enhance the 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 framework for ecological risk assessment should be viewed in an adaptive management context whereby, as new understanding is attained, it is incorporated into the analysis process.

Together, these changes would accelerate the evolving practice of ecological risk assessment. They would also enable more effective use of the ecological risk assessment approach 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 will allow consideration of validity of data and its scale of reference, connection to major management problems, and involvement of stakeholders. There are clearly big challenges ahead in applying and using the ecological risk assessment approach, yet the discussion at the workshop suggested helpful ways to address current limitations.

2.0 WORKSHOP BACKGROUND AND OBJECTIVES

The U. S. Environmental Protection Agency (EPA or the Agency) *Ecological Risk Assessment Framework and Guidelines* have undergone extensive development and review (U.S. Environmental Protection Agency, 1991; 1992a,b,c; 1993a,b; 1994a,b; 1996a,b, 2004b). The *Framework and Guidelines* were specifically designed to establish a flexible process to promote greater consistency across a wide range of EPA research and regulatory applications. They were not intended to replace programmatic and regional regulatory risk assessment practices, but to foster greater commonality and understanding in a rapidly emerging field. Yet flexibility is not without problems, particularly for regulatory applications where uniformity and standardization are often the norm. Recently, the Agency compiled risk assessment principles and practices (U.S. Environmental Protection Agency, 2004a) with a view toward opening dialogue with the scientific community to enhance the state of the practice. Such dialogue formed the basis of a debate and commentary section in the inaugural issue of *Integrated Environmental Assessment and Management* (Tannenbaum, 2005; Dearfield et al., 2005, DeMott et al., 2005; Bridgen 2005; Stahl et al., 2005).

The EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) is advising the Agency on how to advance the science and application of ecological risk assessment in environmental decision making. As part of this advisory activity, the SAB EPEC convened a public workshop on ecological risk assessment. The primary objective of the workshop was to initiate a broad dialogue on the current state-of-the-practice of ecological risk assessment as applied in environmental risk management and decision making. This document summarizes the key workshop discussion points, which were used by EPEC as part of its further deliberations in preparing an advisory report to EPA.

3.0 WORKSHOP OVERVIEW AND SUMMARY

3.1 Introductory Presentations

The workshop (*Agenda in Appendix A*) was designed to stimulate discussion of the state of the practice of ecological risk assessment in environmental risk management and decision making. The introductory presentations offered broad overviews of:

- *Ecological Risk Management and Decision Making at EPA* – Ms. Denise Keehner, Director, Standards and Health Protection Division, Office of Science and Technology, EPA Office of Water (*Presentation in Appendix B*);

- *Ecological Risk Assessment – Overview of Development and Application of the Science* – Dr. Glenn Suter, Science Advisor, National Center for Environmental Assessment, EPA Office of Research and Development (*Presentation in Appendix C)*;

- *EPA's Ecological Research Strategy and Multi-Year Plan* – Dr. Michael Slimak, Associate Director for Ecology, National Center for Environmental Assessment, EPA Office of Research and Development *(Presentation in Appendix D)*;

- *Strengths of the Ecological Risk Assessment Process for Use in Decision Making* – Dr. Lawrence Barnthouse, President and Principal Scientist, LWB Environmental Services *(Presentation in Appendix E)*; and

- *Limitations of the Ecological Risk Assessment Process for Use in Decision Making* – Dr. Lawrence Kapustka, Senior Ecotoxicologist, Golder Associates, Ltd. *(Presentation in Appendix F).*

The introductory presentations identified important issues regarding ecological risk assessment in environmental risk management and decision making. Selected presentation highlights are summarized below.

- EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992a; 1998) have provided a structured yet flexible approach to risk assessment for nearly a decade.

- Numerous EPA program-specific and problem-specific ecological risk assessment documents have been developed and are being applied across the Agency.

- The *Ecological Risk Assessment Framework and Guidelines* are widely imitated outside of the U.S.

- EPA's *Ecological Risk Assessment Framework and Guidelines* has helped risk managers and assessors understand the importance of problem formulation for evaluating a range of chemical, physical and biological stressors in decision making.

- Better methods are needed to quantify and communicate the risks and benefits of ecological protection and mitigation to ecological risk managers and the public.

- Mechanisms to improve the recognition of ecological concerns in risk management decisions are needed across the Agency (e.g., heightening managers' awareness of the importance of such questions as: what will happen to a local stream community if there are no sensitive fish, or if fish are reduced in size and number, and what problems are associated with reduced diversity?)

- Ecological research is necessary for improving ecological risk assessment in a number of areas:

  – Status and trends of ecological condition at regional and national scales;

  – Causes of degraded and undesirable condition;

  – Management practices that protect and restore ecological resources;

  – Ecological services important to resource managers; and

  - Appropriate spatial and temporal scales for restoring ecological services.

- Ecological risk assessment issues that require additional consideration and development include:

  - Probability, uncertainty and variability;

  - Levels of biological organization;

  - Ecological epidemiology;

  - Weight-of-evidence approaches; and

  - Cost-benefit analyses.

- Ecological risk assessment strengths include:

  - Its value as a systematic approach to organize scientific information in support of environmental decision making;

  - Its value as a source of analytical tools applicable to a wide array of environmental problems; and

  - Its value as a stimulus for the development of better tools to improve future environmental decisions.

- Difficulties that affect the utility of ecological risk assessment in decision making include:

  - Differential societal values for the protection of ecological resources;

  - Identifying emergent properties in managing populations, communities, and ecological functions;

  - The stochastic nature of ecological systems and concomitant uncertainty associated with measurement and prediction;

  - Using assessment endpoints that reflect realistic spatial, temporal and biological scales;

  - Obtaining sufficient information to be able to define ecological baselines in context of the issue;

  - Addressing the effects of complex and multiple stressors; and

- Regulatory practices that promote prescriptive measures, stifle innovation, and justify minimalist approaches.

3.2 EPA Case Examples

Following the introductory presentations, EPA officials who work at the interface of ecological risk assessment and environmental decision making provided case examples in three environmental risk management and decision-making contexts.

- *Ecological Risk Assessment for Regulation Under the Federal Insecticide, Fungicide, and Rodenticide Act* – Dr. Steven Bradbury, Director, Environmental Fate and Effects Division, EPA Office of Pesticide Programs (*Presentation in Appendix G*);

- *Application of Ecological Risk Assessment in Management of Contaminated Sites – Case Example, Ecological Risk Assessment of the Clark Fork River Superfund Site* – Dr. John Wardell, Director, Montana Office, U.S. EPA Region 8 (*Presentation in Appendix H*); and

- *Application of Ecological Risk Assessment in Natural Resources Protection – Assessing the Effects of Selenium on Aquatic Life* – Dr. Edward Ohanian, Director, Health and Ecological Criteria Division, Office of Science and Technology, EPA Office of Water (*Presentation in Appendix I*).

The case examples did not cover the full range of ecological risk assessment research and regulatory applications facing EPA. Rather, they offered a window into pragmatic issues associated with applying science in regulatory decisions. Selected highlights follow.

- Ecological risk assessments under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) are conducted by the Office of Pesticide Programs (OPP) to evaluate new pesticides and reevaluate existing pesticides on a regular, statutory schedule.

  - FIFRA requires a determination that a pesticide will not "cause unreasonable adverse effects" taking into account the economic benefits of pesticide use on the target commodity.

  - The primary regulatory decision is the development of pesticide labels that define use sites (i.e., crops), maximum use rates, minimum application rates, allowable application methods, etc.

  - OPP uses a tiered, iterative approach to ecological risk assessment that ranges from preliminary deterministic screening assessments using generic assumptions, to highly site-specific probabilistic assessments at the watershed and ecosystem scales.

  - Several ecological risk assessment examples were presented including:

    - Assessment of vulnerable aquatic sites and effects of copper and metolachlor on national, regional, and action area scales; and

    - Use of geographic information system (GIS) data and spatial modeling to identify vulnerable watersheds where monitoring was required as a condition of pesticide re-registration.

- Ecological risk assessments under the Resource Conservation Recovery Act (RCRA) and Superfund Amendments and Reauthorization Act (SARA) are conducted in the EPA Office of Solid Waste and Emergency Response (OSWER) to identify risks and remediation options for contaminated sites.

  – The case example presented risks and remediation options for mine tailing wastes in the flood plain of the Clark Fork River (Montana) Superfund Site.

  – A conceptual model developed for the Clark Fork Site was used in the problem formulation phase of the risk assessment. This provided information on the primary contaminant source, contaminated media, and food chain and ecological receptors (including a range of aquatic and terrestrial plant, invertebrate, vertebrate, and community endpoints).

  – Risk characterization included a weight-of-the-evidence analysis of predictive, direct testing, and population studies.

  – Fish, riparian vegetation, and wildlife were identified as receptors that were at risk from exposure to mine waste from overland flow during storm events, mine tailings, and contaminated soils.

  – Eight alternative management options were identified for remediation.

  – The final risk management options were selected to remove acute and chronic releases of toxic materials to aquatic and terrestrial life.

- Ecological risk assessments under the Clean Water Act (CWA) are conducted by the Office of Water (OW) to develop water quality criteria for the protection of aquatic life. Water quality criteria represent science-based recommendations (i.e., guidance). Criteria are linked with a designated use by States and Tribes to establish water quality standards which are legally enforceable.

  – Typically, criteria are derived from toxicity data for a range of taxa that are used to construct a species sensitivity curve, and a water concentration that protects 95% of the taxa.

  – The typical criteria derivation procedures were inappropriate for selenium because:

    - selenium exposure occurs through diet, not the water column;

    - selenium bioaccumulates but does not biomagnify; and

  ▪ water concentrations do not adequately predict toxicity of bioaccumulative chemicals.

– After considering selenium criteria options expressed as water, sediment or tissue concentrations, EPA derived a draft criterion as a fish tissue concentration.

– The tissue criterion provided a valid scientific approach for selenium, but also required the development of new implementation guidance to assist risk managers in states and tribes who actually establish enforceable water quality standards. In applying the tissue criterion:

  ▪ tissue criteria should be translated into media concentrations; and

  ▪ field derived estimates of bioaccumulation or food web models can be used to derive national or site–specific values.

– EPA is in the process of revising its general methodology for deriving aquatic life criteria to include tissue criteria for bioaccumulative pollutants.

3.3 Workshop Questions

Following the introductory and case example presentations, the workshop speakers, panelists (*Biosketches in Appendix J*), and participants (*Registered Workshop Participants in Appendix K)* met in three breakout groups corresponding to the product health and safety, management of contaminated sites, and natural resource protection case examples. Each of the breakout groups discussed four cross-cutting ecological risk assessment issues:

1. Effects of spatial and temporal scale;

2. Assessing risks at different biological scales;

3. Problem formulation and adequacy of testable hypotheses; and

4. Decision making in the presence of uncertainty.

The breakout groups were also provided with six suggested questions to initiate discussion of these cross-cutting issues.

1. How does the issue affect the quality of analysis?

2. How does the issue affect the utility of the output?

3. What opportunities exist to reduce the effect of this issue on ecological risk assessment performance?

4. Do you have recommendations for data collection, research, and demonstrations that could mitigate the effect of this issue?

5. How do the cross-cutting issues interact?

6. Can you identify other cross-cutting issues?

The workshop cross-cutting issues and suggested discussion questions were introduced by a panel of invited experts, discussed by all workshop participants, and summarized in breakout group reports at the workshop final plenary session *(complete breakout group summaries for product health and safety, management of contaminated sites, and natural resource protection are found in Appendices L, M, and N, respectively)*.

3.4 Breakout Group Panel Discussion Highlights

Although the individual breakout group panel discussions specifically focused on product health and safety (*Appendix L)*, management of contaminated sites (*Appendix M*), and natural resource protection (*Appendix N)*, several general issues were identified.

- Most ecological risk assessments conducted or reviewed by EPA are for single chemicals and are designed to inform risk management decisions by individual program offices.

- Ecological risk assessments are often prospective risk estimates based on laboratory toxicity studies.

- Problem formulation is often defined by regulations and regulatory guidelines rather than by deliberate and iterative planning and dialogue between risk assessors and risk managers.

- The ecological relevance of toxicity-based risk assessments are often questioned by field ecologists interested in:

  – Communities or mixed assemblages of plants and animals;

  – Cumulative risk from multiple stressors;

  – Longer temporal scales;

  – Large spatial scales; and

  – Multiple levels of biological organization.

- Scientific consensus has not emerged on how to use weight-of-the-evidence approaches for integrating information and data for ecological risk assessment.

- Streamlining analytical and decision-making processes is necessary to provide timely control of the greatest ecological risks.

- Regardless of the specific decision-making context, there is a need for databases that link ecological risk estimates, risk management decision, and monitoring or ground-truthing information and data to document the environmental efficacy of risk assessment and management actions.

- Better tools and guidance are needed for ecological risk assessment planning and problem formulation between risk assessors and risk managers. Such tools and guidance might focus on:

  – Scientific needs and resolving power for risk management decisions;

  – Uncertainty in analyses and decision making;

  – Landscape effects; and

  – Biological scale effects.

4.0 KEY WORKSHOP DISCUSSION POINTS

The workshop findings represent the collective work of more than 120 ecological risk assessors from academia, government, industry, environmental organizations, trade associations, and consulting organizations. General and cross-cutting issues that emerged in the breakout groups are presented first (Section 4.1), followed by summaries of key discussion points for product health and safety (Section 4.2), management of contaminated sites (Section 4.3), and natural resource protection (Section 4.4).

4.1 General and Cross-Cutting Key Discussion Points

General and cross cutting issues emerged in five general categories: 1) EPA's *Ecological Risk Assessment Framework and Guidelines*; 2) risk assessor and risk manager dialogue in planning and problem formulation; 3) linking natural and social sciences in environmental decision making; 4) spatial, temporal and biological scales; and 5) uncertainty in ecological risk assessment.

EPA's Ecological Risk Assessment Framework and Guidelines

- EPA's *Ecological Risk Assessment Framework and Guidelines* (U.S. Environmental Protection Agency, 1992a; 1998) are robust and useful for environmental decision making.

- The *Framework and Guidelines* were designed to establish a flexible process to promote consistency between EPA programs and Regions and have positively influenced the conduct of risk assessments.

- They have stood the test of time, as evidenced by a growing scientific literature, and incorporation into various governmental (international, federal, state, and tribal) voluntary and regulatory programs.

- Most EPA offices have, or are in the process of, updating program specific ecological risk assessment guidance to reflect the *Framework and Guidelines* principles.

- The *Framework and Guidelines* have been applied across a broad range of ecological attributes and chemical, physical, and biological stressors.

- However, the sheer range of applications has made it difficult to develop recognizable Agency wide policy or guidance that defines what ecological attributes the Agency is striving to protect.

Risk Assessor and Risk Manager Dialogue in Planning and Problem Formulation

- Despite the prominence of a collaborative and iterative planning and problem formulation phase presented in EPA's *Framework and Guidelines*, risk assessor and risk manager interactions are often limited.

- Focused risk assessment questions supporting risk management options are needed. How they might be formulated and scientifically tested requires exploration.

- Specific, rather than generic, risk questions or hypotheses are needed during problem formulation because generalized questions may be difficult to interpret in the context of specific risk management decisions.

- Explicit connections between risk measures, data quality needs, acceptable levels of uncertainty, data collection, and risk management decisions are needed during problem formulation.

- For large complex risk assessments, rapid and independent review of the approach 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.

- For smaller risk assessments, guidance and checklists are needed to assist risk assessors and risk managers in planning and problem formulation in order to focus on specific risk questions and direct consideration of management alternatives.

- Case studies that evaluate how ecological data are used in decisions are needed to develop standards of practice for determining ecological condition, identifying appropriate spatial and temporal scales and levels of biological organization, and assessing cumulative risk.

Linking Natural and Social Science in Environmental Decision Making

- The *Framework and Guidelines* focus on the application of ecological risk science within a socio-economic, legal and political decision-making arena. However, there is little elaboration of the how ecological risk estimates might be considered or weighed in these broader decision-making contexts.

- Environmental decision making has become a multi-faceted process and it increasingly requires consideration of human health risk, economics, and other social science assessments.

- Benefit-cost and valuation methods are needed 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. Some type of net benefit analysis would be beneficial, but it should not be used to avoid risk assessment.

- The need for economic valuation of ecosystems and services is clear. The SAB Committee on Valuing the Protection of Ecological Systems and Services (CVPESS)[1] is addressing this need in its work.

- Decision sciences are increasingly important in environmental decision making. The interface between social and environmental sciences is relatively new and needs more development.

- There is no consensus approach for interpreting lines-of-evidence, or weight-of-the-evidence in complex ecological risk assessments, or in evaluating competing technical assessments in environmental decision making.

- Adaptive management was identified as an option for dealing with uncertainties in risk assessment, risk management, and decision making.

    – Adaptive management requires an iterative ecological risk assessment process developed in problem formulation and applied when long-term problems must be addressed.

    – Long-term monitoring with clear performance triggers would be included to account for uncertainty in the management decision.

    – Adaptive management would address the concerns of the environmental and conservation community that the ecological risk assessment process is too lengthy

[1] CVPESS http://www.epa.gov/sab/panels/vpesspanel.html

and encumbered with unnecessary investigations and litigation that do little to protect ecological resources.

- Product life cycle analysis (LCA), while not typically used for ecological risk assessments, was viewed as potentially providing useful information to address future-oriented investigative questions and emerging areas (e.g., nanotechnology). Additional guidance on application of LCA would be helpful.

Spatial, Temporal and Biological Scales

- Scales are not often explicitly considered in problem formulation, even though risk assessments may range from local to global applications, from immediate to long-term effects, and across a number of levels of biological organization.

- Scales should be appropriate to see emerging patterns across space, time, and levels of biological organization.

- The use of scales that are broad enough to see emergent patterns over landscapes, time, and systems will provide insight into cumulative effects.

- The appropriate scale of an ecological risk assessment depends upon such factors as the stressors and media being evaluated, episodic events considered, the specific ecological receptors, and the recovery time of systems.

- Multi-generational analyses or other retrospective ground-truthing analyses are rarely conducted for prospective risk estimates, but should be considered.

- Tools such as geographic information systems, continuous monitors, and models, as well as species life history information, may be used to identify and incorporate appropriate spatial and temporal scales in ecological risk assessments.

- Indirect ecological effects are often revealed at levels of biological organization above populations, and there is a need for techniques for assessing risks at high levels of biological organizations (i.e., community or ecosystem scales).

- The EPA Science Advisory Board's *Framework for Assessing and Reporting Ecological Condition* (U.S. EPA Science Advisory Board, 2002) should be used as a reference checklist to ensure that appropriate levels of organization are considered in assessments.

Uncertainty in Ecological Risk Assessment

- There was general consensus on the need for explicit consideration of uncertainty and probability during problem formulation. The process of problem formulation should include explicit identification of uncertainties, the consequences of the uncertainties, and additional information needed to reduce the uncertainties. Uncertainties should be categorized, and those that profoundly affect results and outcomes identified and openly acknowledged in the assessment. If data are insufficient to conduct analyses at an appropriate scale, this constraint should be acknowledged and addressed in the uncertainty analysis.

  - Failure to identify and prioritize uncertainties, as well as any additional information needed to reduce the uncertainties, can affect the quality of a decision. Uncertainties should be clearly identified so that risk managers can evaluate the need for conservative or risk tolerant decisions.

  - Decision making in the presence of uncertainty is sometimes constrained by statutory or regulatory practices leading to measures that may be over or under-protective.

  - Statutes vary with respect to requirements for consideration of ecological risks and benefits, but ecological risk can become a "nonfactor" when uncertainty associated with ecological risk is high.

- Probabilistic ecological risk assessment can provide a useful approach for understanding uncertainties and how they relate to the protectiveness of various management options.

- Decision making in the face of uncertainty is reduced to three options that should be explored during problem formulation:

  - Conduct more study to reduce uncertainty;

  - Make a decision acknowledging the uncertainties, and move on; or

  - Implement adaptive management decisions and require monitoring that would trigger additional work if appropriate risk reduction is not achieved.

- Additional study data can reduce uncertainty, but there are often tradeoffs between study costs and timeliness of management decisions that need to be made.

- Adaptive management was identified as an option for dealing with uncertainties. Adaptive management would allow a decision to be implemented but would require monitoring that could trigger additional work if appropriate risk reduction is not achieved.

- There was considerable discussion, but no consensus, on the use of rigorous "hypothesis-testing" versus "risk questions" in problem formulation.

  - Some workshop participants noted that often hypothesis statements are not linked to explicitly stated process goals and this leaves risk managers without the information needed to make decisions

  - Some thought that well-defined statistically testable hypotheses with defined Type I and II error rates were necessary.

- Others favored risk questions because "testable hypotheses" are easy to manipulate, may not provide information necessary for estimating risk, and hence are inappropriate for problem formulation.

- It was noted, however, that risk questions are often vague and removing testable hypotheses from risk assessments might sharpen such criticism.

- In some applications, traditional null hypothesis testing may be appropriate, but various alternatives were discussed.

    - Innovative methods such as Bayesian analysis and causal argumentation could be used 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 risk assessment (Regan et al., 2003) is an important approach but it can be difficult to explain and communicate to non-scientific risk managers and the general public.

    - Communication should begin during problem formulation by providing a summary of major uncertainties and by discussing how probabilistic approaches will be applied to assist in understanding different management options.

    - Sensitivity analyses can be conducted to identify sources of uncertainty and determine where additional information may be useful.

    - Risk assessment assumptions, parameters, and the factors driving the uncertainty should be clearly explained and discussed with risk managers.

- While considerable work has been done on how to conduct quantitative uncertainty analyses, good examples are not available to demonstrate how uncertainty analysis was or could be used in making risk management decisions.

- Reducing uncertainty for future risk assessments could be aided by a better understanding of past risk assessments.

    - A national compendium, inventory, and/or database of past ecological risk assessments would provide very useful information to improving certainty of future risk assessments.

    - Such information could be systematically collected, organized, and cataloged.

    - Case examples could be developed to characterize the strengths and weaknesses of various risk assessment approaches.

- EPA is also encouraged to initiate an audit program to evaluate the effects of risk management decisions on ecological receptors and to translate risk reduction into beneficial ecological effects that the public can understand. This is discussed in a recent SAB report (U.S. EPA Science Advisory Board, 2006).

- Post risk assessment ground-truthing and validation should be part of problem formulation for product health and safety decisions, as well as for contaminated site and natural resource management. A better interface between risk assessment and monitoring programs should be developed so that monitoring data could be used to improve risk assessments. Specific monitoring projects could be designed to provide data that would reduce uncertainty in risk assessments

4.2 Product Health and Safety Key Discussion Points

- Guidance is needed on the use of models for population level effects assessments, particularly for terrestrial population assessment.

- Tools are currently available for rapid, accurate screening-level risk assessments.

  - European Union databases can provide ecotoxicology information.

  - EPA's Estimation Programs Interface (EPI) Suite tools provide physical and biological parameters to enable a determination of whether a chemical is biodegradable, toxic, or bioaccumulative.

- Problem formulation for chemical and product risk assessments does not focus on why particular risk assessments are being conducted or what ecological resource should be protected.

- Often contaminants are released into stressed environments. Therefore, tools for cumulative risk assessment need to be developed.

- Research is needed to determine how biomarker and mechanistic data might best be used in exposure and risk assessments for product health and safety decision making.

- Product life cycle analysis (LCA) is not typically used for ecological risk assessments. Guidance for the use of LCA in emerging areas (e.g., nanotechnology) is needed.

- Scale is often not considered in problem formulation or in ecological risk assessments for product health and safety decisions.

- Multi-generational analyses or other retrospective ground-truthing analyses are rarely conducted for prospective risk estimates.

- Levels of concern and risk quotients often drive problem formulation in product health and safety risk assessments, but they may not provide realistic protection goals. Measurement endpoints should be more closely tied to appropriate assessment endpoints.

- In some cases, problem formulation is generic, and therefore not all relevant routes of exposure (e.g., dermal exposure) or receptors are considered. Relevant release pathways, fate and transport, and sensitivity should be considered to optimize appropriate assessment and measurement endpoints. Post risk assessment ground-truthing and validation should be part of problem formulation for product health and safety decisions and addressed in EPA guidance documents.

  - Frequently, problem formulation does not adequately address spatial, temporal or biological scales.

  - Levels of concern should be re-evaluated and validated with monitoring studies.

4.3 Contaminated Site Management Key Discussion Points

- Spatial and temporal scales and representative data collection issues should be considered during problem formulation for ecological risk assessments at contaminated sites.

  - Spatial scale is important in evaluating exposure routes and will influence sampling plans.

  - Temporal scale is important for determining remediation time frames.

  - The appropriate temporal scale for a contaminated site risk assessment depends on the specific chemical contaminants, media, ecological receptors, episodic events, potential for contamination reoccurrence, and recovery time of the system.

- Recent advances in technology and tools for the analysis and interpretation of data can enhance ecological risk assessments. Such tools include: geographic information system mapping technologies; remote sensing technologies; spatial statistics; population and exposure models; and access to large databases.

- Central data exchange technology is improving, and a national data repository would benefit ecological risk assessment by providing information on the strengths and weaknesses of various risk assessment and management approaches (e.g., EPA Superfund program reviews provide useful abstracts of risk assessment study results every five years).

- Basic life history information (e.g., home ranges, organism distribution) is needed to enhance ecological and toxicity information, and to improve exposure and risk assessments for species at risk near contaminated sites.

- Long-term ecological research is needed for some large-scale contaminated sites.

- Post-remediation monitoring is needed to understand how risk assessments might be enhanced.

- Criteria are needed for assessing successful remediation outcomes at contaminated sites.

- Such sites provide opportunities for long-term ecological research and evaluation of the efficacy of adaptive management approaches.

- Benefit-cost and valuation methods are needed to communicate risk management alternatives at multiple scales to different stakeholder groups.

- EPA could develop a checklist to be used for confirming that the necessary ecological risk assessment steps have been completed and explained.

- A rigorous framework could be developed for considering remediation options at contaminated sites early in the process. This would enhance the relevancy and quality of risk assessments.

- EPA should consider early peer review of problem formulation and study design for complex contaminated sites. Such reviews could be conducted by external technical experts, including appropriate social scientists who could help resolve stakeholder issues.

- Long-term monitoring could provide data to reduce uncertainty, improve decisions about remedy selection, and improve future risk assessments.

- Contaminated sites remediated over the past twenty years should be evaluated to develop data on remedy efficacy to inform risk assessment uncertainties and remediation decisions at new sites.

- Probabilistic risk assessments do not always summarize and communicate uncertainty to CERCLA site managers.

- Net benefit analysis may be a useful cross-cutting approach for linking uncertainty analysis and risk management decisions. Some type of net benefit analysis would be beneficial but it should not be used to avoid risk assessment.

4.4 Natural Resources Protection Key Discussion Points

- Risk assessments for natural resource protection are more closely tied to an ecological attributes “values” perspective than the stressor perspective that is typical of chemical specific risk assessments.

- The discrete ecological resources to be protected and options for their protection should be explicitly identified.

- Protecting natural resources requires consideration of "natural" and "global" process change (e.g., global climate change) and how such change influences anthropogenic changes in the system under study.

- Early peer review of the risk assessment study designs is needed.

  – Early peer review should occur between the 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 risk assessments.

  – Early peer review will help assure that the assessment study design and implementation are appropriate for the risk management goals.

- In risk assessments for natural resource protection, assessors may look at broad scales, but specific questions addressed by a study can be local or global.

  – The scale of concern should be identified during the problem formulation stage of the risk assessment.

  – Decisions can be made at very small scales but should be considered in the context of broader scales.

  – Chemicals are not the only stressors to be evaluated in ecological risk assessments for natural resource protection.

- For natural resource protection, spatial scales should be large enough to identify emerging patterns across a landscape such as the declining condition of small streams and the effects of myriad small point sources (e.g., leaking underground storage tanks).

- Spatial and temporal scale analysis may provide information for later integration of a risk assessment into a meta-analysis or larger scale analysis. Such analyses may assist in the development of a larger body of knowledge for assessment projects.

- Although tools are available for spatial and temporal analyses in risk assessment, it is not clear whether there are enough risk assessment practitioners with specialized expertise in the use of these tools to meet the current need.

  – Tools that can be used for spatial and temporal analysis include geographic information systems, continuous monitors, models, and species life history information.

  – If additional spatial resolution is needed to describe species abundance and distribution, this should be considered in the uncertainty analysis.

- Some workshop participants argued that an interagency effort be undertaken to develop an ecological version of the Integrated Risk Information System (IRIS) that would provide information needed for risk assessments.

- Indirect effects can be important in risk assessments and are often revealed at specific levels of biological organization. Risk assessors should consider effects at the individual, species, community, habitat, and landscape scales (e.g., chemical stress predisposing trees to disease).

- It would be useful to develop standard techniques for assessing risks at specific levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by the sediment quality triad of benthic community measures, sediment toxicity tests, and sediment chemistry.

- 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.

- Ecological risk assessors should rethink testable hypotheses and how to move away from traditional hypothesis testing with null models.

  - Such hypotheses can be easy to manipulate and difficult to formulate.

  - In risk assessment, hypothesis testing can result in null models that are developed without considering how to balance Type I and Type II errors.

  - Innovative methods such as Bayesian analysis and causal argumentation are available for use in risk assessments.

  - Hypotheses should focus on causal relationships and weights of evidence.

- A better interface between risk assessment and monitoring programs should be developed so that monitoring data could be used to improve risk assessments.

  - Specific monitoring projects could be designed to provide data to 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.

  - Risk assessors working with existing data can influence how new monitoring data are collected.

- Better integration of work in different disciplines (e.g., biology, chemistry, toxicology, ecology) is needed to prevent fragmentary risk analyses.

   - EPA's separate development of biological and chemical water quality criteria is an example of fragmentary risk analysis.

   - Expert systems could be developed to enable the integration of specific chemical and biological endpoints and identify classes of chemicals to be assessed.

- Elements of uncertainty should be identified and incorporated into problem formulation and built into the design of a risk assessment.

   - Uncertainties in an ecological risk assessment should be categorized, and those that profoundly affect results and outcomes should be identified and acknowledged in the final assessment (transparency).

   - A rich literature exists on disaggregating analytical variability, stochastic variability, and model variability. It would be useful to consider the available tools for use in problem formulation.

- 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.

5.0 BREAKOUT GROUP SUMMARY REPORTS

Summaries of the panel discussions and reports of the product health and safety, contaminated site management, and natural resource protection breakout groups are included in Appendices L, M, and N, respectively.

6.0 CONCLUSION

This workshop presented an integrating vision of ecological risk assessment that connects its early roots in comparative toxicology with recent advances in quantitative and landscape ecology. In this regard, several potential opportunities for advancing the risk assessment process emerged from the workshop. 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, an landscape scales). More systematic, post-assessment monitoring would enhance the 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 changes would accelerate the evolving practice of ecological risk assessment. They would also enable more effective use of the ecological risk assessment approach 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 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 ecological risk assessment approach, yet the discussion at the workshop suggested helpful ways to address current limitations. The Ecological Processes and Effects Committee of the EPA Science Advisory Board will use the information gathered at the workshop to develop an advisory report to the Agency.

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APPENDIX A - AGENDA

U.S. Environmental Protection Agency
Science Advisory Board
Ecological Processes and Effects Committee Workshop (Public)

Ecological Risk Assessment – An Evaluation of the State-of-the-Practice
February 7– 8, 2006

The Westin Embassy Row Hotel
2100 Massachusetts Avenue, N.W.
Washington, D.C.

Agenda

Day 1 – Tuesday, February 7

Plenary Session

8:30 a.m.	**Welcoming Remarks and Workshop Introduction** -- *Dr. Virginia Dale, Oak Ridge National Research Laboratory and Chair, EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC)*
8:40 a.m.	**Ecological Risk Management and Decision Making at EPA** -- *Ms. Denise Keehner, Director, Standards and Health Protection Division, EPA Office of Water*
9:10 a.m.	**Ecological Risk Assessment – Overview of Development and Application of the Science** -- *Dr. Glenn Suter, National Center for Environmental Assessment, EPA Office of Research and Development*
9:40 a.m.	**EPA's Ecological Research Strategy and Multi-Year Plan –** *Dr. Michael Slimak -- National Center for Environmental Assessment, EPA Office of Research and Development*
10:10 a.m.	BREAK
10:30 a.m.	**Strengths of Ecological Risk Assessment Process for Use in Decision Making --** *Dr. Lawrence Barnthouse, LWB Environmental Services*
11:00 a.m.	**Limitations of Ecological Risk Assessment Process for Use in Decision Making** -- *Dr. Lawrence Kapustka, Golder Associates, Ltd.*

11: 30 a.m. **Application of Ecological Risk Assessment in Product Health and Safety Decision Making – Ecological Risk Assessment for Regulation Under the Federal Insecticide, Fungicide, and Rodenticide Act --** *Dr. Steven Bradbury, Director, Environmental Fate and Effects Division, EPA Office of Pesticide Programs*

12:15 p.m. LUNCH

1:30 p.m. **Application of Ecological Risk Assessment in Management of Contaminated Sites – Case Example, Ecological Risk Assessment of the Clark Fork River Superfund Site --***Dr. John Wardell, Director, Montana Office, U.S. EPA Region 8*

2:15 p.m. **Application of Ecological Risk Assessment in Natural Resources Protection – Assessing the Effects of Selenium on Aquatic Life --** *Dr. Edward Ohanian, Director, Health and Ecological Criteria Division, Office of Science and Technology, EPA Office of Water*

3:00 p.m. **Goals and Objectives for Breakout Sessions** -- *Dr. Virginia Dale, Chair, SAB Ecological Processes and Effects Committee*

3:15 p.m. BREAK

3:30 p.m. **Overview of Breakout Session Discussion Questions –** *There will be three overview breakout groups organized by ecological risk assessment type: Group 1-Product Health and Safety Decision Making; Group 2 - Management of Contaminated Sites; and Group 3 - Natural Resource Protection. The breakout groups will begin with a panel discussion to give an overview of the following cross-cutting issues.*

1) *Effects of spatial and temporal scale;*

2) *Assessing risks at different biological scales (e.g., organism, population, and community;*

3) *Problem formulation and adequacy of testable hypotheses;*

4) *Decision making in the presence of uncertainty.*

The breakout group facilitators will also introduce suggested discussion questions for the workshop participants.

Group 1 -- Product Health and Safety Decision Making
(Will meet in the Whitehall Room)

Facilitator: *Dr. Gregory Biddinger, Exxon Mobil Biomedical Sciences*

Rapporteur: *Dr. Charles Pittinger, BB&L Sciences*

Panelists: *Dr. Peter DeFur, Environmental Stewardship*
Mr. Max Feken, Florida Department of Agriculture
Dr. David Fischer, Bayer Crop Science
Dr. Leslie Touart, U.S. EPA

Group 2 -- Management of Contaminated Sites
(Will meet in the Terrace Court Room)

Facilitator: *Dr. Michael Newman, Virginia Institute of Marine Science, College of William and Mary*

Rapporteur: *Mr. Timothy Thompson, Science Engineering and the Environment*

Panelists: *Ms. Vickie Meredith, Wyoming Dept. of Environmental Quality*
Dr. Michael Fry, American Bird Conservancy
Dr. Mark Sprenger, U.S. EPA
Dr. Ralph Stahl, DuPont

Group 3 -- Natural Resource Protection
(Will meet in the Balcony Room)

Facilitator: *Dr. Kenneth Dickson, University of North Texas*

Rapporteur: *Dr. James Oris, Miami University*

Panelists: *Dr. Bruce Hope, Oregon Dept. of Environmental Quality*
Dr. Eugenia McNaughton, U.S. EPA
Dr. Jennifer Shaw, Syngenta
Dr. Terry Young, Environmental Defense

4:45 p.m. **Adjourn for the Day**

Day 2 – Wednesday, February 8

8:30 a.m. **Breakout Group Discussions –** *There will be six breakout groups. The breakout groups should consider how the cross-cutting issues might be better defined and incorporated into the design and performance of ecological risk assessments used in decision making. To facilitate the discussion, the following questions are suggested for each issue.*

1. How the issue affects the quality of the analysis

2. How the issue affects the utility of the output
3. What opportunities exist to reduce the effect of this issue on ecological risk assessment performance
4. Recommendations for data collection, research, and demonstrations that could mitigate the effect of this issue
5. How cross cutting issues interact
6. Identification of other important cross cutting issues

Group #1a Ecological Risk Assessment in Product Health and Safety Decision Making – Facilitator, *Dr. Gregory Biddinger, Exxon Mobil Biomedical Sciences*
(Will meet in the Churchill Room)

- Effects of Spatial and Temporal Scale
- Assessing Risks at Different Biological Scales (e.g., organism, population, community)

Group #1b Ecological Risk Assessment in Product Health and Safety Decision Making – Facilitator, *Dr. Charles Pittinger, BBL Sciences*
(Will meet in the Consulate Room)

- Problem Formulation and Adequacy of Testable Hypotheses
- Decision Making in the Presence of Uncertainty

Group #2a Ecological Risk Assessment in Management of Contaminated Sites – Facilitator, *Dr. Michael Newman, Virginia Institute of Marine Science, College of William and Mary*
(Will meet in the Ambassador Room)

- Effects of Spatial and Temporal Scale
- Assessing Risks at Different Biological Scales (e.g., organism, population, community)

Group #2b Ecological Risk Assessment in Management of Contaminated Sites – Facilitator, *Mr. Timothy Thompson, Science Engineering and the Environment*
(Will meet in the Whitehall Room)

- Problem Formulation and Adequacy of Testable Hypotheses
- Decision Making in the Presence of Uncertainty

Group #3a Ecological Risk Assessment in Natural Resources Protection – Facilitator*, Dr. Kenneth Dickson, University of North Texas*
(Will meet in the Balcony Room)

- Effects of Spatial and Temporal Scale

- Assessing Risks at Different Biological Scales (e.g., organism, population, community)

Group #3b Ecological Risk Assessment in Natural Resources Protection – Facilitator, *Dr. James Oris, Miami University*
(Will meet in the Terrace Court Room)

- Problem Formulation and Adequacy of Testable Hypotheses
- Decision Making in the Presence of Uncertainty

12:00 p.m. LUNCH

1:00 p.m. **Breakout Group Discussions (Continued)**

2:30 p.m. **Breakout Group Reports**
(Plenary Session -- Will meet in Ballroom)

4:00 p.m. **Summary and Next Steps** -- *Dr. Virginia Dale, Chair, SAB Ecological Processes and Effects Committee*

4:30 p.m. Adjourn Workshop

APPENDIX B - ECOLOGICAL RISK MANAGEMENT AND DECISION MAKING AT EPA

Ecological Risk Management and Decision Making at EPA – *Ms. Denise Keehner, Director, Standards and Health Protection Division, Office of Science and Technology, EPA Office of Water*

From her perspective as a manager in EPA's Office of Pesticide Programs and Office of Water, Ms. Keehner discussed how ecological risk assessment is used in risk management and decision making at EPA. She also discussed needed improvements in ecological risk assessment to support Agency decisions.

Ecological Risk Assessment Approaches Used by EPA

A study completed by the Agency in 1994 indicated that, although decisions in different EPA programs were driven by different statutory requirements, there were common ecological risk assessment approaches used across programs.

- Acute mortality to fish and wildlife was the most frequent and widely used ecological effect of concern in EPA program decisions, although chronic and subchronic effects were also used by some key programs.

- Most EPA programs relied on laboratory test data and results to define ecological risk levels for decision making.

- Agency programs generally focused on effects on animals rather than plants in making decisions.

- With the exception of endangered species, the Agency was not focused on the protection of individual organisms. However, EPA had not established "bright lines" defining the magnitude of ecological effects considered to be significant.

    - In its ecological risk assessments, EPA was generally not considering dynamic parameters (such as birth, death, and migration), interaction among species (such as predator/prey relationships), and interaction among animal and plant communities.

    - In 1994, most EPA programs were considering ecological risks in a fairly simplistic manner. Therefore, risk assessments did not provide risk managers information needed to make decisions in cases where economic effects on society were expected to be large.

Since 1994, there have been marked improvements in ecological risk assessment at EPA. Agency programs have been uniformly applying EPA's Guidelines for Ecological Risk Assessment. The Ecological Risk Assessment Guidelines stressed the importance of problem formulation in conducting risk assessments, and implementation of the Guidelines has resulted in early interaction and discussion among risk assessors and risk managers. This interaction has increased the relevance of risk assessment results to risk management questions. Some EPA programs have invested significant resources and effort into developing probabilistic risk assessment methods. These methods have provided information on the magnitude and extent of effects of environmental stressors (such as changes in mortality and growth rates and fecundity). As EPA has moved beyond simplistic ecological risk assessment, the results of risk assessments have been more frequently used in the Agency's risk management decisions.

Remaining Challenges

A number of challenges remain. EPA should further develop ecological risk assessment methods to answer the "real questions" of risk managers in a timely manner at a reasonable cost. Risk managers need answers to questions such as:

- What will happen to a local population of organisms if the predicted concentration of a chemical exceeds the LC50, LC10, or LC20 of a test organism?
- What are the "trip points" across frequency and magnitude of exceedence of an LC50 value for a sensitive species where the local population will not recover and will disappear?
- What will happen to a local stream community if there are no sensitive fish, or if fish are reduced in size and number? What problems are associated with reduced diversity?
- What will happen to wildlife if there are no sensitive fish in a local stream community?
- How sure can we be of effects?

Risk managers need to know enough about the biological, spatial, and temporal effects of stressors to argue persuasively in the political arena for regulatory action that may be needed. Risk managers need to know how confident scientists are in risk assessment conclusions and what ecological improvements can be expected from various risk management options.

As we look to the future, there are a number of actions that should be taken to enhance the consideration of ecological risk in EPA decisions.

- We need to continue using the Agency's Ecological Risk Assessment Guidelines and continue emphasizing the importance of early engagement of risk managers and risk assessors in the problem formulation stage of risk assessment.
- We need to continue investing in improving risk assessment methodologies that will provide better answers to the "so what" question (i.e., probability and magnitude of effects and spatial and temporal implications of effects)
- We need to ensure that resources are available to use methods that provide answers to the "so what" questions.
- We need to ensure continued investment in data collection to support new methodology enhancements.

- We need to keep records of ecologically-based risk management decisions and encourage more sharing of information across EPA on an ongoing basis. Mechanisms for such sharing of information do not exist.

- We need to invest in methods to quantify the benefits of ecological protection and mitigation of ecological risk. We are good at estimating economic effects but not as good at estimating the benefits of ecological improvements.

- We need to improve the communication of ecological risk to risk managers and the public.

In summary, risk managers need ecological risk assessments that more fully answer their most important questions, quantify what is being lost ecologically, and address what can be done to mitigate the loss. Better communication to risk managers and the public of what the science is telling us is also needed. It is hard to overestimate how much non scientists don't understand about ecological risk

Slides of Ms. Keehner's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_g.pdf

APPENDIX C - ECOLOGICAL RISK ASSESSMENT – OVERVIEW OF DEVELOPMENT AND APPLICATION OF THE SCIENCE

Ecological Risk Assessment – Overview of Development and Application of the Science – *Dr. Glenn Suter, Science Advisor, National Center for Environmental Assessment, EPA Office of Research and Development*

Dr. Suter discussed the history of ecological risk assessment. Assessments that were conducted in the late 1960's to meet requirements of the National Environmental Policy Act were largely descriptive and compliance oriented. In the 1970's and 1980's, hazard assessment and tiered testing approaches were developed by EPA to compare exposure to pesticides and toxic substances with organism responses. The Clean Water Act also provided a strong mandate to EPA for protection of ecosystems. Although implementation of the Clean Water Act was not risk oriented, EPA's Office of Water developed ambient water quality criteria, effluent toxicity testing methods, bioassessment methods, and biocriteria.

Development of Ecological Risk Assessment Framework and Guidance

In the 1980's, EPA's Synfuels Program funded development of the first ecological risk assessment methods and methods manuals. Those methods and the first framework for ecological risk assessment were developed by researchers at the Oak Ridge National Research Laboratory. Since 1990 most of the ecological risk assessment activity associated with EPA has been in support of the Superfund program. A number of ecological risk assessment methods and guidance documents have been developed by the Superfund Program. These have included: field and laboratory methods, the Risk Assessment Guidance for Superfund (RAGS), various Environmental Response Team guidance documents, and guidance on ecological risk assessment for contaminated sites.

In 1992, EPA published its Framework for Ecological Risk Assessment. This Framework established an ecological risk assessment process that included: planning and problem formulation, development of assessment endpoints, development of conceptual models, an analysis plan, and inclusion of non-chemical stressors. EPA's Framework for Ecological Risk Assessment has been adapted for use by other organizations.

EPA's *Guidelines for Ecological Risk Assessment*[1] were published in 1998. In the guidelines, EPA provided additional guidance for applying the Framework for Ecological Risk Assessment. The Agency plans to continue developing a "bookshelf" of specific ecological risk assessment guidance documents. One of these documents, guidance on generic assessment endpoints, has been published.

Future Needs

[1] U.S. EPA 1998. *Guidelines for Ecological Risk Assessment.* EPA/30/R-95/002F. U.S. Environmental Protection Agency, Washington, D.C. (http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12460)

The following issues should be considered to make continued advances in the practice of ecological risk assessment:

- Probability and Uncertainty. The first ecological risk assessment methods were probabilistic, but assessments performed by the Agency generally have not been probabilistic. However it is important to consider uncertainty and variability in risk assessment. Tiered approaches and models have been developed for conducting probabilistic ecological risk assessment of pesticides. Ecological risk assessors are ahead of their human health risk assessment colleagues in the application of joint probability distributions to assess risk.

- Levels of Biological Organization. Regulated parties and many ecologists prefer that ecological risk assessments be conducted using higher levels of organization. However, EPA's ecological risk assessments generally use organismal attributes because they are easier to evaluate with currently available data and methods, methods that address organismal attributes are scientifically and legally defensible, they are understandable by decision-makers and the public, and they are protective. When organismal attributes have been used, EPA has been incorrectly criticized for "protecting individuals."

- Ecological Epidemiology. Ecological epidemiology provides tools for assessing ecological risks. Bioassessment guidance has been developed by EPA's Office of Water, Superfund assessments often include observed effects, and pesticide reregistrations include incident reports. Bioassessment can reveal effects of multiple agents and indirect effects, but effects may not be clearly revealed and determining causality is often difficult.

- Weight-of-evidence. Weight-of-evidence approaches enable ecologists to evaluate multiple types of evidence and multiple lines of evidence within a type. Most risk assessment practitioners prefer to consider all available relevant evidence, but some consider the process of weighing evidence to be too subjective.

- Cost-benefit Analysis. Ecological risk assessment is aimed at protecting specific ecological endpoints. These include representative species and ecosystems and sensitive species and ecosystems. Benefits accounting requires estimating all of the ecological effects that are welfare effects and surrogates or representatives are not acceptable. The SAB is providing advice on monetizing benefits, but advice is also needed on how to estimate benefits before they can be monetized.

- Increasing the Influence of Ecological Concerns. In EPA's risk management decisions, human health concerns have often carried greater weight than ecological concerns. To increase the influence of ecological concerns, it will be important to provide decision-makers with an understanding that human health and welfare are dependent upon ecosystem quality.

Slides of Dr. Suter's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_h.pdf

APPENDIX D - EPA'S ECOLOGICAL RESEARCH STRATEGY AND MULTI-YEAR PLAN

EPA's Ecological Research Strategy and Multi-Year Plan– *Dr. Michael Slimak, Associate Director for Ecology, National Center for Environmental Assessment, EPA Office of Research and Development*

Dr. Slimak provided an overview of EPA's Ecological Research Strategy and Multi-Year Research Plan. He described EPA Office of Research and Development resources that are focused on ecological research and the planning process used to target areas of research for funding.

There has been a longstanding relationship between risk managers and risk assessors. The state of the practice of ecological risk assessment is good. It has evolved and is becoming more sophisticated. EPA's Framework for Ecological Risk Assessment has helped risk managers and assessors understand the importance of problem formulation and the importance of evaluating stressors like habitat loss and invasive species. There is, however, low public awareness of some actions that EPA takes to manage ecological risks, such as not approving certain proposed uses of pesticides. These Agency decisions are improving the quality of ecosystems.

Office of Research and Development Multi-Year Ecological Research Plan

EPA's Office of Research and Development (ORD) has developed a number of multi-year research plans that are linked to the Agency's strategic goals. Both core research and problem driven research is conducted by ORD, and ecological research is a large component of the overall ORD research program. The current Ecological Research Multi-Year Plan was written in 2003 and it is being revised to describe research that will be conducted in the 2006-2015 time frame. Revision of the research plan will be based on examination of the program by the Office of Management and Budget, an external program review held in March 2005, and the need to focus research on ecological outcomes.

Long-term Goals

Ecological research is being conducted in support of several long-term goals. The ecological research program with a budget of $80 million and 300 full time equivalent positions is the largest ORD research program. The long-term program goals were developed to provide assessment and management tools needed by national, state, and local decision-makers. Long-term goal #1 states that national policy makers will have the tools and technologies to develop scientifically-defensible assessments of the state of our nation's ecosystems and the effectiveness of existing national programs and policies. To support this goal, research is being conducted to answer some important questions:

- What statistically valid, scientifically defensible frameworks are needed to measure, assess, and report on the status and trends of ecosystem condition at regional and national scales?

- What sensitive and reliable ecological indicators are needed to measure changes in ecosystem condition over broad regions of the country?

- How can environmental monitoring help evaluate the effectiveness of national efforts to protect and improve the environment?

Long-term goal #2 states that states and tribes will apply improved tools and methods to protect and restore their valued ecological resources. Ecological research is being conducted to answer the following important questions associated with this goal.

- How can states and tribes best assess the condition of their ecological resources?

- What are the causes of degraded and undesirable conditions?

- How will the condition of ecological resources and the causes of degraded conditions change in the future?

- Which management practices are most successful for the protection and restoration of ecological resources?

Long-term goal #3 states that decision makers will use tools to make informed proactive management decisions that consider a range of choices and alternative outcomes, including effects on ecosystem services. Ecological research is being conducted to answer the following questions associated with this goal.

- What set of ecosystem services are most important to resource managers?

- What are the ranges of choices managers have to reduce the loss of ecosystems services?

- What are the available approaches to restoring ecosystem services?

- What are appropriate spatial and temporal scales for restoring ecosystem services?

ORD's ecological research program has resulted in numerous publications in the peer reviewed literature and has involved collaborators in a number of different universities and federal agencies. Planned new areas of ecological research include the development of forecasting tools for population, community, and ecosystem assessment, ecological forensics, research on large river basins (historically ecological research has been at a smaller scale and has overlooked large basins), ecological services research to identify benefits provided by ecosystems, and global earth observation system research to take advantage of ground and ocean–based observing systems as well as satellites.

Slides of Dr. Slimak's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_i.pdf

APPENDIX E - STRENGTHS OF THE ECOLOGICAL RISK ASSESSMENT PROCESS FOR USE IN DECISION MAKING

Strengths of the Ecological Risk Assessment Process for Use in Decision Making - *Dr. Lawrence Barnthouse, President and Principal Scientist, LWB Environmental Service*

Dr. Barnthouse discussed the strengths of ecological risk assessment for use in decision making. Methods and processes for conducting ecological risk assessments have been developed in recent time. In 1981 the term ecological risk assessment had not yet been invented and the process was non-existent. Assessments were performed independently by different organizations using different principles and methods. Little communication occurred among those organizations, and there were no opportunities to compare methods, identify common approaches, and advance the state of the science. Risk management judgments were often hidden within assessment procedures.

Unified Conceptual Approach to Ecological Risk Assessment

The pioneers of ecological risk assessment developed a unified conceptual approach to environmental assessment and facilitated the cooperation and collaboration between assessment related disciplines. They also increased the transparency of risk assessments to users (the decision makers), provided standardized tools and techniques and generally dispelled the common perception that "ecological risk assessment was impossible." Presently, ecological risk assessment is being applied to all levels of decision making. EPA's *Ecological Risk Assessment Framework and Guidelines h*ave been in place for nearly a decade. Numerous EPA program-specific and problem-specific ecological risk assessment documents have been developed and are being applied across the Agency. The *Ecological Risk Assessment Framework and Guidelines* is also being widely imitated outside of the U.S.

Case Examples Illustrate Strengths of Ecological Risk Assessment

The key to success in the practice of ecological risk assessment has been recognition of the importance of ecological risk assessment as a process, not a technique. Three case studies illustrate the application of a common ecological risk assessment framework to diverse regulatory assessments.

- A baseline ecological risk assessment of the Clinch River provided a site-specific assessment of remediation requirements at a Superfund site. In the Clinch River baseline ecological risk assessment, the fish community was the assessment endpoint. Exposure to measured chemical concentrations in water was determined. Literature-derived toxicity data, site-specific toxicity tests, and local and regional fish community composition were used to measure ecological effects, and risk characterization was based on multiple lines of evidence.

- EPA's special review of the herbicide, atrazine provided a regional/continental assessment of the need for risk reduction. In the special review of atrazine, the aquatic community was the assessment endpoint. Atrazine exposure was measured and modeled, and literature–derived toxicity data for various aquatic taxa were used to measures of effects. A probabilistic approach was used to characterize the risk or exceeding an effects threshold for 10% of aquatic taxa.

- Validation of the European Union pharmaceutical ecological risk assessment procedure provided an evaluation of the standardized hazard classification process. In this ecological risk assessment, the assessment endpoint was aquatic ecosystem function. Measured and modeled concentrations of chemical concentrations in water were used to determine exposure, and a hazard quotient approach was used for risk characterization.

These three case studies demonstrate use of a consistent approach for application of diverse types of data in ecological risk assessments to be used in decision making. Field and laboratory data were used in the Clinch River baseline ecological risk assessment, and a species sensitivity distribution approach was used in the atrazine and pharmaceutical ecological risk assessments. The case studies also demonstrate effective transfer of assessment methods between risk assessments. A triad approach was used in the Clinch River baseline ecological risk assessment, and the species sensitivity approach was used in the atrazine and pharmaceutical ecological risk assessments. In all of these case examples, a consistent format was used for reporting risks and uncertainties.

Nonregulatory risk assessments for decision making can be effectively conducted using a relative risk model. In this model, assessment endpoints may be diverse, as defined by stakeholders. Quantitative and qualitative information may be used to determine the sources of stressors affecting assessment endpoints. Quantitative and qualitative information on the effects of stressors may be used to determine effects, and risk characterization may be based on multiplication of ranked exposure and effects indices. The Cherry Point Pacific Herring ecological risk assessment exemplifies this approach. In this case assessment, endpoints were defined with stakeholder input. The abundance of the spawning run was the assessment endpoint. A conceptual model was used to clearly relate exposures to effects. Risk characterization was completed using an integrative model, and the results were linked to management objectives, in this case management of the Cherry Point Aquatic Preserve.

The strengths of ecological risk assessment exemplified in the case studies discussed are that it:

- Provides a systematic approach to organizing scientific information to support environmental decision making;

- Provides a source of analytical tools applicable to a wide array of environmental problems;

- Provides a stimulus for the development of better tools to improve future environmental decisions.

In order to effectively take advantage of these strengths, risk assessors should ensure that assessments address management needs. The distinction between management and science must be maintained. In addition, the best available relevant science should be used, the process should be transparent, and methods and results should be comprehensible to decision makers and stakeholders.

Slides of Dr. Barnthouse's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_j.pdf

APPENDIX F - LIMITATIONS OF THE ECOLOGICAL RISK ASSESSMENT PROCESS FOR USE IN DECISION MAKING

Limitations of the Ecological Risk Assessment Process for Use in Decision Making - *Dr. Lawrence Kapustka, Senior Ecotoxicologist, Golder Associates, Ltd.*

Dr. Kapustka identified a number of important limitations of ecological risk assessment as it is applied in decision making. The use of ecological risk assessment in decision making is limited by the difficulty of assigning value to ecological resources. Ecological resources are assigned values differently by different humans based on cultural, ethnic, class, age, and gender differences. In addition, the emergent properties of ecological systems should be considered if one is to manage populations, communities, and ecosystem functions. However, problems are encountered in managing ecological systems because they cannot be restored, they can only be emulated, change in ecological systems is inevitable, and predictions of future conditions are tenuous at best.

Inherent and Contrived Limitations of Ecological Risk Assessment

Ecological risk assessment is also limited by uncertainties associated with

- The stochastic nature of ecological systems. Due to the stochastic nature of ecological systems, uncertainty is certain. Risk statements can therefore be easily interpreted as lacking understanding.

- Consideration of space and time scales that may be unrealistic. Space and time scales should be considered in ecological risk assessment. However, it can be difficult to choose assessment endpoints that reflect realistic scales of time and space.

- Difficulties in establishing ecological baselines. Establishing ecological baselines can be difficult because ecological processes occur over decades or even centuries. Short-term trajectories may provide a false indication of a long-term trend. Fortuitous change that coincides with a hypothesis can also be misleading.

- Toxicological profiles. Variation in toxicity profiles for different taxa can make it difficult to predict toxicity. At higher taxonomic levels, toxicity profiles are less accurate.

- Exposure conditions. It can be difficult to predict exposure because of variations caused by dietary preferences, dietary availability, metabolic (caloric) demand, incidental ingestion of soil and sediment, bioavailable fraction of contaminants, and behavioral dynamics (such as seasonal patterns and eco-regional patterns).

- The effects of multiple stressors. The effects of multiple stressors introduce uncertainty in to the ecological risk assessment process because: no organism resides at the optimum position for all of its niche parameters, acclimation and adaptation are mechanisms that can cause organisms and populations to adjust to changing environments, and the cumulative effects of multiple stressors can confound predictive capacity regarding particular stressor effects.

- Complex stressors. Complex stressors can have different effects under different conditions. Examples include the effects of essential nutrients, acclimation regimes, co-occurrence of stressors, and sequences of exposure.

Contrived limitations or obstacles to the use of ecological risk assessment in decision making processes have also been created. These contrived limitations include:

- Legal/regulatory limitations. Practices specified by law and established regulations may have unintended consequences. Potential liability can promote avoidance of risk assessment and prescriptive measures can stifle innovation or provide justification for minimalistic approaches.

- Policy and precedent. Policy and precedent may establish the use of inappropriate endpoints or risk characterization approaches.

- Ecotheocracy. Ecotheocracy derived from Clementsian views of grand design, the goodness of nature, and the evil of humans may lead to the use of measurement endpoints such as ecosystem health, integrity, stability, the balance of nature, recovery, and restoration that are not defensible for science-based assessment.

- Use of point estimates. The validity of point estimates such as No Observed Adverse Effects Concentration (NOAEC), Lowest Observed Adverse Effects Concentration (LOAEC), and Maximum Allowable Toxic Concentration (MATC) has been widely refuted over the past 20 years. An alternative is to use all of the available data in non-linear regression models to derive an effects concentration thereby avoiding serious deficiencies of the NOAEC approach.

- Data quality. Data obtained from the peer reviewed literature can be unusable in an ecological risk assessment because of poor study design and poor reporting standards. The taxonomic diversity of terrestrial toxicity test species is highly restrictive and the costs of toxicity testing make it unlikely that more species will be added. Risk assessors currently have a limited ability to place species accurately along a species sensitivity gradient relative to test species. Too much data are reported as point estimates, and conflicts stemming from animal rights concerns effectively preclude gathering new data.

- Perceived value/cost. Ecological risk assessments are sometimes viewed as "make work" efforts completed to "check a box." The connection of such risk assessments to management decisions is often obscure or lacking. Such risk assessments are not seen as identifying key problems that could be addressed through meaningful management strategies, and commonly there is a failure to match the level of effort of a risk assessment to the magnitude of the problems being investigated.

- Trustworthiness. Some of the major stakeholders are sometimes excluded from the ecological risk assessment process. In such cases there can be a perception that decisions are made in advance of an ecological risk assessment. Then there is the perception that data are manipulated to justify decisions. Finally, there is little focus on follow-up measurements to monitor, calibrate, and corroborate the risk assessment, which strains the relationship among stakeholders.

Actions to Improve the Process of Ecological Risk Assessment

Actions can be taken in the near term (less than three years) and the long-term (more than three years) to improve the process of ecological risk assessment for use in decision making. In the near term, policies and practices should be aligned with the state-of-the-science.

- Effects concentrations (EC_x) should be used for screening and complete response profiles could be used for higher tiered assessments.

- The use of hazard quotients should be restricted to screening level assessments, and effects response relationships should be used for higher tiered assessments.

- Contemporary ecological theory and practices should be adopted in defining assessment endpoints, conducting analysis steps, interpreting consequences, and proposing risk mitigation/reduction actions.

- Focused follow-up monitoring, calibration, and corroboration activities should be undertaken to evaluate risk predictions.

- Integration of ecological risk assessment into the environmental management decision process should be promoted.

- Long range research programs should be initiated. In the long term it will be important to fill data gaps to improve the process of ecological risk assessment.

- Additional toxicity data are needed to improve species sensitivity analyses.

- The scope of ecological risk assessments should be expanded to explicitly include biological and physical stressors and put chemical stressors in an ecological context.

- Ecological risk assessments should explicitly focus on functional ecological processes at population and community levels.

- Necessary regulations and policies should be configured to require landscape-level assessments that approach meaningful ecological scales. To conduct such assessments, effects should be aggregated at eco-regional levels, and risk predictions should be evaluated with analyses contained in state of the environment reports.

Slides of Dr. Kapustka's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_k.pdf

APPENDIX G - ECOLOGICAL RISK ASSESSMENT FOR REGULATION UNDER THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Application of Ecological Risk Assessment in Product Health and Safety Decision Making - Ecological Risk Assessment for Regulation Under the Federal Insecticide and Pesticide Act *– Dr. Steven Bradbury, Director, Environmental Fate and Effects Division, EPA Office of Pesticide Programs*

Dr. Bradbury provided an overview of ecological risk assessment conducted by the U.S. EPA Office of Pesticide Programs to support pesticide regulation under the Federal Insecticide, Fungicide, and rodenticide Act (FIFRA). Under FIFRA, the Agency may approve a pesticide if its use will not "cause unreasonable adverse effects on the environment." The Agency evaluates ecological risks to wildlife, aquatic life, and their habitat. The statute requires US EPA to weigh risks against benefits from the use of a pesticide. In addition, US EPA regulatory actions should be in compliance with the Endangered Species Act. The Program makes over 5,000 regulatory decisions annually for biopesticides, agricultural chemicals, and antimicrobial products. These decisions concern requested registrations for new active ingredients, new uses of existing pesticides, re-registrations for existing products, emergency exemptions, and experimental use permits.

Currently there are approximately 1,100 active ingredients and 19,000 pesticide products on the market. Consequently, there are many potential adverse outcomes over space, time, and levels of biological organization that should be addressed in the context of finite resources and specified, statutory timeframes. To meet its mission, the Program should determine sufficient, credible amounts of data needed for assessment and management decisions, as specified by specific statutes, and analyze these data in a scientifically sound, transparent, and timely manner.

The Program uses the Agency's Ecological Risk Assessment Guidelines to assess potential risks of pesticides, as summarized at: http://www.epa.gov/espp/consultation/ecorisk-overview.pdf and http://www.epa.gov/oppefed1/ecorisk/index.htm

While substantial advances in the field of ecological risk assessment have been achieved, the following significant challenges remain: 1) quantifying exposures and effects at appropriate biological scales in a spatially, temporally-explicit manner to facilitate evaluations that inform risk management decisions relevant to public policy and economic considerations and 2) assessing environmental conditions and identifying causes of impairment to quantify outcomes of risk management actions and effectively focus future environmental protection activities.

Quantifying Exposures and Effects in an Explicit Manner

A stepwise or tiered approach to risk assessment is intended to incorporate the most efficient use of resources by facilitating credible decisions at the earliest possible stage, while at the same time maintaining ample margins of safety so that protection of the environment is ensured. The tiered approach allows scientific expertise; test laboratory capabilities; test organisms; time needed to conduct, interpret, and report tests; and costs to be allocated to the issues of greatest concern. The challenge is to advance the scientific means to refine and characterize ecological risk projections at appropriate biological, spatial, and temporal scales that are responsive to the scales associated with corresponding social and economic considerations in the overall risk management decision.

The challenge to provide increasingly explicit information to support risk management decisions can be simply expressed as the extent to which useful answers to the "So what?" questions can be provided. For example, what can happen to a population of fish if the predicted environmental concentration exceeds an LC50 derived from an acute toxicity test? What are the potential consequences to a fish population if X% of the fish has Y level of reproductive impairment at a given exposure level? How long can it take for the population of fish to be affected? Will these population effects happen in certain places? Which places? Some places more than others?

A number of international organizations are pursuing the means to answer the "So what?" question on several fronts. For example, the US EPA Office of Pesticide Program's on-going efforts are focused on the development of probabilistic techniques to estimate the risk of pesticide exposures to aquatic life and wildlife (see http://www.epa.gov/oppefed1/ecorisk/index.htm). Immediate efforts are designed to move risk estimates of effects at the individual-level beyond single-point deterministic assessment approaches that relate an estimated environmental concentration to a specific adverse effect (e.g., an LC50 or NOAEL). Probabilistic techniques help in answering the "So what?" questions by estimating the magnitude and extent of mortality rates, growth rates, fecundity, and other effects for varying exposure scenarios. This approach to characterizing risks more fully employs available information (e.g., dose-response data when available) and provides risk managers with a more complete understanding of the potential effects associated with a chemical stressor.

When deterministic or probabilistic techniques are used to characterize risks of mortality or reproductive fitness at the individual level, additional and significant "so what?" questions remain. For example, "To what degree do changes in survival or reproductive performance translate to changes in populations and communities?" and "To what degree are these mortality or reproductive effects, and for that matter, population and community effects, expected to be significant at the field, watershed, or regional scale?"

Regulatory decision making for environmental effects may require information at biological, temporal, and spatial scales that is typically not addressed with current techniques. For example, environmental management evaluations, especially those that are required to evaluate the costs and benefits of a decision, operate at spatial scales that can encompass eco-regions, watersheds, or the habitat range of a species. Clearly, environmental management decisions concerning potential chemical effects require the means to provide spatially-explicit estimates of chemical exposure, population responses, and potential risk to aquatic life and wildlife.

Aquatic life and wildlife populations, and the associated community structure and function that provide habitat for forage and reproduction, are potentially affected by many stressors related to human activity, including habitat alteration, introduced species, and chemical use, among others. The magnitude and extent of population responses and the sustainability of a population to changes in the landscape is a function of the interactive and cumulative effects of the associated stressors. Populations and stressors are distributed in a heterogeneous manner within the landscape. Understanding relationships between spatial and temporal patterns of stressor exposures and the spatial and temporal distribution of populations is a major facet to estimating or interpreting the severity of population responses.

Developing spatially-explicit population estimates requires techniques for generating quantitative chemical exposure-response relationships and habitat-response relationships at the individual level. The development of such capabilities should be tailored to address applications that range from general, broad screening-level assessments to realistic and situation-specific applications. Associated with these developments is the need to improve approaches for extrapolating toxicological data across species. Models appropriate for these applications should be established to generate outputs describing population growth rates or other appropriate population-level endpoints as a function of stressor relationships to fecundity, life-stage specific survival, and related demographic rates. Finally, if these relationships can be projected in the context of generic/representative or actual spatial and temporal characterizations of stressors and populations in a landscape, it may be possible to assess effects from chemical exposure in the context of habitat modification.

Creating the means to answer these "So what?" questions through GIS will be contingent on the development of interactive information management systems that link databases for species-specific toxicity, demographics, life history, and habitat quality requirements. These knowledge bases, linked to models that can estimate missing values from existing information, may provide the means for projecting population responses for specified species in defined locations. This conceptual approach can be broadly applied to a wide range of risk assessment applications. For applications with limited toxicological data (measured or predicted) and generic representations of appropriate landscape scenarios, bounding conditions and assumptions can be explored in problem formulation and simple, but insightful, "What if?" analyses can be employed to help characterize and communicate potential risks. In cases where the species' toxicological, population demography, and associated landscape information are increasingly resolved and rich, more explicit risk assessments are possible. Obviously, all risk assessments will have limited or missing data in one or more facets of an analysis. Use of this modeling construct may provide the means to evaluate uncertainties related to missing information and determine the extent to which generation of additional, specific data can make a material difference in the risk estimate.

Assessing Ecological Condition and Identifying Causes of Impairment

Two different perspectives influence the regulatory pressure for advancing eco-epidemiology and diagnostics. The first perspective concerns the need to track and document the environmental outcomes of regulatory decision making to evaluate whether or not environmental management has improved or maintained ecological condition. The second perspective concerns the need to identify likely causative agents within impaired ecosystems. Proper diagnosis of the chemical and/or non-chemical stressors responsible for impairment is essential to forming a cost-effective and efficient approach to risk mitigation.

Advancement of eco-epidemiology and diagnostic methods addresses a wide range of management questions: How has the reduction of non-point source loading of a pesticide in a watershed changed the status of the fish community? Has the introduction of a new class of lower risk pesticides maintained or improved the condition of bird populations in the associated agro-ecosystems? Has reduction in the use of persistent bioaccumulative pesticides resulted in lower wildlife body burdens and improved fitness? The ability to answer these questions in a systematic fashion will help risk assessors inform decision makers if previous regulatory actions need refinement and will help inform priority-setting for future efforts.

The ability to assess the current condition of the environment and to monitor change in condition over time is needed to quantify environmental outcomes derived through regulatory decisions. Development of probability-based survey designs are needed to assess ecological condition at local, state or province, regional, national and continental scales in such a way that data can be aggregated in a cost-effective manner (see http://www.epa.gov/emap). Through the use of comprehensive and comparable methods, these designs also provide the means to compare ecosystem conditions across common spatial scales of regulatory interest The combination of sound survey designs with the use of ecological and exposure indicators, developed through rigorous evaluation criteria, provide the means to evaluate trends in environmental condition with stressors most likely associated with impaired condition. Establishing unbiased estimates of environmental trends in a scientifically- and statistically-credible manner provides the means to associate ecological condition with land-use activities and stressors so as to identify those regulatory actions that are meeting performance goals and to establish priorities for future risk management activities. Developing sound methods to establish baseline environmental conditions and trends is a universal need that transcends ecosystem types, classes of stressors, and regulatory programs.

While techniques to assess ecological condition and to identify impaired ecosystems are advancing, the need to establish diagnostic capabilities to determine cause-effect relationships within impaired systems remains a significant challenge. A diagnostic evaluation should provide a definition of the primary causes of impairment (chemical or non-chemical) and an apportionment of adverse effects across multiple stressors and their potential interactions. The development of diagnostic techniques is critical for refining leading causes of impairment in specific ecosystems or classes of similar ecosystems, for determining the extent to which existing remediation programs are effective, and for identifying situations where further refinements in risk management activities are required.

In the context of chemical stressors, research to date has established numerous indicators at the molecular, biochemical, and organismal level that can establish whether exposure has or is occurring to specific chemicals or classes of chemicals. What continues to be a major gap in the science is the lack of effect indicators that establish the extent to which adverse outcomes are occurring or are likely to occur in the future.

Slides of Dr. Bradbury's presentation are available at: http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_l.pdf

APPENDIX H - APPLICATION OF ECOLOGICAL RISK ASSESSMENT IN MANAGEMENT OF CONTAMINATED SITES – CASE EXAMPLE, ECOLOGICAL RISK ASSESSMENT OF THE CLARK FORK RIVER SUPERFUND SITE

Application of Ecological Risk Assessment in Management of Contaminated Sites – Case Example, Ecological Risk Assessment of the Clark Fork River Superfund Site – *Dr. John Wardell, Director, Montana Office, U.S. EPA Region 8*

Dr. Wardell discussed the ecological risk assessment conducted in support of risk management decisions at the Clark Fork River Superfund site in Montana. At this site, fluvial deposition of mine wastes over a period of 100 years had resulted in contaminated media (soils, river bank, and surface water). Challenges in conducting the risk assessment at this site were to identify the risks, evaluate remedies and communicate the benefits of the remedies to ranch owners along the river.

Problem Formulation

A number of assessment endpoints were selected for evaluation in the problem formulation phase of the risk assessment. Site specific toxicity studies provided data to evaluate assessment endpoints for terrestrial receptors. These endpoints included:

- Survival, growth, diversity and abundance of the riparian vegetation community under chronic exposure to contaminants and other chemical and physical stressors in the 100 year flood plain habitats of the Clark Fork River.

- Survival, growth, and reproduction of wildlife populations under chronic exposure to contaminants and other chemical and physical stressors in the 100 year flood plain habitats of the Clark Fork River.

Site specific toxicity studies also provided data to evaluate assessment endpoints for aquatic receptors. A species of special concern in the Clark Fork River was the endangered Bull Trout. Endpoints for aquatic receptors included

- Survival of fish, aquatic invertebrates, and algal populations under acute exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

- Survival, growth, and reproduction of fish, aquatic invertebrates, and algal populations under chronic exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

- Survival, growth, and reproduction of Bull Trout under acute and chronic exposure to contaminants of concern and other chemical and physical stressors in the Clark Fork River.

During problem formulation, a site conceptual model for ecological exposures was developed for the Clark Fork River Operable Unit. The conceptual model identified the primary source of contaminants (historic disposal of mine waste to surface soils, streams, and rivers) and described exposure pathways from contaminated media (soils, overbank deposits, surface water, and river sediments) through the food chain to ecological receptors. A weight-of-evidence approach was developed to characterize risk. Weight-of-evidence conclusions concerning risk were developed by evaluating exposure pathways and toxicity reference values, field and laboratory site specific toxicity studies, and field observations of taxa richness and abundance.

Exposure and Risk Characterization

Exposure point concentrations and risks were characterized separately for the aquatic community as a whole, fish, macroinvertebrates, algae, terrestrial plants, terrestrial vertebrates and soil organisms. Exposure pathways were identified and hazard quotients were predicted. Site specific toxicity testing was conducted using water effect ratio tests with rainbow trout, ceriodaphnia, and fat head minnows. In addition, site-specific receptor population and demographic data were collected. The weight-of-evidence analysis indicated that

- Copper is imposing an intermittent low-level chronic stress to the aquatic community. Observed effects on fish populations are most likely the result of acute pulses of high concentrations of high concentrations of copper. Metals are likely to be altering the composition of the macroinvertebrate community but not the overall abundance. Dissolved metals are causing low to minimal stress to algae.

- The weight-of-evidence is strong that mine tailings materials present in the root zone of riparian area soils are significantly phytotoxic to terrestrial plants.

- Dietary exposure to contaminants is likely to pose risks to small terrestrial vertebrate insectivores and herbivores. However there are little site-specific data available, and hence these receptors had the greatest amount of uncertainty.

Alternatives Considered

The common theme developed in the risk characterization process was that mine waste presents stress to the aquatic environment and, to a lesser extent, to the terrestrial environment. To address the problem of mine waste and contaminated soils in the floodplain and river banks, the following alternatives were considered

- No further action.

- In-place reclamation of exposed tailings.

- In-place reclamation of exposed tailings and other impacted soils and vegetation areas.

- In-place reclamation of exposed tailings and other impacted soils and vegetation areas with stream bank stabilization.

- Removal of exposed tailings and other impacted soils and vegetation with stream bank stabilization.

- Total removal unless overlain by woody vegetation.

- Total removal of all exposed and buried tailings areas (i.e., essentially a complete recovery)

- Construction of the entire floodplain of the Clark Fork River.

The anticipated outcomes of the alternatives were evaluated. None of the alternatives considered, if individually implemented, would completely achieve all of the remedial action objectives. For example, the State of Montana's water quality standard for copper would not be met because of continued copper loading from tributary, upstream, and residual contamination sources left onsite. A remedy was developed to balance long-term and short-term effectiveness and permanence, reduction of mobility, toxicity, and volume of wastes as well as concerns with implementation.

Proposed Remedy

The proposed remedy calls for:

- Removal of most "slickens" (fine textured mining wastes that are detrimental to plant growth) where uncertainty is greater regarding the effectiveness of in-situ treatment. It was most cost effective to dig up these wastes from which potentially large-scale releases of toxic materials could occur into the river. The ecological risk assessment identified this type of contamination problem as an acute risk to aquatic life.

- In-situ treatment where success of this technique was deemed likely to decrease the mobility of wastes. The ecological risk assessment identified this type of contamination problem as a chronic risk to aquatic life.

- Stream bank stabilization where appropriate to minimize erosion of contaminated materials into the river to reduce episodic large-scale releases of toxic materials that the ecological risk assessment identified as a chronic risk to aquatic life.

- Revegetation of slickens, other areas as appropriate, and stream banks was needed to address terrestrial risks identified in the ecological risk assessment.

  It was determined that this set of remedies could be completed in a reasonable period of time (approximately 10 years) at a reasonable cost (approximately $100 million) and at a reasonable impact to current use of land by ranchers and farmers on whose property the remedy would be carried out.

  Slides of Dr. Wardell's presentation are available at: http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_m.pdf

APPENDIX I - APPLICATION OF ECOLOGICAL RISK ASSESSMENT IN NATURAL RESOURCES PROTECTION – ASSESSING THE EFFECTS OF SELENIUM ON AQUATIC LIFE

Application of Ecological Risk Assessment in Natural Resources Protection – Assessing the Effects of Selenium on Aquatic Life - *Dr. Edward Ohanian, Director, Health and Ecological Criteria Division, Office of Science and Technology, EPA Office of Water*

Dr. Ohanian discussed EPA's development of a proposed water quality criterion for selenium. In 2004, EPA proposed a draft criterion for selenium that has been expressed as a fish tissue concentration. The Agency is now addressing comments received on the criterion and will determine whether additional studies should be conducted. Section 304(a) of the Clean Water Act requires EPA to develop and publish, and from time to time to revise, criteria for water quality accurately reflecting the latest scientific knowledge. Within the context of their Clean Water Act application, EPA should be able to defend its criteria as being sufficiently protective but not unnecessarily stringent relative to what is needed for achieving aquatic life use goals.

Within the risk assessment paradigm, the derivation of criteria is an effects assessment. Exposure assessment comes into play during criteria implementation, when determining whether criteria are being attained at a site.

Since 1980, EPA has preferred to derive its criteria concentrations following agreed upon methodologies. The methodology for deriving aquatic life criteria was published in 1985. This methodology calls for compiling toxicity data for a diverse set of taxa, constructing a Species Sensitivity Distribution with the toxicity values, and interpolating or extrapolating to the water concentration needed to protect 95% of taxa. This methodology is still in use, although efforts to revise it are currently underway.

The 1985 methodology is not particularly well suited to deriving aquatic life criteria for bioaccumulative pollutants. It was designed for pollutants where aquatic life are exposed predominantly via water. That is, in ordinary chronic toxicity tests, the organisms are placed in contaminated water, but are fed an uncontaminated diet.

On the other hand, because algae and aquatic plants bioconcentrate selenium, aquatic animals in the real world are exposed to selenium primarily through their diet. Nevertheless, in contrast to the mercury, selenium is not biomagnified in the upper trophic levels.

As a consequence of this bioaccumulative behavior, when aquatic organisms consume food grown in the contaminated water, effects are seen at far lower concentrations than when fed an uncontaminated diet in ordinary toxicity tests. Because of this phenomenon, in 1987 when EPA published its current chronic criterion, 5 μg/L, EPA did not use such toxicity test data but rather relied on field data collected at Belews Lake, North Carolina, comparing sunfish health with the water concentration of selenium in different parts of the lake.

EPA is currently in an extended process of revising the 1987 selenium criterion to reflect the considerable amount of additional toxicity data that has since become available. EPA has examined the new information and prepared a draft revised criterion. After considering the potential for a selenium criterion expressed as a water, sediment, or tissue concentration, EPA has derived the draft criterion as a fish tissue criterion. This has allowed use of numerous laboratory, field, and mesocosm studies where tissue concentrations were measured. This step also removes site-to-site variations in food chain bioaccumulation from the numeric value of the criterion.

When the adult life stage of sensitive fish species are exposed to excessive levels of selenium, the sensitive endpoints are manifested in the early life stages of the offspring, not in the adults themselves. For this reason, a tissue criterion can be applied with the expectation that adult fish will be available for sampling even at sites where effects are occurring.

Nevertheless, unlike water, fish tissue is not an exposure medium shared by numerous species. When compared across the various species that may reside at a site, the same tissue concentration may have different significance not only because of species differences in their tolerance of elevated tissue levels, but also because of species differences in their propensity to bioaccumulate selenium.

As part of its ongoing efforts to revise the general methodology for deriving aquatic life criteria, EPA is in the process of addressing the issues involved in developing and applying tissue criteria for bioaccumulative pollutants.

Slides of Dr. Ohanian's presentation are available at:
http://www.epa.gov/sab/pdf/ecorisk_workshop_summary5_appendix_n.pdf

APPENDIX J - BIOSKETCHES OF INVITED SPEAKERS AND PANELISTS

Speakers

Dr. Lawrence Barnthouse is the President and Principal Scientist of LWB Environmental Services, Inc. Before he became a consultant, he was a research staff member and Group Leader in the Environmental Sciences Division at Oak Ridge National Laboratory. In 1981 he became co-principal investigator (with Glenn Suter) on EPA's first research project on ecological risk assessment. Since that time, he has been active in the development and application of ecological risk assessment methods for EPA, other federal agencies, state agencies, and private industry. He has chaired workshops on ecological risk assessment for the National Academy of Sciences and the Society of Environmental Toxicology and Chemistry, and served on the peer review panels for the Framework for Ecological Risk Assessment and the Guidelines for Ecological Risk Assessment. He continues to support the development of improved methods for ecological risk assessment as the Hazard/Risk Assessment Editor of *Environmental Toxicology and Chemistry* and a Founding Editorial Board Member of *Integrated Environmental Assessment and Management*.

Dr. Steven Bradbury is Director, Environmental Fate and Effects Division, Office of Pesticide Programs, U.S. EPA**.** The Division's ecological risk assessments and drinking water exposure characterizations support risk management policies and decisions concerning the registration and re-registration of pesticides. Efforts are integrated with other USEPA Offices and Regions, as well as other Federal and international agencies, and stakeholder organizations. Before assuming his current position Dr. Bradbury led and managed EPA Office of Research and Development (ORD) laboratory facilities in Duluth, MN and Grosse Isle, MI. This Division's programs advanced ecological monitoring and assessment designs and indicators for the Great Lakes and Great Rivers; understanding of the effects of stressors on freshwater ecosystems, aquatic like and wildlife to support ecological risk assessment methods; and computational toxicology approaches to assess industrial chemicals and pesticides. Dr. Bradbury also led, managed and undertook research on effects of industrial chemicals and pesticides on aquatic life and wildlife to support risk assessment methods for TSCA, FIFRA, CERCLA and RCRA. He is a member of EPA risk assessment forum and contributor to EPA's Ecological Risk Assessment Guidelines. He is also holds an adjunct appointment in the toxicology degree program in the graduate school of the University of Minnesota. Dr. Bradbury holds a Ph.D. in Toxicology and Entomology (Insecticide Toxicology) Iowa State University, an M.S. in Entomology (Insecticide Toxicology) Iowa State University, and a B.S. in Molecular Biology, University of Wisconsin-Madison. He has published over 75 peer-reviewed journal articles and book chapters.

Dr. Lawrence A. Kapustka joined Golder Associates in July 2005 as a Senior Ecotoxicologist. He is focusing on the use of spatially-explicit risk assessments, integrating environmental assessment practices with environmental management decision processes, and advancing the emerging methods in the field of ecological valuation. In the previous 15 years, at ecological planning and toxicology, inc., Corvallis, Oregon he worked in the areas of ecological risk assessments, plant ecotoxicology, and other aspects of ecological applications. Dr. Kapustka received his Ph.D. in Botany from the University of Oklahoma, Norman in 1975. He received his M.S. (1972) and B.S. Ed. (1970) from the University of Nebraska-Lincoln. Before entering the private sector, Dr. Kapustka was a Research Ecologist and Team Leader of the Plant Toxicology and Hazardous Waste Teams with the US EPA, Environmental Research Laboratory, Corvallis, OR (1988-1990). Dr. Kapustka was on the faculty in the Botany Department, Miami University, Oxford, OH from 1978-1988 where he was tenured and held the rank of Professor. From 1975-1978 he was on the staff with the Biology Department and Center for Lake Superior Environmental Studies, University of Wisconsin-Superior, Superior, WI. Dr. Kapustka is active in several professional societies including the Ecological Society of America (ESA), the International Association of Landscape Ecologists (IALE), Society for Environmental Toxicology and Chemistry (SETAC), and the American Society for Testing and Materials (ASTM). He is a Certified Senior Ecologist (ESA)

Ms. Denise Keehner is the Director of the Standards and Health Protection Division in the Office of Water at EPA Headquarters. In this position Ms. Keehner has responsibility for overseeing the implementation of the Water Quality Standards Program, the Beach Program and the Fish Advisory Program. Prior to moving to the Office of Water in 2003 Ms. Keehner was the Director of the Biological and Economic Analysis Division in EPA's Office of Pesticide Programs (OPP) and also served as the acting Director of the Environmental Fate and Effects Division in OPP. Ms. Keehner has also held management positions in the EPA Office of Solid Waste and Emergency Response and in the former EPA Office of Toxic Substances. In her 27 years with EPA she has participated in risk management decision making under the Clean Water Act, the Resource Conservation and Recovery Act, the Federal Insecticide Fungicide and Rodenticide Act, the Food Quality Protection Act, and the Toxic Substances Control Act.

Dr. Edward Ohanian is the Director of the Health and Ecological Criteria Division, Office of Water, United States Environmental Protection Agency (U.S. EPA), in Washington, D.C. The Division is responsible for conducting human and ecological risk assessments as required under both the Safe Drinking Water Act and Clean Water Act. Recently, he has been appointed the Chairman of the U.S. EPA Risk Assessment Forum. He also serves as an Adjunct Associate Professor with the School of Public Health and Tropical Medicine at Tulane University Medical Center, and with the School of Public Health and Health Services at George Washington University Medical Center. Previously, he served as the Acting Director of U.S. EPA Office of Research and Development's National Center for Environmental Assessment at Cincinnati, Ohio. Dr. Ohanian received his bachelors in Biological Sciences from Columbia University and his Masters in Physiology from the New York Medical College. His Doctorate in Biomedical Sciences was obtained from Mount Sinai School of Medicine. He has contributed over 60 articles and chapters to scientific journals and books.

Dr. Michael Slimak is beginning his 29th year of service at the U.S. EPA. Located in Washington, D.C., he is currently the Associate Director for Ecology in the National Center for Environmental Assessment, one of five major research units at EPA. He is responsible for developing and implementing assessment programs in a number of important areas such as ecological risk, conservation biology, global climate change, invasive species, and water quality. During his tenure at EPA he has worked in a variety of programs and has been involved in a number of critical environmental issues. Dr. Slimak is a recognized authority on ecological risk, has authored numerous government-sponsored reports, has published in peer-reviewed journals and books, and has received numerous EPA awards. He holds a BS in Biology, an MS in Wildlife Ecology and a Ph.D. in Environmental Science.

Dr. Glenn W. Suter II is currently Science Advisor in the U.S. Environmental Protection Agency's National Center for Environmental Assessment-Cincinnati, and was formerly a Senior Research Staff Member in the Environmental Sciences Division, Oak Ridge National Laboratory, U.S.A. He has a Ph.D. in Ecology from the University of California, Davis, and 29 years of professional experience including 24 years of experience in ecological risk assessment. He is the principal author of two texts in the field of ecological risk assessment, editor of two other books and author of more than a hundred open literature publications. He is Associate Editor for Ecological Risk of "Human and Ecological Risk Assessment," and Reviews Editor for the Society for Environmental Toxicology and Chemistry (SETAC). He has served on the International Institute of Applied Systems Analysis Task Force on Risk and Policy Analysis, the Board of Directors of SETAC, an Expert Panel for the Council on Environmental Quality, and the editorial boards of "Environmental Toxicology and Chemistry," "Environmental Health Perspectives," and "Ecological Indicators." He is the recipient of numerous awards and honors; most notably, he is an Elected Fellow of the American Association for the Advancement of Science and he received SETAC's Global Founder's Award, their highest award for career achievement, and the EPA's Level 1 Scientific and Technical Achievement Award. His research experience includes development and application of methods for ecological risk assessment and ecological epidemiology, development of soil microcosm and fish toxicity tests, and environmental monitoring. His work is currently focused on the development of methods for determining the causes of biological impairments.

Dr. John Wardell is Director of the U.S. EPA Region 8 Montana Office. He served on active duty and reserves in the U.S. Army and he was Chief of the U.S. EPA Region 8 Superfund Program. He holds a Ph.D. in Plant Pathology from Michigan State University and an MBA from Colorado State University.

Panelists

Dr. Peter L. DeFur is an independent consultant and part time faculty member at Virginia Commonwealth University in Richmond, VA. Most of his work is for government agencies and citizen organizations regarding environmental cleanups and regulatory programs and activities. Dr. DeFur's expertise includes ecological and human health risk assessment, endocrine disrupting chemicals, coastal eutrophication and public participation. He worked for Environmental Defense for six years and served on the National Research Council (NRC) Board on Environmental Studies and Toxicology, as well as on a number of NRC study committees. Dr. DeFur has served on the planning committees for a number of SETAC workshops on ecological risk topics.

Dr. David L Fischer is currently the Head of Bayer CropScience's Ecotoxicology Section in the U.S. Dr. Fischer holds a B.S. degree in Zoology from the University of Massachusetts, a M.S. degree in Zoology from Western Illinois University, and a Ph.D. in Zoology from Brigham Young University. He has been working in the field of ecotoxicology and risk assessment since 1986 and has supervised the conduct of hundreds of laboratory and field studies of pesticides and animal pharmaceuticals, authored dozens of chemical risk assessments, and published more than 20 peer-reviewed scientific papers. Dr. Fischer's expertise is in the area of wildlife toxicology and risk assessment.

Dr. Michael Fry is an avian toxicologist whose research interests over the past 28 years have focused on the effects of pollutants and pesticides on ecological systems, with a focus on wild birds. Before joining American Bird Conservancy, Dr. Fry was Senior Environmental Toxicologist at Stratus Consulting, a firm specializing in environmental consulting in the public interest. Prior to 2003, he was a research physiologist in the Department of Avian/Animal Sciences at the University of California, Davis, for 25 years. Dr. Fry has been a panel member for the National Academy of Sciences on hormone active chemicals in the environment, and has participated in toxicology reviews and international symposia for the Organization for Economic Cooperation and Development (OECD), and for the United Nations University in Japan. He has been a committee member for EPA and OECD in revising avian toxicity test methods, and was a member of the EPA Ecological Committee for FIFRA Risk Assessment Methods (ECOFRAM) (1997-1999), and an EPA Science Advisory Panel (SAP) member for EPA terrestrial risk assessment in 2004. Dr Fry was a member and Chairman of the Department of Interior, Minerals Management Service Advisory Board Scientific Committee, from 1989-1966. Dr. Fry reviewed lead exposure sources and lead toxicity issues of California Condors for the CA Department of Fish and Game, publishing a comprehensive report in 2003. Dr. Fry received his Ph.D. in physiology from the University of California, Davis, in 1971, and has had held postdoctoral research and teaching positions in Australia and at the Cardiovascular Research Institute at University of California, San Francisco.

Dr. Bruce K. Hope is with the Oregon Department of Environmental Quality (DEQ), where he currently serves as the senior environmental toxicologist for the Air Quality Division. Previously, he worked with the Water Quality Division to develop aquatic food web biomagnification and mass balance models for the Willamette River Mercury Total maximum Daily Load (TMDL) and in the Land Quality Division, reviewing human health and ecological risk assessments for specific cleanup sites, developing risk assessment guidance (human health, ecological, probabilistic) to support implementation of Oregon's cleanup law, and leading the State's efforts to implement probabilistic human health and population-level ecological risk assessments. In 2000-01, he was on leave from DEQ as an American Association for the Advancement of Science (AAAS) risk policy fellow at the U.S. Department of Agriculture in Washington DC. Prior to joining DEQ in 1995, he was a private sector consultant managing human health and ecological risk assessment projects for commercial and government clients at CERCLA, RCRA, and BRAC sites throughout the U.S. and Pacific Rim. Dr. Hope has been an adjunct faculty member at Oregon Health & Science University (in both the Oregon Graduate Institute and the School of Nursing), Concordia University (Portland), and Portland State University. He holds M.S. and Ph.D. degrees in biology (aquatic toxicology) from the University of Southern California and a B.A. degree from the University of California (Santa Barbara).

Mr. Max Feken is an environmental toxicologist for the Florida Department of Agriculture where he performs ecological risk assessments for pesticides registered in Florida. He is also the Coordinator for the Department's Endangered Species Protection Program.

Dr. Eugenia McNaughton is currently Chief of the Quality Assurance (QA) Office in U.S. EPA Region 9. Dr. McNaughton has worked for EPA for 11 years. She started in the QA Office, moved to the Water Division to work on the U.S.-Mexico Border Team, and came back to QA this past year. She received her Ph.D. in Biology from the University of California, Santa Cruz and worked in the private sector on aquatic toxicology projects. Her interest in selenium impacts on the environment began at that time. She has represented EPA for the past ten years on a multi-agency team working to reduce selenium load discharge into the San Joaquin River associated with tile water coming from agricultural fields.

Ms. Vickie Meredith is a graduate of the University of Wyoming and a Wyoming Registered Professional Geologist. She has worked for the Wyoming Department of Environmental Quality (WDEQ) for 16 years and has been the project manager on several RCRA Subtitle C and voluntary cleanup sites in Wyoming - most notably, the former BP Amoco refinery site in Casper, Wyoming. The former BP Casper site covers over 3000 acres of land and the site assessments included three different ecological risk assessments which helped her make risk management and cleanup decisions for several types of land uses and habitats. Ms. Meredith has worked on and chaired several WDEQ workgroups and been instrumental in the development of guidance for the state's Voluntary Remediation Program including; human health and ecological risk assessment, monitored natural attenuation, remedy selection, establishing points of compliance and technical impracticability determinations. In addition to overseeing two former refinery cleanups, Vickie is currently developing a Targeted Brownfield Assessment program and an orphan site cleanup program for the WDEQ.

Dr. Jennifer Shaw is currently head of Syngenta's Stewardship function where she leads initiatives on environmental stewardship, sustainable agriculture and environmental issues management. She has a BS degree in Agricultural Science and a Ph.D. in Ecology and Epidemiology from the Universities of Glasgow and Aberdeen in Scotland. In the past 17 years with the Crop Protection industry Dr. Shaw has managed large scale environmental field studies, headed a facility that researched effects of pesticides on aquatic ecosystems, and led development of ecological risk assessment to inform decision making. For the past decade she has been involved in data generation and risk assessments for threatened and endangered species. Since 1990, Dr. Shaw has served in leadership positions in various industry task forces, trade association committees and expert workgroups including serving as an invited expert on U.S. EPA's Ecological Committee on FIFRA Risk Assessment Methods (ECOFRAM) and as an Ecological Risk Editor for the "Environmental Toxicology and Chemistry" journal.

Dr. Mark Sprenger is an environmental scientist with the U. S. Environmental Protection Agency's - Office of Superfund Remediation and Technology Innovation - Environmental Response Team. He received a B.S. in Biology from the State University of New York at Stony Brook, and a M.S. and Ph.D. in Environmental Science from Rutgers, the State University of New Jersey. His doctorate research and post-doctorate work focused on alteration in metals availability resulting from acid deposition as well as post-doctorate work on the impacts of DDT on a salt marsh. He is a coauthor of the national Superfund ecological risk assessment guidance and has been active in the development of ecological risk assessments both in terms of new technical applications and national consistency. His current responsibilities are nationwide and international in scope, with a focus on ecological risk assessments, contaminant fate and transport, site environmental monitoring; and most recently on the assessment of innovative remedial technologies and ecological restoration in the context of Site remediation.

Dr. Ralph Stahl joined the DuPont Company in 1984 and in the intervening years has held both technical and management positions in the research and internal consulting arenas. His research over the last 23 years has focused primarily on evaluating the effects of chemical stressors on aquatic and terrestrial ecosystems. Since 1993 Dr. Stahl has been responsible for leading DuPont's corporate efforts in ecological risk assessment and natural resource damage assessments for site remediation. Dr. Stahl received his B.S. in Marine Biology from Texas A&M University (*cum laude*) in 1976, his M.S. in Biology from Texas A&M University in 1980, and his Ph.D. in Environmental Science and Toxicology from the University of Texas School of Public Health in 1982. After receiving his Ph.D., he was a Senior Postdoctoral Fellow in the Department of Pathology at the University of Washington in Seattle where he investigated the impact of genetic toxins on biological systems. Dr. Stahl is a member of the US EPA's Science Advisory Board (Advisory Council on Clean Air Compliance Analysis, Ecological Effects Subcommittee) and is active in the Society of Environmental Toxicology and Chemistry (SETAC), serving on the Ecological Risk Assessment Advisory Group. He is board certified in General Toxicology and is a Diplomate of the American Board of Toxicology. He has authored over 30 peer reviewed publications on topics in environmental toxicology, ecological risk assessment, and risk management. He recently edited two books and is currently co-editing a third book stemming from a SETAC Education Foundation-sponsored workshop on the valuation of ecological resources.

Dr. Leslie Touart is currently a senior ecotoxicologist with EPA's Office of Science Coordination and Policy in the Office of Prevention, Pesticides and Toxic Substances. Primary duties involve the development and validation of ecotoxicity assays for the Endocrine Disruptor Screening Program. Dr. Touart earned a Ph.D. from George Mason University in Environmental Biology and Public Policy. He served briefly with EPA's Office of Research and Development, Gulf Breeze laboratory conducting estuarine organism toxicity tests early in his career. He spent 20 years with the U.S. EPA Office of Pesticide Programs performing ecological risk assessments. He interacts with the OECD in the development of internationally harmonized test guidelines and risk assessment practices.

Dr. Terry Young is an independent consultant, and has managed projects for Environmental Defense for more than twenty years. Her recent work includes the design of a system that uses economic incentives, including input pricing and tradable discharge permits, to control farm pollution in California's San Joaquin Valley. Additional work includes the development of ecological indicators to track management and restoration of ecological systems such as the San Francisco estuary. She has published on topics of economic incentives for environmental protection, indicators of ecological integrity, and market solutions for water pollution Dr. Young received her bachelor's degree in chemistry at Yale University and her Ph.D. in Agricultural and Environmental Chemistry from the University of California at Berkeley.

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APPENDIX L – SUMMARY OF PRODUCT HEALTH AND SAFETY DECISION MAKING BREAKOUT GROUP PARTICIPANTS, PANEL DISCUSSION, AND REPORT

Facilitator: Gregory Biddinger, Exxon Biomedical Sciences

Rapporteurs: Wayne Landis, Western Washington University and Charles Pittinger, BB&L Sciences

Panelists:
Peter Defur, Environmental Stewardship
Max Feken, Florida Department of Agriculture
David Fischer, Bayer Crop Science
Leslie Touart, U.S. EPA

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Panel Discussion – Ecological Risk Assessment for Product Health and Safety Decision Making – *Facilitator: Dr. Gregory Biddinger, Exxon Biomedical Sciences; Rapporteur: Dr. Charles Pittinger, BB& L Sciences; Invited Panelists: Dr. Peter DeFur, Environmental Stewardship; Mr. Max Feken, Florida Department of Agriculture; Dr. David Fischer, Bayer Crop Science; Dr. Leslie Touart, U.S. EPA Office of Pollution Prevention and Toxic Substances (See Panel biosketches in Appendix J)*

Dr. Biddinger introduced the members of the panel who presented different perspectives on needs to advance the practice of ecological risk assessment for product health and decision making.

Dr. Defur's Presentation

Dr. Defur discussed issues of concern in the conduct of ecological risk assessments supporting product health and safety decision making.

- The practice of ecological risk assessment is currently focused on protecting populations. Therefore, the condition of individual plants or animals is often ignored. Ecological risk assessment measures are designed to provide information that can be used to determine whether a population is persisting over time in space (e.g., will a fish population exist in a particular water body in ten years?). The morbidity of fish is often ignored in a risk assessment and although fish can be terminally ill, their reproduction is the only measure considered. This risk assessment approach is unacceptable because it ignores health. A stable population of sick animals or plants is not an adequate outcome. Ecological risk assessors should consider more than just gross population levels and measures of biomass. Condition is an extremely important measure.

- Ecological risk assessors focus on populations and seldom assess communities or mixed assemblages of plants and animals. This is not because measures for assessing communities are unavailable. Rather, it is because that knowledge has not been translated into ecological risk assessment.

- Ecological risk assessment does not currently address cumulative risk (i.e., the addition of a single stressor upon an already stressed condition). An example of this is failure to consider cumulative risk in assessment of a forest that has experienced acid rain for 10 years when another stressor is introduced. These issues have relevance to product health and safety assessments. Although ecological risk assessment does not presently consider biological stress (e.g., imposition of an exotic species), product health and safety assessments increasingly should address genetic or biological components of products.

- Time and space issues are particularly challenging in making decisions about many products (e.g., pesticides, plastics, perflourooctanoic acid [PFOA]), yet ecological risk assessments often do not consider long time scales or multiple levels of organization. Assessing the risks of lead and mercury on adequate temporal and spatial scales would lead to questions concerning the use of these substances in any product. National Institutes of Health (NIH) has questioned any use of mercury in a product because either its manufacturing or disposal will result in further releases into the environment. Gasoline additives, pesticides, PFOA, polybrominated dibenzodioxin (PBDD), nickel and cadmium are all introduced into the environment in ways that have not been considered.

It is important that ecological risk assessors think about the kinds of problems that might not be readily predicted or foreseen. With this consideration, the use of lead in products could have been recognized as dangerous from the outset.

Mr. Feken's Presentation

Mr. Feken discussed ecological risk assessment practices supporting decisions concerning pesticide use in Florida. He stated that to protect Florida's unique environment, risk assessments should address such issues as double cropping in agriculture, production of unique crops, environmental conditions such as annual rainfall of more than 60 inches in Tallahassee, and unique natural communities. To conduct risk assessments, meteorological data are used to run models that provide predictions for periods of 30 years.

A worst-case spatial scale is used. The scale varies depending upon the crop of concern. Different crops are grown throughout Florida; citrus is grown in the central region of the state and different vegetable crops and field crops produced in other parts of the state. Several areas are modeled for each crop in order to refine assessments beyond a worst case scenario. However, there are a number of significant weaknesses in ecological risk assessment practices.

- It is not possible to model the effect of reducing runoff into nearby surface water bodies. It is not possible to model the effects of buffers on runoff. It is assumed that water bodies at risk are adjacent to fields where pesticides are applied, but ecological risk assessors need to understand how pesticide exposure in water bodies can be modeled in order to expand the spatial scale of risk assessments. Models are needed for canal systems and estuarine systems.

- The State of Florida needs additional EPA guidance on models that can be used for terrestrial ecological risk assessment. Currently, organism-level effects on vertebrates are evaluated by looking at risk quotients for individual mortality. Species sensitivity distributions have been used to conduct ecological risk assessments and the State is considering use of the slope of the LC50 for assessments of risk to endangered species. However, there is a need for models to conduct population level effects assessments. Mesocosms and microcosms are currently used to demonstrate magnitude of effects and potential for recovery of populations.

Prospective risk assessments are conducted and data gaps are filled using information from simulated runoff studies. Developing testable hypotheses is important for these kinds of risk assessments. In conducting these risk assessments, uncertainty is quantified to the maximum possible extent so that decision making can be as transparent as possible.

Dr. Fischer's Presentation

Dr. Fischer also discussed ecological risk assessment practices to support pesticide use decisions. He identified a number of opportunities to improve risk assessment practices.

- If ecological risk assessments are to be believable, they should be of high quality and should focus on the things that can be assessed well. It is impossible to assess everything.

- There is value in applying standardized scenarios of known spatial and temporal scale. Greater level of detail in ecological risk scenarios is associated with less certainty.

- There is value in focusing on individuals, not populations, under the assumption that if individuals can be protected, populations can also be protected.

- Problem formulation is the most important part of a risk assessment. Risk assessors often mistakenly start with measurements and determine endpoints. Endpoints should be selected keeping goals for the landscape in mind.

- Some subjective assumptions are important in the face of uncertainty (e.g., how different is a risk quotient of 3 from a risk quotient of 0.3 ?)

Dr. Touart's Presentation

Dr. Touart discussed how ecological risk assessment is conducted under the requirements of different statutes that address product health and safety. There are many different statutory authorities that require ecological risk assessment (e.g., Federal Insecticide, Fungicide and Rodenticide Act [FIFRA], Toxic Substances Control Act [TSCA], and Clean Water Act [CWA]). Ecological risk assessments conducted under each of these statutes will be quite different depending upon legal constraints and who is asking questions. Ecological risk assessment is an iterative process and the information available for an assessment depends upon the statutory authority. Under FIFRA, industry should demonstrate that products will not cause harm. Under TSCA, the burden of proof is upon EPA to prove potential harm. Sometimes states should conduct risk assessments. There are a number of limitations to the current practice of ecological risk assessment and opportunities for improvement.

- Data requirements for pesticides and industrial compounds are based on hazard quotients, so the kinds of studies conducted are limited to a few species.

- New probabilistic approaches are being developed and will advance the practice of ecological risk assessment.

- New tools are being developed to assess endocrine disrupters, but demands for validation of new methodologies will slow the process of developing risk assessment tools.

- Risk assessment is an iterative process, and assessments are refined until actionable information is developed. New data should, however, feed back into old ecological risk assessments.

- Conservatism is built into risk assessments because assessors are striving to deal with the worst cases.

Discussion of Points Raised by Panelists

After presentations by the panel members, workshop participants raised the following issues concerning the limitations of ecological risk assessment supporting product health and safety decisions, and opportunities for improving the practice.

- It is important to note that many tools are currently available to conduct accurate screening level risk assessments for product health and safety in a short period of time. There are many sources of information available for conducting these rapid assessments. European Union databases can provide ecotoxicology information. EPA's EPI Suite tool can provide physical and biological parameters to enable a determination of whether a chemical is biodegradable, toxic or bioaccumulative.

- It is important for ecological risk assessors to consider the question of why risk assessments should be conducted and what should be protected. As currently described in EPA guidance, the process of problem formulation does not focus on this important question.

- In considering the appropriate spatial and temporal scales of ecological risk assessments, it is important to consider differences between predictive risk assessments of new chemical releases, and assessments of chemicals that have already been in the environment for long periods of time. If effects are not observed in the latter case, an assessor should determine whether this is because effects did not occur, could not be found, or whether compensation had occurred.

- Tiered risk assessment approaches can help risk assessors to foresee the ecological risks of substances like lead, but there is a need to develop additional tools for evaluating cumulative risks. Contaminants are being released into environments that are already stressed, and regulations do not address cumulative stress. Cumulative risk tools are not available.

- A challenging question that should be answered in considering cumulative risk is, "what are the conditions of watersheds right now?" This information is needed to frame the problem and consider the issue of cumulative risk in pesticide reregistrations or expanded use registrations. Field data are generated over the lifespan of a chemical, and these data should be considered.

- Ecological risk assessments for product health and safety decisions are conducted to allow permitting, and there is pressure to allow permitting. However, it is important to consider society's goals and consider baseline conditions in ecological risk assessments.

- In terrestrial systems, accelerated changes are frequently being driven by product registration requirements of the Food Quality Protection Act. Improved ecosystem and community-level measures are needed to assess these changes in the field. Old products were associated with intense short term impacts on ecological systems. Newer products are associated with less severe impacts that occur over longer periods of time, and pesticide registration decisions have been made on the basis of human health protection. Data obtained from land that is under integrated pest management can be useful for developing measures of ecosystem and community structure.

- There is a tremendous amount of data in the ecology literature that could be tapped to improve assessments of ecosystems and communities (e.g., production functions). There are "tens of thousands" of models that could be generalized and adapted to other contexts.

- Ecological risk assessments should also consider the effects of invasive species, exotic species, genetically modified organisms, and water transfer.

- It is important to find ways to closely tie risk assessment science to product health and safety decisions made by organizations. Pesticide re-registration decisions should be ecosystem-level decisions.

Ecological Risk Assessment for Product Health and Safety Decision Making Breakout Group Summary Report

Definition of Spatial and Temporal Scale in Risk Assessments for Product Health and Safety Decision Making

- Defining and incorporating the appropriate spatial and temporal scales in ecological risk assessments for product health and safety is a major challenge. The broadest scale of product use is often considered in risk assessments.

- In defining spatial scale, it is important to consider biological processes (ecological and phylogenetic considerations) as well as management processes. The scale of management processes may necessarily be the largest.

- Spatial and temporal scales should be explicitly considered in the problem formulation stage of ecological risk assessments. Appropriate scales will vary with the context of the risk assessments and the decisions to be made. Broadening the risk assessment context (i.e. evaluating landscape scale effects) demands broader consideration of receptors and other stressors (e.g., cumulative risk).

- A shift is needed in EPA's approach to the application of ecological risk assessment to move from program driven decisions toward managing and assessing risk at a place-based or landscape level. Regulations "perform" within a local context (i.e., protection risks and politics are local).

Definition and Incorporation of Biological Scale into Ecological Risk Assessments for Product Health and Safety Decision Making

- EPA needs to incorporate a broader approach to consideration of biological scale, beyond population levels, into ecological risk assessment.

- Data on phylogenetic responses to stressors (comparative toxicity) should be expanded and applied in ecological risk assessments.

- New biomarker and mechanistic data should be incorporated into ecological risk assessments. Additional research should be completed to determine whether such data can be used to indicate exposure or risk.

Problem Formulation and Incorporation of Testable Hypothesis into the Design of Ecological Risk Assessments for Product Health and Safety Decision Making

- Problem formulation should be an iterative process

- The problem formulation stage of ecological risk assessment may be limited by the lack of approaches for considering the life cycle of a product. For example, the first question considered in problem formulation is the decision to be made. Questions addressed in the decision to register a pesticide are different from "end-of-life" questions concerning the product.

- Life cycle analysis is not addressed in regulations, and additional guidance is needed in this area. An example is the regulation of nanotechnology. In the past, product life cycles were not considered, but the Agency should now look ahead and correct past mistakes.

- Life cycle issues should be considered with care. "Front-end" issues should be carefully evaluated in product decisions. Life cycle considerations are "future oriented." Folding life cycle considerations into ecological risk assessment could be useful for evaluating future technologies.

- There currently appears to be good guidance available on how to conduct problem formulation. Often, however, generic problem formulation is conducted and assessment endpoints do not account for long-term dynamics of populations. This problem is more a technical issue of what can be measured than a problem of ecological risk assessment design. For example, assessment endpoints for pesticides are very generic, concerned with aquatic and terrestrial animals and plants. Population density and other technical questions are ignored. Better definitions of assessment endpoints are needed.

- Scale is often not properly considered in problem formulation and ecological risk assessment. Assessors are not conducting multi-generational analyses to determine whether population failures have occurred. There are no legal requirements to conduct this kind of follow-up analysis. There is currently very little ground truthing of risk assessments. EPA's pesticide program is, however, working with the Agency's Environmental Monitoring and Assessment (EMAP) program to establish baselines to determine whether regulatory decisions are making an impact on the environment.

- Participants expressed the opinion that problem formulation for product health and safety risk assessments should be focused on dealing with specific issues of decisions such as:

  - The effectiveness of EPA's decisions to regulate pesticide use.

  - Individual pesticide registration and re-registration decisions and constraints that should be placed on products to maintain safety.

  - Manufacturing permits for chemicals or processes.

  - Determinations regarding the safety of genetically modified organisms.

  - Industry decisions to bring a new product or formulation to the market.

  - National Pollution Discharge Elimination System (NPDES) permit decisions to regulate thermal pollution and other non chemical stressors.

  - Regulation of compounds falling under multiple agency jurisdictions (e.g., military production).

  - Assessing the ecological risks and uncertainties of exotic new technologies for which there may not be existing regulation (e.g., nanotechnology, regulating polyhalogenated organics).

  - Determination of whether non-indigenous species should be introduced into a region. It is not clear whether there is sufficient guidance on how to conduct problem formulation for this kind of risk assessment. For example, is problem formulation guidance robust enough to conduct problem formulation for assessing the risks of introducing the Asian oyster into Chesapeake Bay? How should uncertainty be handled?

- Determination of how regional considerations should be factored into the use and application of products (e.g., the use of commodity chemicals like boron in various ecoregions with different soils and characteristics).

- Decisions accounting for the spatial distribution of product-use patterns (e.g., decisions concerning the use of pesticides on 100,000,000 acres are different from decisions concerning the use of product on 100,000 acres).

- Determining differences between the ecological risks of formulated product mixtures and constituent ingredients.

- Decisions concerning disposal of products (e.g., should current disposal techniques for pharmaceuticals be modified to avoid harm to the environment from wastewater release.

- The following problem formulation issues associated with product health and safety decisions were identified.

  - Pesticide registrants conduct problem formulation to identify assessment endpoints, measurement endpoints, and a range of conceptual models. A tiered approach to risk assessment is used. However, the tiered approach may not capture all effects. Passing a screening level does not mean that there are no adverse effects associated with the proposed use of a product.

  - Levels of concern and risk quotients are used to drive problem formulation in product health and safety risk assessments, but they may not represent realistic protection goals. Measurement endpoints should be more closely tied to appropriate assessment endpoints.

  - The problem formulation stage of product health and safety risk assessment should address all routes of exposure and tiered assessments. However in some cases problem formulations are generic and therefore all routes of exposure (e.g., dermal exposure) or receptors are not considered. There is a need to consider release pathways, fate and transport, and sensitivity to target the risk assessment and tie measurement endpoints to the appropriate assessment endpoints.

  - Currently, problem formulation in product health and safety risk assessments is often not oriented toward decision making (e.g., it may not be realistic to ask whether there is a risk, it may be more appropriate to question the magnitude of the risk). Available tools and data can drive the direction of problem formulation (e.g., if dermal exposure models are not available, skin is not considered as a route of exposure).

  - Ground truthing, follow up to risk assessments, and validation should be part of problem formulation. Frequently, problem formulation does not adequately address the complexity of a system in terms of time and space. The need for monitoring should be addressed in the problem formulation stage of a risk assessment. Levels of concern should be re-evaluated and validated with monitoring studies. These concerns should be addressed in EPA's guidance documents.

- The following issues concerning the use of testable hypotheses in ecological risk assessments were identified.

  – Because testable hypotheses may represent "yes/no" answers, they may not always be useful in risk assessments. Problem formulation should be designed to provide an evaluation or quantitative description of magnitude of risk along a continuum. Hypotheses are embedded in a conceptual model, but the objective of an ecological risk assessment is to describe the likelihood, probability, magnitude, and consequences of effects. Therefore, well formulated risk questions (e.g., what is the probability and magnitude of the effect of pesticide y on endpoint x?) may be more useful than testable hypotheses.

  – Testable hypotheses can be framed in such terms as statistically significant effects and quantile endpoints. Such hypotheses may be useful because they may not represent yes/no answers. However, if desired outcomes are clear to decision-makers yes/no answers can support management decisions.

  – Testable hypotheses may be useful if applied to appropriate tiers of evaluation. In this regard, questions such as "does exposure exceed a concentration at time x in a river?" or "does a model provide adequate protection against releases to the environment?" may be useful. However, hypotheses should not be confused with regulatory decision criteria.

- In risk assessments for product health and safety decision making, a generic approach to problem formulation is often followed. Problem formulation is often dictated by regulatory constructs, especially for screening level risk assessments that are conducted in the same way for many chemicals. In early tiers of risk assessments, problem formulation may be defined more by precedent and policy, but problem formulation becomes more refined in subsequent tiers. Stakeholders can offer criteria and levels of concern that enable such refinements. A dialogue with risk managers is a key step in completing an improved problem formulation process. Additional tools such as software packages could be developed to assist in problem formulation. Risk assessments conducted for pesticide registration decisions require careful problem formulation.

- A concern discussed by the group is that risk assessments currently do not provide a complete understanding of risks posed by cumulative effects, interactions among communities, and multiple stressors and impacts. To develop this knowledge, monitoring efforts should be better coordinated within multiple agencies of the federal government to support ecological risk assessments. Coordination is needed to integrate monitoring programs and use resources for multiple purposes.

- Data collection activities can be improved and focused on providing the most important information by evaluating the current level of confidence in decisions. Sensitivity analyses can be conducted to parse out sources of uncertainty and determine what additional information is useful.

- Laws that drive various product health and safety programs articulate protection goals differently. Therefore explicit cross-cutting ecological protection goals have not been defined. There is a need to develop consistent definitions of what should be protected across media.

Health and Product Safety Decision Making in the Face of Uncertainty

- Ecological risk assessments often fail to identify and prioritize additional information that would be needed to reduce the uncertainty of the assessment. The risk assessment process could be improved by explicitly identifying uncertainties, the consequences of those uncertainties, and the additional information that would reduce those uncertainties. "What if" questions could be posed for each uncertainty. A specific example discussed was the need to develop tools to provide additional information for conducting improved ecological exposure assessments.

- Although various statutes require consideration of risks and benefits, ecological risk can be relegated to a "nonfactor" in decision making if there is great uncertainty in identifying risks. Uncertainties should be clearly identified to risk managers so that they can evaluate the need for conservative or risk tolerant decisions.

- Decisions in the face of uncertainty will be made using extrapolation factors, and therefore conservative management decisions may be needed.

- Tools that can be developed and applied to help focus problem formulation, reduce uncertainty, and refine risk assessments. These include tools for evaluating geospatial data, and probabilistic risk assessment methods.

- Stakeholders should also provide input on "value" issues. Risk management decisions should reflect stakeholder values.

- It would be useful to develop a case study to show how uncertainty could be reduced by assessing cumulative risk for an emerging technology or a new product. This case study could focus on building a conceptual model, constructing a screening approach, and completing a risk assessment. Potential case examples discussed included pressures from invasive species and chemical exposures. It would be difficult to develop such a case example on a national scale, so a regional scale might be considered. The Heinz Center report on the State of the Nation might provide knowledge that would be useful in considering responses of ecosystems to multiple stressors.

- Additional tools are needed to develop more efficient screens for assessing ecological risk. Additional sources of data and models should be considered, evaluated, and adapted. It will be important to leverage the efforts underway in a number of different federal agencies and academia to seek multiple values from data and tools

APPENDIX M - SUMMARY OF MANAGEMENT OF CONTAMINATED SITES BREAKOUT GROUP PARTICIPANTS, PANEL DISCUSSION, AND REPORT

Facilitator: Michael Newman, College of William and Mary

Rapporteurs: Richelle Allen-King, University of Buffalo and Timothy Thompson, Science, Engineering and the Environment

Panelists:
Vicki Meredith, Wyoming DEQ
Michael Fry, American Bird Conservancy
Mark Sprenger, U.S. EPA
Ralph Stahl, Dupont

Participants:
John Bascietto, DOE
Matthew Behum, Integral Consulting
Nancy Bettinger, MA DEP
G. Allen Burton, Wright State University
Patricia Casano, General Electric
William Creal, Michigan DEQ
Gregory DeCowsky, DNREC
Anne Fairbrother, U.S. EPA
Thomas Forbes, U.S. EPA
Barry Forsythe, U.S. FWS
Carolyn Hammer, U.S. EPA
Laura Haynes, U.S. EPA
Miranda Henning, ENVIRON Corp.
Dale Hoff, U.S. EPA
Michael Johns, Windward Environmental
Ron Josephson, U.S. EPA
Thomas La Point, University of North Texas
Jeff Margolin, Environ
Joseph Meyer, University of Wyoming
Anne Rea, U.S. EPA
Kevin Reinert, AMEC Earth and Environmental
Keith Sappington, U.S. EPA
Lisa Saban, Windward Environmental
John Schaffer, Tetra Tech
Sean Smith, US Navy
Glenn Suter, U.S. EPA
Kristen Wandland, ENSR
John Wardell, U.S EPA
Randall Wentsel, U.S. EPA
Kathleen White, U.S. EPA

Panel Discussion - Ecological Risk Assessment in Management of Contaminated Sites - *Facilitator: Dr. Michael Newman, Virginia Institute of Marine Science, College of William and Mary; Rapporteur: Mr. Timothy Thompson, Science Engineering and the Environment; Invited Panelists: Ms. Vickie Meredith, Wyoming Department of Environmental Quality; Dr. Michael Fry, American Bird Conservancy; Dr. Mark Sprenger, U.S. EPA, Office of Superfund Remediation and Technology Innovation; Dr. Ralph Stahl, DuPont Corp. (See Panel biosketches in Appendix J)*

Dr. Newman opened the discussion by providing context for the panel discussion and the breakout group session. He described four cross-cutting issues for the discussion of ecological risk assessment for remedial decision making at contaminated sites:

1. Evaluating the effects of spatial and temporal scales
2. Assessing risks at different biological scales
3. Problem formulation and testable hypotheses in risk management
4. Decision making in the presence of uncertainty

The panelists provided initial perspectives on these issues from the points of view of a state decision maker (Vickie Meredith), the environmental and conservation community (Dr. Michael Fry), an EPA ecological risk assessment practitioner (Dr. Mark Sprenger), and the regulated industries (Dr. Ralph Stahl).

Ms. Meredith's Presentation

Ms. Meredith is a geologist and contaminated site manager with the Wyoming Department of Environmental Quality (WDEQ). She noted that her experience as a geologist and a risk manager makes understanding all of the elements of the overall ecological risk assessment process a challenge. From a state decision maker's perspective, Ms. Meredith noted that the ecological risk assessment process is one of several decision-making tools to (1) diagnose the problem; (2) provide input on how to remedy the problem; and (3) evaluate whether the remedy itself is going to cause other problems.

Ms. Meredith discussed the application of the ecological risk assessment as part of a cleanup determination at a former refinery site in Casper, Wyoming. The refinery was originally a Resource Conservation and Recovery Act (RCRA) site. As part of a settlement of a citizen's lawsuit in 1998, the responsible party (BP/Amoco) was required to conduct corrective action at the site, and oversight of the program was transferred from the U.S. EPA to the Wyoming Department of Environmental Quality (WDEQ). The site was a unique challenge because the community of Casper wanted to redevelop the property, but a decision on cleanup levels and actions to protect both ecological and human health risk had to be made within three years.

In order to meet this deadline, a collaborative process was established to bring together all of the stakeholders to develop the assessment and study, and formulate the remedial decision. While ultimate decision making rested with the WDEQ, the stakeholders included the BP/Amoco, EPA, the U.S. Fish and Wildlife Service, Wyoming Game and Fish, Wyoming Department of Transportation, and the community (city, county, and citizens groups). Use of the ecological risk assessment paradigm was helpful because it provided an established process to support decision making. Problem formulation and articulation of data quality objectives (DQOs) were done in collaboration among all of the stakeholders, and all decisions were made as transparent and open as possible.

Risks and remedies for the 3000-acre site included upland receptor risks and risks to benthic infauna, fish and birds from historic contamination and groundwater discharge to the North Platte River. The assessment also evaluated risks to fish, birds, and piscivorous mammals from refinery wastewater and residuals that were pumped into a playa lake in the central bird flyway. The risks and remedy decisions needed to be made rapidly and safely. Problem formulation was done very early, followed by the development of DQOs as initial investigations were conducted at the site. There were no presumptive remedies going into the process. While ecological receptors at the playa lake and river were judged to have "moderate risk" using a weight-of-evidence approach, remedies that removed the sources were chosen in collaboration with BP/Amoco.

From the lessons learned at this site, WDEQ developed its Voluntary Cleanup Program (VCP) guidance documents (http://deq.state.wy.us/volremedi/index.asp). The overall VCP risk assessment process is similar to EPA's. Wyoming incorporated initial screening steps that allow for "off-ramping" the process for smaller sites. For example, the ecological exclusion assessment allows exclusion of a site from assessment by answering simple questions, such as, "is there habitat?", and, "are there threatened or endangered species?" Wyoming's perspective is that an ecological risk assessment would not be needed for such uses as a parking lot.

Discussion of Points Raised by Ms. Meredith

Group discussion following Ms. Meredith's presentation focused on what constitutes weight-of-evidence. Workshop participants noted that:

- The ecological risk assessment process lacks a common understanding of what weight-of-evidence means, and that more clarity would be helpful. It was stated that there were at least four different definitions, but as yet there is no common consensus on what weight-of-evidence means.

- The National Research Council[1] recently advocated the use of weight-of-evidence, without providing context for what that means. A general recommendation suggested by members of the panel and group was that the EPA SAB further investigate the issue of what constitutes weight-of-evidence.

[1] National Research Council. 1996. Understanding risk. Informing decisions in a democratic society. National Academy Press, Washington, D.C.

Dr. Fry's Presentation

Dr. Fry stated that from the perspective of the environmental and conservation community, the ecological risk assessment process is too long and at times is encumbered with extensive and unnecessary investigations that do little to aid the exposed ecological resources. After the ecological risk assessments are complete, there may be long and costly litigation that delays cleanups even further. During these delays, little is done to aid the ecological resources that are subject to continued exposure over the entire period of time. A streamlined risk assessment process (e.g., a "programmatic" ecological risk assessment) that would lead to more rapid cleanups would greatly benefit natural resources.

Dr. Fry noted that the four focus questions posed to the group for consideration emphasized the problem formulation stage of risk assessment instead of clean-up and reducing the immediate risks to ecological receptors. From the perspective of the environmental community, when a contaminated site is identified or listed EPA has already made an assessment that the release of a hazardous substance has occurred and the environment is at risk. With regard to risk assessment for management of contaminated sites he noted that:

- Focusing on the effects of spatial scale is not relevant in determining whether or not the site is contaminated.

- Furthermore, focusing on larger populations effects can mask the fact that smaller highly contaminated sites are causing mortality in individuals. The main emphasis in ecological risk assessments for contaminated site management should be on how to clean up the site as opposed to determining whether a site should be cleaned up.

- Dr. Fry asserted that the first question to be answered is how to remove or control the greatest risks in a timely fashion. The next step is to assess whether there is additional environmental contamination that should be addressed. Dr. Fry discussed two contrasting cases where this important question was addressed differently.

- The Exxon Valdez oil spill was a case of a large environmental release that, while large, was a relatively simple site from the perspective of problem formulation and cleanup. The problems and risks were identified quickly, cleanup was conducted, and a long-term monitoring program was put in place to determine if the system was recovering or additional actions were required.

- By contrast, DDT releases into the southern California Bight involved 20 years of investigation and an additional 10 years of litigation, during which ecological resources continued to be exposed to DDT.

Dr. Fry commented on the use of probabilistic risk assessment for management of contaminated sites and the influence of politics on risk management decisions.

- He acknowledged that a modeling assessment may be useful in making judgments about the relative importance and uncertainty of the risks, but probabilistic assessments are not a substitute for field data. Field data are needed to make remedial decisions.

- Dr. Fry also expressed the view that the environmental community often perceives that good science is circumvented by political decisions. EPA's proposal to publish a tissue-based selenium criterion instead of the well developed water quality criterion was, in his view, a good example of this. This appeared to be a political decision based upon relaxing the selenium water quality standard rather than basing the decision on good science. He stated that when the politics of cleanup undermines science, it corrupts the system.

Discussion of Points Raised by Dr. Fry

After Dr. Fry's presentation the group discussed the following points.

The group discussed Dr. Fry's observation that ecological risk assessments and associated investigations have not been focused on whether to clean up, but how much to clean up. Workshop participants noted that investigations of the nature and extent of contamination and evaluations of potential risk reduction associated with resources expended are required elements under contaminated sites statutes. Dr. Fry agreed, but stated that the paradigm could be shifted to focus first on clear and obvious hot spots or source removal and then use a long term monitoring program to determine what else should be done. A workshop participant expressed the opinion that it is important to keep the science in the ecological risk assessment separate from the political process.

One participant offered the observation that for some contaminated sites, it may not be necessary to factor ecological risk assessments into cleanup decisions. As an example he cited the Tannery Bay site in White Lake (near Lake Michigan), where the sediment clean up criteria were based on the extent of observed color (purple) and the presence of hides and hair. Even though there were high levels of chromium and mercury found in the sediments (up to 5,000 ppm), there were no adverse effects observed in toxicity testing of the sediments. In this case, the site was remediated mainly because the lake was used as a "landfill", not because of ecological risks.

Dr. Sprenger's Presentation

Dr. Sprenger is an ecotoxicologist with U.S. EPA's Office of Solid Waste and Emergency Response (OSWER) and one of the authors of EPA's 1997 ecological risk assessment guidance for Superfund. Dr. Sprenger stated that his experience is principally with Superfund contaminated sites. Under the Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) and the associated National Contingency Plan (NCP), ecological risk assessments are inherently part of a legal process, bounded by the laws of that process, and are therefore constrained by the legal process and social pressures associated with these sites. Dr. Sprenger described some of the legal/regulatory requirements and constraints for ecological risk assessment under CERCLA.

- As defined by regulations under CERCLA, the role of the ecological risk assessment is that it (1) establishes a legal authority for an action, and (2) develops the information that can be used to set the preliminary remediation goals.

- CERCLA constrains the ecological risk assessment process in that it may only consider chemical releases, the ecological risks should be evaluated within the confines of the site, and the protective remedies should address the standard set in the law.

- Many Superfund sites are relatively small, 2 to 10 acres, and by legislative requirement a remedy should be protective of human health and the environment within the site boundaries. By law, the site investigation (including the ecological risk assessment and the remedy) should focus on the site, or the investigation is not a legal expenditure of resources under the law. This can preclude looking at larger spatial, temporal, or even population-level effects that would occur outside the site.

- There is sufficient flexibility written into the ecological risk assessment guidance documents to consider the issues of scale, time, and populations. However, application of scales in contaminated site risk assessments is constrained by:

    1. Legal requirements under CERCLA;
    2. Timing and funding issues associated with conducting the site investigation; and
    3. Uncertainty by site managers as to how the additional information will assist them in making site management decisions.

Dr. Sprenger described a paradoxical situation arising in the case of point source releases to a stream. At the local site level, a community level response could be readily demonstrated. However, relative to a population level view of the entire stream, there may not be an impact even though a point impact might be observed. Under CERCLA, a remedy should protect resources at the point release (i.e., "the site"). While the Agency is open to assessing risks at different scales, practical considerations make this difficult. There is a need to explore how the Agency could implement spatial, temporal, and biological scales within the confines of the law.

Dr. Sprenger commented on problem formulation in ecological risk assessments for CERCLA and decision making in the presence of uncertainty. He observed that:

- Formulation of specific problems incorporating testable hypotheses has not been effectively conducted across all CERCLA site evaluations. There is a need to explore how to bring more specificity into the problem formulation and risk question setting, as this process has not been changed for many years.

- Decision making in the presence of uncertainty is constrained by the legislative program regulating the site. Where there is uncertainty, Agency decision-makers should select the conservative protective remedy.

- Additional data can reduce the uncertainty associated with decision making, but there is a financial tradeoff between study cost and remediation cost that needs to be considered.

- There are sites where a remedy will always be the same in terms of scale and cost, and additional study won't change the risk management decision. For example, in the case of industrial lagoons a lot of money can be spent on investigations and risk assessments, but the need for remediation is known and the options and scale of the remediation are known. Sometimes this is misconstrued as selecting the remedy beforehand and then constructing an ecological risk assessment to fit the preconceived notion.

- Under CERCLA, ecological risk assessments are conducted to provide information for site-specific remedies. There are opportunities at some sites to conduct good studies that can influence remedy costs in a positive way. The Clark Fork River in Montana is an example that illustrates how the study and the ecological risk assessment helped point out opportunities to protect human health and the environment while not having to undertake the costly removal of all contaminated soils and sediments.

- The risk assessment community could benefit by having additional examples or case studies that highlight how the conduct and findings of the ecological risk assessment did or did not impact the final remedy decision.

Discussion of Points Raised by Dr. Sprenger

The group discussed the following points in response to Dr. Sprenger's observations on questions related to spatial, temporal scale and population level risk assessments.

- Some participants noted that incorporating spatial considerations into an ecological risk assessment is a "slippery slope" in the sense that one should determine how far to go down that path before the site assessment is meaningless.

- Incorporation of temporal scale can be equally "slippery." Temporal scale is discussed even less than spatial scale. Implicit in remedial decision making for contaminated sites is that sites should be returned to functionality as soon as possible. However, it is also important to think of these decisions in terms of ecological timelines.

- Dr. Sprenger noted that consideration of spatial and temporal scale can be feasibility study questions that define bounds beyond which no further action or natural attenuation can be considered. However, he noted that if temporal and spatial boundaries are large enough, toxic effects could be lost in the noise.

- A participant pointed out that the problem of assessing effects which are often severe at a point of maximum exposure versus assessing effects for an entire stream, lake, or forest (where the effect may be negligible) can be avoided by defining an assessment population or assessment community using EPA's generic ecological assessment endpoints[1]. This problem may be addressed by recognizing that the endpoint attribute for a population or community may be defined at a lower level of organization[2]. For example, if the assessment population is the clapper rails in a marsh treated with pesticides or sunfish in a stream reach receiving waste leachate from a storm event, then the attribute may be the proportion killed by a treatment or leaching event (an organism-level attribute). It is not necessary to apply a population-level attribute such as changes in the population growth rate.

- A participant pointed out that in ecological risk assessment additional investigations can be balanced against reduction in remediation costs as well as reduced uncertainty associated with the nature and extent of contamination and exposure.

Dr. Stahl's Presentation

Dr. Stahl has been involved with ecological risk assessment for DuPont since 1993. He noted that DuPont has conducted work at 188 sites in the U.S. and others overseas, and that about 20 sites are under active consideration at any one time. He stated that risk-based decisions are being made in Europe as well as Latin America and Asia. Dr. Stahl expressed the opinion that ecological risk assessment of contaminated sites can be improved, and he focused his comments on the workshop's cross-cutting issues.

- The problem of addressing spatial scale may be made more tractable by finding areas with commonalities and parsing out some of the space issues. He noted that historically there have been many ecological risk assessments conducted at small sites, but large sites such as the Hudson, Housatonic, or Passaic Rivers are being or will be assessed in the future and the issue of scale can be better examined. Mining sites are also examples of large sites.

- Adding temporal scale to risk assessment is difficult because many sites have slow, chronic releases of contaminants, but there are no available data on original conditions to assess the ecological effects that may or may not have occurred. It is difficult to predict what a site will look like after implementing a remedy, and temporal scale issues may not receive attention because industry does not view remediation as a long-term business opportunity. Companies are in the business of

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[1] U.S. EPA. 2003. *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessmen*t. EPA/630/P-02/004B. Risk Assessment Forum, Washington, DC.
[2] Suter, G.W. II., S.B. Norton, A. Fairbrother. 2005. Individuals versus Organisms versus Populations in the Definition of Ecological Assessment Endpoints. *Integrated Environ. Assess. & Manage*. 1:397-400.

removing liabilities from their corporate books. Generally, follow-up monitoring is not done, possibly because risk managers may not want to find out they made the wrong decisions.

- An approach to risk management decisions in the face of uncertainty might be to provide a mechanism for making and implementing remedial decisions, and then requiring long-term monitoring that could trigger additional work if the expected risk reduction is not achieved.

- Regarding the assessment of risks at different biological scales, Dr. Stahl noted that it is easier and cheaper to do small-scale individual studies, and then extrapolate those to populations. While tools are available to conduct population-level studies, it is important to understand whether the decision is so important that it is necessary spend the money and time to conduct those kinds of investigations. The Department of the Interior has started a Natural Resource Damage Assessment and Restoration Advisory Committee under the Federal Advisory Committee Act to look at similar issues. One of the objectives of this committee is to determine if there is a way of constraining investigations and get to an answer in a reasonable amount of time, and these findings will likely relate to risk assessments.

- The problem formulation stage of risk assessment seems to be receiving greater attention than it has in the past and is involving EPA and stakeholders earlier in the process. A difficult part of problem formulation is getting the risk managers to spend the time to talk through all of the issues. It is important that the risk assessment team talk through data collection and actions to be taken based on the results. It is important to identify testable hypotheses, but they need not necessarily be statistically-testable. Rather, they are a set of conditions that the parties believe may be occurring and are tested accordingly.

- For decision making in the face of uncertainty, there are really three options:
    - More study to reduce uncertainty;
    - Make a decision and move on; or
    - Make a decision with monitoring and triggers for further action if needed.

Dr. Stahl identified two big issues that require additional attention to improve ecological risk assessments: 1) assessment of multiple stressors, and 2) watershed level assessments.

Discussion of Points Raised by Panelists

Workshop participants discussed a number of points following the panel presentations.

- A participant asked whether looking specifically at the ecological conditions at a site would result in more conflict with local authorities. Ms. Meredith responded that for her site she brought all the stakeholders together early to articulate their needs, but in the end the WDEQ made the final decision. Dr. Sprenger pointed out that at the

Coeur d'Alene Superfund site the remedy was well received in Idaho where there was support for the mining industry, it was not well received downstream by constituents in Spokane, Washington. In this case, a watershed approach to the risk assessment was needed because there were multiple constituencies.

- A commenter observed that the ecological risk assessment guidelines discuss "the likelihood of adverse effects," but this can mean different things. Most risk assessments just look at harm and are not predictive. There is not consensus on what is "harm." Dr. Sprenger stated that this is why problem formulation needs more attention. Superfund risk assessments might apply environmental epidemiology or toxicology studies but not probabilistic risk assessment. Dr. Sprenger stated that in fact, most Superfund ecological risk assessments are more "toxicological risk assessments" or "hazard assessments" – not necessarily a true "risk assessment."

- A state site manager stated that he wants to know what risks need to be mitigated and the level of certainty associated with those risks. He stated that assessors and managers need to sit down together early and, without compromising the integrity of the science, make sure the assessors understand the kind of information the manager will need. Furthermore, there is a need to understand not only the cost of the remedy and the resultant reduction in risk but also to understand the impact to the environment of implementing the remedy. This analysis is generally not done in the ecological risk assessments but could be part of problem formulation.

Ecological Risk Assessment in Management of Contaminated Sites Group Summary Report

Definition of Spatial and Temporal Scale in Ecological Risk Assessments for Management of Contaminated Sites

- During the problem formulation stage of an ecological risk assessment, it is important to consider spatial and temporal scale and representative data collection issues. Spatial scale is important in evaluating exposure routes at contaminated sites. Spatial components have a major influence on large sites, and sampling plans should match the scales of sites. Temporal scale should be considered when determining time frames for remediation of contaminated sites.

- The appropriate temporal scale of a risk assessment will depend on the chemical contaminants, media, and episodic events to be considered. Other issues to be considered in determining temporal scale include specific ecological receptors, possible reoccurrence of contamination, and recovery time of the system. It is important to reach agreement with stakeholders on scale issues during the problem formulation stage of the risk assessment.

- It is also very important to understand the hydrology at a contaminated site in order to address issues of connectivity and deposition, and determine the appropriate spatial scale of the risk assessment.

- It will be important for EPA to provide information to states on "lessons learned" about the effect of spatial and temporal scale issues on the quality of analyses. It is very difficult to pull this kind of information from existing state and EPA databases.

- During the problem formulation stage of the risk assessment, it is important to match the scale of exposure sampling with the effects questions being answered (i.e., the receptors). It is not possible to complete an accurate risk characterization unless exposure is linked to effects.

- In the problem formulation stage of the risk assessment, it is important to consider whether neighboring sites within a watershed should be included in the assessment. It is current practice to sometimes assess risk at contaminated sites without considering the cumulative risks within a watershed.

- At small sites, a "streamlined" risk assessment process is often used. This approach can result in insufficient problem formulation and affect the quality of analyses. During problem formulation, it is particularly important to link the data quality objectives process to the risk assessment so that representative data can be collected.

The group discussed how spatial and temporal scales can affect the utility of analyses. The following issues were discussed and recommendations for improvements in the process were identified.

- The utility of analyses conducted in ecological risk assessments are dependent on the linkage of spatial and temporal scale with biological organization. It is essential to match the scale of a risk assessment with the questions that should be answered.

- The scale of a study conducted to assess ecological risks at a contaminated site should match the scale of the remediation alternatives considered. Remedial alternatives such as bulldozing and dredging are associated with differing levels of precision and a risk assessment of one size may not provide appropriate information to support these activities.

- An iterative ecological risk assessment process should be applied at contaminated sites where long-term problems should be addressed. This procedure would enable adaptive approaches to be applied to risk management.

- Peer review should be conducted after the problem formulation stage of a contaminated site risk assessment and then repeated at points throughout the process.

- The technical sophistication of a contaminated site ecological risk assessment is not always justified by the utility of the information provided. More resource requirements and higher costs for the risk assessment do not always equate to higher quality and utility. It is important to ensure that representative data are collected.

- It is important to ensure that sampling plans for ecological risk assessments at contaminated sites match the scale of the site to be assessed.

- Ecological risk assessments could be enhanced by making the process more iterative and conducting peer review after problem formulation and throughout the process.

- Risk assessors should take advantage of recent advances in technology and tools for the analysis and interpretation of data. Application of such tools can enhance ecological risk assessments. These tools include: geographic information system mapping technologies, remote sensing technologies, spatial statistics, population and exposure modeling, and improved access to large databases.

- Risk assessors should focus more attention on data quality relative to representativeness of the data.

- Ecological risk assessments conducted at sites where the chronic sublethal effects are of concern could be enhanced by applying population and community models. Such models are not often used and additional guidance is needed for application of these kinds of models.

- There is a need for a national database containing information on ecological risk assessments that have been conducted for management of contaminated sites and other purposes. Case examples could be included in such a database to provide useful information on the strengths and weaknesses of various risk assessment approaches. Central data exchanges are improving. For example, five year EPA Superfund program reviews provide useful abstracts of risk assessment study results.

- Additional basic life history information, such as home ranges and organism distribution, is needed for many species to improve assessment of exposure to contaminants and ecological risk. There is often a mismatch between available ecological and toxicity information for species at contaminated sites.

- Long-term ecological research is needed for some large scale contaminated sites. Post remediation monitoring is needed to improve our understanding of how risk assessments can be enhanced. Criteria should be set for assessing the outcome and success of contaminated site remediation. Exploratory long-term ecological research can also be conducted at these sites, and adaptive management approaches can be demonstrated.

- Ecological risk assessment for management of contaminated sites should be approached from a watershed perspective, not from only the perspective of operable units.

Definition and Incorporation of Biological Scale into Ecological Risk Assessments for Management of Contaminated Sites

- It is important to initially define what resources are to be protected (answer the "so what?" question) and identify the appropriate assessment endpoints. The main concern of ecological risk assessors should be effects on populations. However, risk assessments are currently often focused on the protection of individuals and therefore may not be of high quality.

- Species distributions of LC50s do not relate to protection of communities and therefore may or may not be protective. There is a high level of uncertainty in the level of protection associated with the use of species sensitivity distributions.

- Ecological risk assessments are not often focused on assessing indirect effects such as those associated with habitat loss or competition. Toxicity studies may not reflect the state of populations in the field.

- Attributes of populations may be incorrectly applied in ecological risk assessments. For example, concepts such as the protection of functional feeding classes should be considered. There is a need to communicate why higher level entities such as feeding classes should be important as receptors and endpoints in a risk assessment.

- It is important to link the nature of contaminants to the appropriate receptors and develop an understanding of why particular organisms should be studied.

- The question of remediation versus restoration of contaminated sites drives study designs for ecological risk assessments at contaminated sites. The consequences of making a mistake also drive the design of the study (e.g., consideration of the effects of persistent organic pollutants versus consideration of the effects of nutrients).

- In some but not all cases, protecting individuals may protect populations. Focusing risk assessments on individuals will therefore result in some level of uncertainty in the assessment of effects on populations. The level of certainty associated with ecological risk assessments can be increased by using multiple lines of evidence of biological responses. However, all lines of evidence are not equal in quality, and rules are needed to define how multiple lines of evidence should be evaluated.

- Evaluating a small number of species a site will lead to uncertainties that can hamper decision making. The power of various lines of evidence should be assessed during problem formulation to determine which line of evidence is useful for decision making.

- The ecological risk assessment process could be enhanced by using population models. More models could be used early in the risk assessment process and "pre-surveys" could be used to look at the power of various kinds of analyses. Sensitivity analyses would be useful in this regard. EPA should consider recommending or identifying appropriate models for various uses and developing a menu of optimal tools for use in certain risk assessment scenarios.

- "Informed consent" during problem formulation is important. Risk assessors should determine how and when the assessments, and data generated, will be used.

- Data and metrics on rates are needed to make predictions concerning appropriate levels of biological organization.

- Life history information could be augmented for many species of concern. There is great need for additional life history information for vertebrates. Information for more species should be included in EPA's exposure factors handbook. Additional research is needed to provide more life history information for common or important species and to link tissue residues and toxicity test results to biological levels of organization (e.g., to link tissue residues to community effects).

- The quality of ecological risk assessments should be improved so that decisions are legally defensible.

- Benefit/cost assessments are needed. Ecologists and economists do not communicate well because typical monetization methods cannot be used for ecological systems. However, it is important to assess the benefits associated with risk management alternatives. More information is needed for valuation of resources and assessment of ecological services and this information should be provided on multiple scales and from the perspective of multiple stakeholders.

Overarching Recommendations Concerning Spatial and Temporal Scale for Ecological Risk Assessment at Contaminated Sites

- Methods exist to conduct ecological risk assessment at different scales, but more relevant data and explicit guidance are needed to do this. It is particularly important to have more guidance on how to evaluate lines-of-evidence.

- In the problem formulation stage of the risk assessment, it is essential to get clear "buy in" from stakeholders on the scales to be considered. It is also important that stakeholders understand that large spatial scales and long temporal scales require modeling. Outside peer review and stakeholder input is necessary during problem formulation. Use of an iterative process and adaptive management will also promote stakeholder buy in to the process. In addition, is important to emphasize the importance of problem formulation in driving the risk assessment.

- Models should be applied in the problem formulation stage of the risk assessment. During problem formulation, applicable population, community, and landscape models should be selected for use. These models should be used to identify uncertainties and conduct sensitivity analyses.

- A very clear statement of the consequences of remediation should be developed (i.e., risk versus remedy versus time scale). Development of such a statement is essential for risk assessments conducted at large scales.

- It is important to consolidate lessons learned from previous risk assessments to guide future risk assessment activities.

- There is a great need for short- to long-term post remediation monitoring activities in order to conduct improved outcome assessment (e.g., long-term ecological research model). These activities should be part of original planning for a baseline comparison.

- Effective communication with stakeholders and relevant professionals is absolutely essential in conducting risk assessments at critical scales, especially broad scales.

- Tangible action from EPA to address guidance and research needs is essential in order to realize the full potential of considering spatial and temporal scale issues in ecological risk assessments.

Problem Formulation

- A number of preliminary issues were discussed by the group including:

  - The need for clarification during the problem formulation of the natural resource goals and cleanup management decision that would be made under CERCLA, RCRA, and state programs. For example, if managers will be making a decision based on human health concerns, should the problem formulation reflect this early on?

  - What role could, or should, net benefit analysis have in problem formulation? Net benefit analysis (NBA) compares incremental positive effects as a result of removing or mitigating a contaminant or pathway, with incremental negative effects that can occur such as disturbing habitat for threatened and endangered species. The need for, and tools to conduct NBA should be considered during the problem formulation.

  - What role should cost benefit analyses (CBA) have and what are the tools available to do that? Participants noted that conducting cost-benefit analyses would require more work than is usually completed for an ecological risk assessment. Participants questioned whether cost-benefit issues should be separated from other science-based questions.

- An "up front" analysis of questions that are critical to decision making can be useful in deciding what to measure in a risk assessment. For example, if decision makers knew that their decision might be based on effects on a particular species, they might not want to invest heavily in certain measures. In this regard, there is tension between a managers' need for a timely, economical, implementable solution to a contaminated site problem and the scientists' desire to reach the best possible answer through research.

- A participant expressed concern that limited studies do not provide a basis for a comprehensive cost-benefit analysis for contaminated site remediation. In this regard, it is important to consider not just the population protected, but how protection affects interactions with other species. Because risk assessments always focus on a subset of organisms, assessors do not gather data needed to assess all of the benefits of remediation.

- Other participants noted that assessors might work with stakeholders to prioritize risks during problem formulation and decide which are the most important. Concern was expressed that it might be difficult to do this early in the process and that an iterative problem formulation approach might be useful.

- EPA's Guidelines for Ecological Risk Assessment should be more widely and consistently used in problem formulation. A reviewer checklist associated with the Guidelines should be developed. The goal of the checklist is 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. The implementation of such a checklist would improve the clarity and consistency of the process for all involved. The checklist could be evaluated by all parties at the end of problem formulation, or could be the basis for a peer review.

- A recommendation is that a peer review be conducted at the end of the problem formulation stage to ensure that the science applied in the risk assessments is appropriate to the management goals. Currently, scientific review of risk assessments does not occur until after the data have already been collected and analyses completed. Independent review at the end of the problem formulation stage of a risk assessment would insure that assessment endpoints could be linked to goals, and that the science applied would provide the data needed to answer the risk management questions. An additional peer review, at the completion of the draft risk assessment, will continue to be useful.

- The group discussed the stage of the process when peer review occurs, and the extent to which modifying the timing of peer review could improve the process. For high priority (i.e., high risk, high cost) sites, problem formulation and study design should be submitted for peer review by an independent scientific panel prior to implementation of the study. Such peer review early in the process will strengthen ecological risk assessments. Peer review would be beneficial at sites where there is conflict about the study design as well as at sites where there are no conflicts. The identification of sites where early peer review would be triggered could be based on a recommendation or predetermined criterion or based on a post remediation audit evaluation of prior risk assessments. The composition of a panel convened for problem formulation may be different from the composition of a panel formed for a study design review.

- Problem formulation could also be improved by identifying very specific endpoints such as effects on populations. However it is important to link measurement endpoints to assessment endpoints. A concern to be considered when quantifying measurement endpoints in the problem formulation stage is the possibility of prejudging an assessment. It is important to distinguish between the data quality objectives process and a determined level of effect that would trigger management action. These are problems associated with implementing EPA's Guidelines for Ecological Risk Assessment rather than problems associated with the Guidelines document itself.

Incorporation of Testable Hypothesis into the Design of Ecological Risk Assessments for Management of Contaminated Sites

- Participants expressed the opinion that the term "testable hypothesis" does not belong in the problem formulation step and actually confuses the issue or creates conflict. Testable hypotheses with well defined error rates may not provide the information needed to estimate risk. Estimation of risk is the purpose of the risk assessment.

- Regulated parties at contaminated sites frequently criticize contaminated site risk assessments as being too vague; removing testable hypotheses from the assessment could make this criticism sharper. However, estimation methods could be substituted for hypothesis testing. For example, after formulating a risk management decision that is based on an unacceptable (i.e., remediable) risk or toxic response for a specific receptor group, an estimator in the form of an expected toxicity testing a dose response curve should be developed. Participants noted that consideration of testable hypotheses or estimation methods could be moved from the problem formulation into the data collection step of an assessment.

- Participants suggested that it might not be necessary to require testable hypotheses. However, if they are to be applied in risk assessments it will be necessary to provide improved definition and guidance for their development. It is particularly important to provide guidance concerning the statistical element of the testable hypothesis (e.g., Type I and II error).

- EPA's Framework for Ecological Risk Assessment is very useful and is "standing the test of time." However there are differences in the practice of ecological risk assessment from site to site, and additional help or guidance would be useful.

- There is a general lack of understanding of whether remediation of contaminated sites has resulted in the ecological improvements upon which the requirement for action was based. This is not a problem associated with the existing ecological risk assessment framework but with follow-up monitoring and evaluation of remedial actions. However, it is difficult to measure the success of remediation, and it has not been sufficient to demonstrate that a limited number of contaminated site remediations, permits, or other actions have been successful. Two recommendations from the discussion were that (1) to the degree practicable the Agency or SAB should evaluate improvements brought about by site remediation, and that (2) long-term monitoring should be explicitly considered during the problem formulation, and in the remedy decision documents. The latter may require development of an appropriate guidance document.

- It is important to involve risk managers in problem formulation at an early stage of the risk assessment. A rigorous framework for addressing risk management decisions at an early stage of the assessment, without compromising the process and precluding important alternatives, would be useful. Greater attention should be focused on ensuring that the selected measures of risk for which data will be collected are appropriate in the context of their intended use in decision making. It may be beneficial to use a conceptual site model for initial analyses needed to facilitate these kinds of discussions.

Contaminated Site Decision Making in the Face of Uncertainty

- There are cases in which a probabilistic risk assessment can be useful in conveying the uncertainty of an ecological risk assessment. However, in many cases a probabilistic ecological risk assessment that incorporates the variety of uncertainties associated with ecosystems may not help management decisions. Dealing with ecological risks is unlike human health risk assessments in which a large amount of data are available to assess effects on a single species. Therefore, it is important to have clear exposition of the magnitude of the factors driving the uncertainty of the ecological risk assessment, the sources of the parameters, and the assumptions used. In some cases sensitivity analysis can be useful in this regard.

- Risk assessors should be aware that some uncertainties, such as those associated with interspecies extrapolation, are not easily quantified. Moreover, explaining probabilistic risk assessments to the public can be difficult, and these kinds of risk assessments can be difficult to interpret. It is easier to communicate a deterministic hazard quotient used in a risk assessment than a probabilistically derived hazard quotient. If probabilistic risk assessments are conducted, risk assessors should ensure that those who review and use the results know what the results mean and can distinguish “good” results from “bad.” Probabilistic risk assessments can also be correct but may miss major issues.

- Probabilistic approaches are, however, useful in understanding the implications and degree of protectiveness of various remediation options.

- A post remediation audit program could reduce decision-making uncertainties at new contaminated sites. EPA, in conjunction with other agencies, should evaluate the effects of clean-up on sites remediated 5-20 years ago. Such a retrospective analysis will build a database that could be used to reduce uncertainty in decision making.

Net Environmental Benefit

- Net environmental benefit analysis is an important tool that could be used to a greater extent in the practice of ecological risk assessment. Net environmental benefit analysis can be used to evaluate the risks of a contaminated site remedies to the ecosystem and answer questions such as “does cleanup cause more harm than good?” Net environmental benefit analysis can also be used to compare the risks of various remedy options to the ecosystem. Where appropriate and warranted, net environmental benefit analysis could be incorporated into a risk identification feasibility study. This concept has already been incorporated into EPA’s Guidelines for Ecological Risk Assessment; however EPA should develop a process and/or tools for conducting net environmental benefit analysis at an appropriate spectrum of sites.

APPENDIX N - SUMMARY OF NATURAL RESOURCE PROTECTION BREAKOUT GROUP PARTICIPANTS, PANEL DISCUSSION, AND REPORT

Facilitator Kenneth Dickson, University of North Texas

Rapporteurs Judith Meyer, University of Georgia and James Oris, Miami University

Panelists
Bruce Hope, Oregon Dept. of Environmental Quality
Eugenia McNaughton, U.S. EPA
Jennifer Shaw, Syngenta
Terry Young, Environmental Defense

Participants:
Steve Bay, SCCWRP
Pietr Booth, Exponent
Grant Cope, Congress
Clifford Duke, Ecological Society of America
Robert Frederick, U.S. EPA
Tala Henry, U.S. EPA
Chester Joy, U.S. Government Accountability Office
Lawrence Kapustka, Golder Associates
Iain Kelly, Bayer Crop Science
Danny Lee, U. S. Forest Service
Deborah Lester, King County Natural Resources
Lawrence Master, NatureServe
Bernalyn McGaughey, Compliance Services International
Angela Nugent, U.S. EPA
Marianne Ottinger, University of Maryland
Judith Meyer, University of Georgia
Joan Pioli, Menzie-Curie and Associates
Damian Preziosi, Integral Consulting
Amanda Rodewald, Ohio State University
Andy Rowe, GHK International
James Sanders, Skidaway Institute of Oceanography
Stephanie Sanzone, George Mason University
Rita Schoeny, U.S. EPA
Michael Slimak, U.S. EPA
Robin Stewart, USGS
Eric Stokstadt, AAAS
Vivian Turner, U.S. EPA
Ivor van Heerdon, Louisiana State University
Steven Wharton, U.S. EPA
Rick Ziegler, US EPA

Panel Discussion – Ecological Risk Assessment in Natural Resources Protection *– Facilitator: Dr. Kenneth Dickson, University of North Texas; Rapporteur: Dr. James Oris, Miami University; Invited Panelists: Dr. Bruce Hope, Oregon Department of Environmental Quality; Dr. Eugenia McNaughton, U.S. EPA Region IX; Dr. Jennifer Shaw, Syngenta Corporation; Dr. Terry Young, Environmental Defense (See Panel biosketches in Appendix J).*

Dr. Dickson introduced the panelists and stated that the purpose of the session was to discuss how to advance the state of the practice of ecological risk assessment for natural resource protection. He commented on how risk assessments for the purpose of natural resources protection are different from other kinds of risk assessments. He noted that in these kinds of risk assessments assessors should often be concerned about stressors other than just chemicals. Such assessments should often be conducted at landscape scales. He encouraged the panelists and participants to discuss issues, challenges, and make the recommendations necessary to "take ecological risk assessments for natural resource protection to a higher level." He also introduced four cross-cutting issues to be discussed in the session: 1) Effects of spatial and temporal scales; 2) Biological organization; 3) Problem formulation and testable hypotheses; and 4) Decision making in presence of uncertainty.

Dr. Young's Presentation

Dr. Young introduced a document developed by the EPA Science Advisory Board Ecological Processes and Effects Committee, *A Framework for Assessing and Reporting on Ecological Condition*[15] (SAB Framework Report). Dr. Young discussed the following points:

- The SAB Framework Report was developed to provide advice and recommendations to EPA on how to evaluate the ecological condition of systems.

- The SAB Framework Report establishes a hierarchical scheme to describe systems, and provides endpoints and factors to consider during the problem formulation stage of an ecological risk assessment.

- The SAB Framework Report is focused on attributes, not stressors. EPA is good at focusing on stressors, but condition parameters can be used to evaluate multiple stressors.

- Many attributes are associated with ecological condition. Therefore, a hierarchical scheme and guiding principles are needed to look at patterns and processes. Dr.

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[15] U.S. EPA Science Advisory Board. 2002. *A Framework for Assessing and Reporting on Ecological Condition: An SAB Report*. Edited by T. F. Young, and S. Sanzone, EPA-SAB-EPEC-02-009. U.S. Environmental Protection Agency, Washington, D.C. (http://www.epa.gov/sab/pdf/epec02009.pdf)

Young referred to Table EF-1 in the SAB Framework Report and described how biotic condition could be described using the hierarchy to explicitly focus on the species and population level while also looking at communities and ecosystems.

- In conducting ecological risk assessments it is important to ask the question, "are there landscape effects?" Biological scales are embedded in the hierarchy in the SAB Framework Report. Processes are also embedded in the hierarchy. Use of the hierarchy also enables the consideration of time scales. Dr. Young suggested that the group might talk further about how the might be useful for looking at ecological risk assessment.

Dr. Shaw's Presentation

Dr. Shaw commented on the issues proposed for discussion in the workshop breakout session. She talked about the importance of the following issues and offered suggestions for improvements to enhance the practice of ecological risk assessment for natural resources protection.

- Effects of spatial and temporal scale. Consideration of scale is very important to informed decision making. Species location and distribution will drive the spatial and temporal scale of an assessment. Spatial and temporal scales need explicit definition during the problem formulation stage to be most accurate and useful for decision making. If risk assessors are explicit about this at the beginning of the process, they can provide information to make management decisions more accurate and reduce the potential economic impact of actions taken. Dr. Shaw identified the following opportunities for improvements in consideration of spatial and temporal scale:

  - The quality of risk assessments could be improved by having better information to characterize stressors, species distribution, and land-use characteristics.

  - There is an opportunity to use more standardized methods and tools to form a working basis for characterizing stressors.

  - There is an opportunity to have more consistent development of higher quality spatial data layers.

  - There is an opportunity for improved efficiency through single reviews of metadata with enhanced updating and managing of data layers.

  - There is an opportunity for multiple stakeholders to provide different types of data and data layers used in risk assessments. More information can also be made available to stakeholders.

- Consideration of level of biological organization. It is important to be specific about resources that need to be protected. EPA is implementing regulations, policy, and guidance at the programmatic levels that will affect assessment endpoints. To improve the performance of the risk assessments, there is a need to ensure that risk assessments can inform decisions that have to be made. Dr. Shaw stated that an appropriate biological scale should be well defined for effective risk management decisions. It is important to know how decisions will be made. It is important to understand what the risk manager is protecting, and this should drive the biological scale of the risk assessment.

- Problem formulation and adequacy of testable hypotheses. It is important to ensure that risk assessments will provide the information needed to support risk management decisions. Problem formulation needs to clearly identify protection goals. Policy goals should also be established. Dr. Shaw identified the following opportunities for improved efficiency and effectiveness in problem formulation and use of testable hypotheses:

  - It is important to recognize that improved problem formulation processes effectively set up the work of risk assessment.

  - Toolboxes of conceptual models are needed for use in problem formulation. It is important that risk assessors have the ability to easily modify such models for application to particular types of regulatory action.

  - Increased consistency in development of testable hypotheses is needed.

  - Species-specific conceptual models are needed.

  - The toolbox should contain a tool that could be used to develop an analysis plan. This would eliminate redoing work that has already been completed by others.

- Decision making in presence of uncertainty. The reality of risk management is that decisions are made with some degree of uncertainty. To decide how much uncertainty can be accepted, it is necessary to look at the quality and relevance of risk assessment. It is necessary to consider how much additional work should be done to reduce uncertainty and how much the assessment is improved by this work. Additional information can provide an understanding of factors such as exposure route and can significantly reduce uncertainty. Risk assessments can drive risk management decisions that result in tradeoffs affecting natural resources. Such tradeoffs should be carefully considered. For example, risk management decisions may result in loss of pesticide products needed to manage invasive species. Risk management decisions may result in loss of agricultural areas. It is necessary to put risk management decisions into a bigger context and consider the practicality of implementation. Dr. Shaw identified the following opportunities for improved risk assessment to enhance decision making in the face of uncertainty:

- It is important to spend time looking at the practicality of risk assessments and risk management decisions.

- It is important to make an effort to separate science from policy.

- Risk assessors and risk managers need to ensure that they are using the best available science.

- Careful consideration of risk communication is needed.

- Statements concerning risk need to be much clearer. Risk assessors need to identify "things that risk managers can't do anything about."

- Risk assessors need to separate variability from uncertainty in order to determine where risk assessments are inadequate.

Dr. McNaughton's Presentation

Dr. McNaughton discussed assessment of ecological risks posed by selenium in the Central Valley of California. She described the assessment and issues that were addressed to focus on the protection of natural resources.

- The Central Valley in California is an area where there is alluvial soil and it is dominated by farming.

- The land in this area is drained for agriculture. The Bureau of Reclamation has been concerned with how the salt water can be drained and removed from the land. The Bureau decided to move drained water into vacant land. It was drained into the Kesterson Wildlife Refuge.

- In draining the soil, selenium was mobilized. It bioaccumulated and was found to be toxic to birds. The grasslands district is north of this area, and grasslands farmers also moved water into a different site in certain times of year.

- EPA and other federal agencies have been working with farmers to find solutions to the selenium problem. Farmers proposed using the drainage water and moving it to the San Joaquin River. They agreed to reduce the selenium in the drainage water by using on-farm practices. This has been a very positive step toward finding a solution to the problem and it has evolved into the first monthly nonpoint source Total Maximum Daily Load (TMDL) determination in California.

- The area now has a very good monitoring program. Toxicity testing on fish is conducted once per month. Water quality, sediment quality and biological monitoring is conducted monthly.

- The State of California can be proud of accomplishments. The project has met the TMDLs in seven out of eight years. Levels of selenium going into and out the grasslands have been reduced. In some areas (e.g., Mud Slough) levels of selenium have stayed high, but in other areas (e.g., Salt Slough) levels have declined in the water and in the tissues of monitored species. Biological monitoring has allowed risk assessors and risk managers to determine how well risk management measures are working.

- It is important to note that consideration of bioaccumulation has added much complexity to the ecological risk assessment and there is work yet to be done because there is still selenium in system.

- In conducting the risk assessment it was necessary to rely on water quality criteria that had already been developed. Initial objectives were based on those water quality criteria. However, bioaccumulation occurred, and the ecological system was impacted.

- Migratory bird species and sturgeon in rivers are now found in lesser numbers. Initially there was not enough information available to make decisions. However, it was necessary to make decisions and it is now necessary to keep reviewing these decisions as more monitoring information becomes available. EPA has been unable to look at the larger question of whether the environment benefited from the decisions that have been made.

Dr. Hope's Presentation

Dr. Hope stated that he has been with the Oregon Department of Environmental Quality for ten years. During that period of time he has been applying science in risk assessments to support the development of regulations. He commented on the issues to be discussed in the session from his perspective as a risk assessor in a state regulatory agency.

- Spatial and temporal scale. Dr. Hope pointed out the importance of considering spatial and temporal scale issues in ecological risk assessments. Spatial and temporal cale are important issues to consider because of habitat requirements of organisms. These issues are less important in human health risk assessments. However, inappropriate legal or other constraints may prevent risk assessors from addressing ecologically relevant spatial and temporal scales. Scales that are ecologically relevant may not be manageable on legal scales.

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- Biological scale. Dr. Hope pointed out that Oregon is the only state that requires evaluation of populations of organisms in its regulatory risk assessments. However, it is problematic to create rules that protect populations. Many say that population assessments are too data-intensive, and habitat boundaries are too difficult to define, to conduct risk assessments at these levels of biological organization. However, moving from science to regulation or from research to operations typically takes from five to twenty years. We are really just beginning to understand to how to move from science to regulation in ecological risk assessment.

- Decision making in presence of uncertainty. Dr. Hope pointed out that regulators are always looking for "bright line" standards. A "bad" number is often considered to be better than no number. Oregon is one of two states that have published regulations on ecological risk assessment. These regulations require more data and competent practitioners to interpret the data. In many cases there is too much work and few who can complete the work. Risk assessors and managers have found that going from good ecological risk assessment research to practical use is difficult.

- Problem formulation. Problem formulation is the most important thing to consider in the ecological risk assessment. More data, time, and money should be focused on problem formulation. Unfortunately there is pressure to conduct assessments quickly and inexpensively, and this has resulted in the development of conservative screening systems that may be of limited use. The results of analyses conducted using these screening systems may not provide definitive results. This is a problem because the public does not like to see regulators changing their minds.

- Needs for application of "cutting edge" risk assessment methods. The State of Oregon is trying to apply cutting edge methods in ecological risk assessment. But these require money. It will be necessary to ask whether we value resources enough to spend the money to conduct cutting edge risk assessments. We may not need a twenty five year study, but we do need better definition of habitat boundaries. It is important to understand that:

  - Risk assessment work only needs to go "far enough" to be practical.

  - It is hard to get people to articulate testable hypotheses but they need to be spelled out.

  - An analysis plan has to answer a question posed by a testable hypothesis.

  - Problem formulation can save time in the field and help avoid work that is not needed.

Discussion of Points Raised by Panelists

Participants discussed the following points in response to panelists' presentations:

- A participant noted that the state of Delaware has taken "a beating" over revision of the arsenic standard. He stated that there is not enough money to reassess the standard. The participant stated that perhaps the burden of proof of standards should be on those who want to exploit public trust resources.

- A participant questioned how much responsibility scientists have in educating decision makers about the limits of risk assessment methods and tools. He stated that clients ask how risk assessments should be conducted, but scientists have a responsibility to explain the complexity of risk assessments.

- A participant commented that the polluter should pay for ecological protection. He noted that this issue is built into statues. However, there is a need to better define goals. A level of problem formulation needs to occur in the societal realm.

- A participant commented that if a goal of risk management is to conserve populations, the present way of going about risk assessment (i.e., use of single species tests to assess risks before contaminants are registered) will never accomplish that goal. The commenter noted that he was not convinced that it is cheaper to use single species tests in risk assessments.

- A participant commented on the SAB Framework Report presented by Dr. Young. She noted that there might be some procedural steps that people should go through during problem formulation (e.g., landscape effects, hydrology, and geomorphology) that would enhance risk assessment. There may be a need for a professional checklist. She stated that an example to be considered is the protection of wetlands. Assessors need to look at landscape level attributes and the hydrology of the area. Assessors need to look at geomorphology and disturbance regimes. Formulas and a checklist could be used to develop problem formulation templates

- A participant noted that the language used in the SAB Framework Report is appropriate, but it is important to plug it into problem formulation. Assessors may find that regulated industries will need to provide better information. It is also important to show regulators the benefits of more transparency. The participant also noted that laws and regulations have not been chiseled in stone. Progress can be made by influencing laws and regulations.

- A participant noted that the concept of natural system protection is important. For example, a great value of wetlands protection is reduction of storm surges. The participant noted that he would like to see the value of a system "beyond the critters" to be brought into ecological the risk assessments.

Dr. Dickson's Summary

- Dr. Dickson noted that that a number of topics and ideas for improving risk assessments had been raised, and that the discussions would continue the following day.

- He reiterated Dr. Young's idea of assessment of biological condition. He noted that if condition were understood, it could be communicated to the public. He noted that there is also a need to understand habitat quality conditions at the beginning of a risk assessment.

- He noted that there is a need for more guidance and information on appropriate tools for ecological risk assessment and how they can be linked together. The inadequacy of toolboxes might be an area for further discussion.

Ecological Risk Assessment in Natural Resource Protection Breakout Group Summary Report

- Members of the group commented that the definition of quality and utility of an ecological risk assessment should reflect the needs of both risk managers and stakeholders.

- It is important to consider appropriate spatial and temporal scales in the risk assessment in order to avoid missing underlying processes.

- Early peer review of the risk assessment study designs is needed.

  - Peer review should occur between Problem Formulation and Analysis stages of risk assessments where appropriate (e.g., natural resource protection or management of contaminated sites)

  - Peer review of study designs prior to initiating work plans will enhance the quality and efficiency of risk assessments.

  - Early peer review will help assure that the assessment study design and implementation are appropriate for the risk management goals.

- Resource constraints may limit the spatial and temporal scales that are applied in a risk assessment, and this may impact the quality of the risk assessment. Insufficient analysis may, however, be worse than no analysis.

- It is important to use spatial scales that are large enough to see patterns emerging across a landscape. This viewpoint will provide insight into the assessment of cumulative effects. Examples of emerging effects that should be considered at a broad scale include declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

- Broad scales bring the interests of more stakeholders into consideration and can also blur details. However, fine scales may exclude regional and global trends that affect local conditions. This perspective may leave the process subject to influences of local politics.

- Spatial and temporal scale analysis may help to integrate a risk assessment into a meta-analysis or assessment of a larger scale impact. Such an analysis may also develop a body of knowledge useful for other risk assessment projects.

- It is important to explicitly incorporate spatial and temporal scale into a conceptual model, report it out transparently, and incorporate scale into uncertainty analysis.

- Tools are available to bring spatial and temporal considerations into the analysis. It is not clear whether the number of practitioners with expertise in these areas is sufficient to meet risk assessment needs. Useful tools include geographic information system continuous monitors, and models as well as species life history information. If additional spatial resolution is needed to describe species abundance and distribution, this perspective should be included in the uncertainty analysis.

- It would be useful to assemble case studies that document the value of incorporating the appropriate spatial and temporal scales into a risk assessment. These case studies should be marketed to risk managers.

- Tools for completing common risk assessment activities, such as vulnerability analysis, should be provided to risk assessors.

- An interagency effort could be undertaken to develop an ecological version of the Integrated Risk Information System (IRIS) that would provide information needed for risk assessments.

Levels of Biological Organization in Ecological Risk Assessments for Natural Resource Protection

- The EPA Science Advisory Board Framework for Assessing and Reporting Ecological Condition should be used as a reference checklist to ensure that appropriate levels of organization are considered.

- It is important to be cognizant of the fact that indirect effects are important in risk assessments and they are revealed at levels of biological organization above populations. Risk assessors should consider effects at the community, habitat, and landscape scales (e.g., chemical predisposing trees to disease).

- It would be useful to develop standard techniques for assessing risks at specific levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by the sediment quality triad (this includes information on: benthic community measures, sediment toxicity tests, and sediment chemistry).

- In determining the biological scale for assessment endpoints, it is useful to identify the level where the effect is most obvious and then look one level up and one level down.

- The state of the science of ecology is not the state of the practice of ecological risk assessment. It is important to facilitate the transfer of science into practical use.

Ecology is a science and ecological risk assessment is the art of practically applying a continuum of tools.

- Opportunities for research, data collection and demonstration tools to enhance ecological risk assessment include:

  – Studies (including data mining) to assess the value of and uncertainty associated with moving from individual to population level assessments.

  – Studies to search for emerging patterns for groups of chemicals (e.g., quantitative structure activity relationships to predict community or landscape-level effects).

  – Side-by-side demonstrations of different tools for assessing effects on populations and communities. Such studies are needed to test the relative efficiency of methods.

Cross-cutting Issues Concerning Spatial, Temporal and Biological Scale in Ecological Risk Assessment for Natural Resources Protection

- A website is needed to provide ecological risk assessment information that is truncated in journal article publications or that is otherwise unavailable to ecological risk assessment practitioners. It would be useful to investigate how to make data from work performed under government contracts available to risk assessors.

- Risk communication training is needed for both risk assessors and risk managers.

- Cumulative risk should be rigorously incorporated into risk assessments.

- Findings from reactive risk assessments should be used to inform proactive risk assessments. Scientists should clearly identify what relationships are testable and determine which testable alternatives provide the most information for the cost.

- Uncertainty analysis concerning spatial and temporal scale and higher order effects should be explicitly included in risk assessments.

- Incorporation of appropriate scales and consideration of multiple levels of biological organization in ecological risk assessments will provide a record and body of knowledge to improve future risk assessments.

Other Points and Issues Concerning Scale and Level of Biological Organization in Ecological Risk Assessments for Natural Resources Protection

- Problem formulation is a critical step in ecological risk assessment to adequately define appropriate scale and biological organization. Peer review of this phase would help assure that the assessment study design and implementation are appropriate for the risk management goals.

- Standards of practice are needed for ecological risk assessment. These standards should include a checklist of ecological condition assessments to consider; spatial and temporal scale and biological levels of organization to consider; standards for assessing cumulative risk; standards for developing case studies; and standards for transparency in ecological risk assessment.

- If data are insufficient to conduct analysis at an appropriate scale, this deficiency should be acknowledged "up front" (transparency) and addressed in the uncertainty analysis.

- Case studies are needed to demonstrate the use of practical tools for incorporation of appropriate spatial and temporal scales and levels of biological organization into ecological risk assessments.

Unique Issues Associated with Ecological Risk Assessment for Natural Resources Protection

- Risk assessments for natural resources protection differ from other kinds of risk assessments. Risk assessments for natural resources protection are more closely tied to a "value" oriented paradigm. Other kinds of risk assessments are conducted from a stressor perspective. In assessments for natural resources protection, there is a need to identify the ecological attributes that should be protected and to determine how they can be protected.

- In protecting natural resources, it is important to consider "natural" change, or changes driven through global processes (like climate change). There is a need to know how natural change will influence other changes that might be noted in the system under study.

- In protection of natural resources it is necessary to consider linkages between ecological risk assessments and effects assessments. For example, setting water quality criteria is an effects assessment because when the criteria are developed little is known about exposure. When a discharge permit is written more information is provided about exposure that can lead to a risk assessment. There is a continuum of processes between effects assessment and risk assessment.

- In natural resources protection assessors are looking at broad scales, but the specific questions addressed by a study can be local or global. This difference in scale should be clearly addressed in the problem formulation stage of the risk assessment. Decisions can be made at very small scales but they should be made in the context of much broader scales. It is also important to consider the point that chemicals are not the only stressors to be evaluated in ecological risk assessments for natural resources protection.

Problem Formulation and Testable Hypotheses

- Both problem formulation and incorporation of testable hypotheses affect the quality of a risk assessment. Paying proper attention to both concerns leads to higher quality decisions, but testable hypotheses can be misused and this problem can lead to degraded decision making.

- Natural resources protection should begin with an examination of critical ecological attributes. Specific endpoints can then be established on the basis of specific hypotheses. This process will result in more useful (higher quality) analyses.

- In many risk assessments there has been a lack of problem formulation. Some studies have been designed with drivers such as a total maximum daily load or a permit in mind, and these studies may measure the wrong attributes of the system. By initiating a study with careful problem formulation, these problems can be avoided. At times, risk assessors also work with available data without identifying data gaps. Decisions are then made with incomplete information, and conclusions are not supportable. Higher quality decisions will result if problem formulation, testable hypotheses, and data collection are designed "up front."

- It is important to change the way we think about hypotheses. It is important to move away from traditional hypothesis testing with null models that can be easy to manipulate and difficult to formulate. In risk assessment, hypothesis testing will result in null models that are developed without considering how to balance Type I and Type II errors. There is a need to move toward more innovative methods such as Bayesian analysis and causal argumentation. Hypotheses should focus on causal relationships and weights of evidence.

- Problem formulation and testable hypotheses narrow the focus of questions to be asked and allow risk assessors to apply the most appropriate tools.

- In the problem formulation process, it is necessary to first identify sensitive and realistic measurements. For example, endocrine disrupters do not often kill animals so it is necessary to look at their potential effects over fifty years, not two years. It is not always necessary to look at catastrophic effects. Assessors should consider long-term effects. Linkages should be made between tools that can sensitively measure impact and actual effects at a more appropriate (e.g., population or landscape) level.

- It is important to build a mechanistic link between toxicity and other stressors and effects on populations and communities. There is a need to take mechanistic approaches from the laboratory and apply the appropriate relationship at a population or community level. This approach will require more work to identify and assess true links between molecular, cellular, and organismal responses and impacts that can be noted in populations or communities.

- Ecology should be brought back into the process. There are many innovative approaches that can be used to look at risk assessment issues from a different perspective. Risk assessors should not be caught in the traditional paradigm of using the endpoints from toxicity tests in risk assessments. Individual mortality may not be the most sensitive endpoint for assessing risks to a population. Risk assessors should consider effects on populations or communities and endpoints such as the number of impaired individuals using resources and not reproducing.

- It is important to ensure close and frequent communication between risk managers and risk assessors. Both groups should be involved in problem formulation and the development of testable hypotheses.

- Most risk assessments are carried out at the local level and often local intellectual capital is not enough to provide adequate problem formulation. There is a need to ensure that training and guidance are available for people who are involved in risk assessment. EPA has developed some good risk assessment documents and these should be used to train risk assessors.

- Monitoring programs need better direction to provide information that can be used to conduct risk assessments. Monitoring programs should be redesigned so they can provide information to help test improved hypotheses. Risk assessors who are working with existing data should influence how new data are collected by monitoring programs.

- To avoid fragmented analyses, there is a need to better integrate work that has been conducted in different disciplinary areas (e.g., biology, vs. chemistry, toxicology vs. ecology). For example, EPA has developed biological and chemical water quality criteria separately. Expert systems could be developed to enable the integration of specific chemical and biological endpoints and to identify classes of chemicals to be assessed.

- In problem formulation, it is important to look at problems at multiple levels of organization.

- Problem formulation should include the development of site conceptual models that represent interactions and ecological processes that could be important at a community landscape level (e.g., habitat fragmentation).

- More innovative techniques should be used for hypothesis testing or alternative analyses. Likelihood statements could be incorporated into problem formulation rather than binary (yes/no) statements.

- Explicit identification of multiple stressors is needed in problem formulation. It is important to move beyond the single stressor model.

- It will be important to consider providing guidance to formalize the development of specific linkages that indicate how data will actually be used to inform decision-makers and lead to appropriate decisions. This step should occur in the problem formulation stage.

- Hypothesis statements should be linked to explicitly stated process goals. Risk managers often do not have the information needed to make decisions and may not know how to get it. Causal arguments should be systematically included in problem formulation. Confidence intervals should be built into testable hypotheses, and a process should be followed to determine whether indicators are appropriate for a purpose.

- Scientific review is another important tool that should be applied. In many cases scientific review of risk assessments has occurred when data have already been collected and analysis has been completed. Independent review at the end of the problem formulation stage of a risk assessment would ensure that assessment endpoints could be linked to goals.

Natural Resource Decision Making in the Face of Uncertainty

- Uncertainty can drive conclusions that identify risk when, in fact, there may be no adverse effects. It is therefore important to identify appropriate measures and assessment endpoints. Uncertainty can be minimized by using appropriate analytic measures with sufficient power.

- It is important to remember that risk managers and risk assessors address uncertainty differently. Risk managers should decide what level of uncertainty is acceptable. Risk assessors should select methods that enable quantification of uncertainty. The Guidelines for Ecological Risk Assessment identify many different kinds of uncertainty, and it is important to be able to say which ones affect risk. Risk managers and risk assessors should therefore communicate effectively, and the most profound uncertainties should be identified *a priori*.

- Uncertainty in risk assessments can reduce the utility of an assessment by leading to paralysis in the decision-making process. Uncertainty also gives more weight to factors like cost in a risk management decision. In addition, uncertainty affects the ability of risk assessors to extrapolate results between sites. When there is a large amount of uncertainty, only site-specific risk assessments are possible.

- There is a need to conduct relative assessments of uncertainties so that risk managers can "plan around them." It is particularly important for risk managers to articulate how much uncertainty they can tolerate.

- It is important to recognize the difference between uncertainty and variability. Variability can be written into assessment endpoints as part of the data quality objectives process. This allows assessors to avoid mistakes like using analytical methods with bad detection limits that are higher than effects concentrations.

- Uncertainty also affects the utility of a risk assessment because the timeline for a decision and the timeline needed to observe effects in the field may be disconnected.

- Risk assessors should explore the use of alternative methods of analysis such as likelihood matrices and Bayesian methods. EPA might consider developing guidance on how to construct likelihood arrays that can be integrated into risk assessments.

- Risk assessors should explore opportunities to use statistical methods that better inform the risk assessment process such as power analysis and sensitivity analysis.

- Elements of uncertainty should be identified and incorporated into problem formulation and built into the design of a risk assessment. From a qualitative perspective, uncertainties should be categorized, and those that profoundly affect results and outcomes should be identified. There is a rich literature on disaggregating analytical variability, stochastic variability, and model variability. It would be useful to consider available tools for use in problem formulation.

- The uncertainty associated with key variables in risk assessments should be assessed to help reduce overall uncertainty.

- Each ecological risk assessment represents an opportunity to understand uncertainty. EPA should take advantage of this for future risk assessments. In this regard data should be mined from EPA Superfund and other documents.

- A better interface with monitoring programs should be developed so that data could be collected for the purpose of improving risk assessments. Specific monitoring projects could be designed to provide data that could reduce uncertainty in risk assessments.

- It was suggested that specific white papers on the following topics could be developed to reduce uncertainty and provide information for improved ecological risk assessments:

  - Methodological guidance to describe multiple outcomes in a likelihood matrix.

  - Quantitative inspection of dose-response models to determine slopes, functional forms, and error rates.

  - Determining differential sensitivity of test animals in the field vs. laboratory responses.

  - Guidance on the use of cumulative stress and effects models.

  - An approach to address fluctuating variability in exposure models.

  - Conceptual and arithmetic flaws associated with the use of hazard quotients.

  - Determining sources of variability in species responses and sensitivity.
  - Reviewing how to evaluate and express perturbations.
  - Exploring the notion of individual vs. population distinctions (e.g., what the distinctions are and how they should be described).

- An improved interface could be developed for use of current assessment and management tools available from management agencies.

- A key question to be answered is how much uncertainty a risk manager can tolerate. It is important to dissect types of uncertainty in a qualitative assessment to provide information that can help answer this question.

- There is a need for a systematic data collection and organization effort to catalog and make available information from past risk assessments in order to reduce the uncertainty of future risk assessments. This effort should provide better metadata and a centralized data repository for: ecological risk assessment data, endangered species information, FIFRA risk assessment information, Superfund risk assessment information, and the peer reviewed literature.