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Ecological Risk Assessment – An Evaluation of the State of the Practice

A Workshop of the EPA Science Advisory Board
Ecological Processes and Effects Committee

--DFO Note: This is a preliminary draft for Committee review. Presentation summaries in Section 4.0 have not yet been reviewed by the workshop speakers--

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1.0 Workshop Background and Objectives

Ecological risk assessment (ERA) has been practiced for approximately 20 years in a variety of environmental applications. It has a longstanding history in pollution investigations and a wealth of ecological risk assessment and decision-making experience has accumulated. EPA recently published a staff paper[1] describing how risk assessment is conducted at the Agency, and calling for a dialogue with interested parties to improve the practice of both human health risk assessment and ecological risk assessment. In response to EPA's call for recommendations to enhance ERA, the EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) initiated a project to evaluate the current state-of-the-practice and provide advice to advance ERA science and application in environmental decision-making. This workshop was held to gather information that will inform SAB activities leading to advice and recommendations to EPA.

2.0 Workshop Overview

Workshop participants included members of the SAB EPEC, a workshop steering committee comprised of members of the chartered EPA Science Advisory Board, the SAB EPEC, and EPA staff; invited speakers and panel members, workshop facilitators, ecological risk assessment researchers, and practitioners; and members of the public. Workshop participants came together to discuss their cumulative experience, and suggest steps for improving the utility of ecological risk assessments in environmental decision-making. Participants addressed ecological risk assessments in three decision-making contexts: product health and safety; management of contaminated sites, and natural resource protection. For each of the three decision-making applications, workshop participants evaluated four overarching issues: problem formulation and hypothesis testing; spatial and temporal scale; biological scale; and decision-making in the presence of uncertainty.

This document summarizes: key findings and cross-cutting recommendations of the workshop, presentations of invited speakers, the panel discussions, and breakout group reports addressing the overarching issues in ecological risk assessments conducted for product health and safety decision-making, contaminated site management, and natural resources protection.

3.0 Key Workshop Findings and Crosscutting Recommendations

[1] U.S. EPA 2004. *An Examination of EPA Risk Assessment Principles and Practices: Staff Paper Prepared for the U.S. Environmental Protection Agency by members of the Risk Assessment Task Force.* EPA/100/B-04/001. Office of the Science Advisor, U.S. EPA, Washington, D.C. (http://www.epa.gov/osa/pdfs/ratf-final.pdf)

The workshop participants discussed the current state-of-the-practice of ecological risk assessment and came to several general conclusions. Problem formulation is a critical step in ERA and advancing the state-of-the-practice will require: improved communication between risk managers and risk assessors; careful consideration of critical ecological attributes; and moving beyond traditional null hypothesis testing and toward innovative analytical approaches (e.g., Bayesian analysis, causal argumentation). Current methods are available to conduct ERA's at different spatial, temporal and biological scales. However, effective implementation of landscape level ERAs will require more relevant data and explicit guidance to better integrate multiple lines of evidence for a range of biological responses. The utility of ERAs for decision-making can also be increased by application of probabilistic risk assessment methods that include quantitative uncertainty estimates. In addition, the uncertainty associated with ERAs can be reduced by applying systematic approaches to post-ERA monitoring, data collection and data storage. Specific findings and recommendations to enhance ecological risk assessments for various kinds of decisions were provided by workshop speakers and participants.

Key General Findings and Recommendations to Advance the Practice of Ecological Risk Assessment

- It is important to consider uncertainty and probability in risk assessment. Tiered approaches and models have been developed for conducting probabilistic ecological risk assessment and these should be applied in practice. Ecological risk assessors are ahead of their human health risk assessment colleagues in the application of joint probabilities of distributions to assess risk.

- Higher levels of biological organization should be evaluated in ecological risk assessments. Regulated parties and many ecologists prefer that ecological risk assessments be conducted using higher levels of organization. EPA's ecological risk assessments generally use organismal attributes because they are easier to evaluate with currently available methods, and they are understandable by decision-makers and the public. However, when organismal attributes have been used, EPA has been criticized for "protecting individuals."

- Ecological epidemiology useful 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 all effects, but they may not be clearly revealed and determining causality is often difficult.

- Weight of evidence approaches enable ecologists to evaluate multiple types of evidence and multiple lines of evidence within a type and should be applied in ecological risk assessments. Most risk assessment practitioners prefer to consider all

available relevant evidence but some consider the process of weighing evidence to be too subjective. Additional guidance is needed in this area.

- Additional guidance should be developed for conducting cost-benefit analyses. The SAB is currently providing advice on monetizing benefits, but advice is also needed on how to estimate benefits before they can be monetized.

- 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.

- It would be useful to use effects concentrations (EC_x) for screening level assessments. 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 ecological risk assessment endpoints, conducting analysis steps, interpreting consequences, and proposing risk mitigation/reduction actions.

- Focused ecological risk assessment 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.

- Additional toxicity data should be generated to improve species sensitivity analyses used in ecological risk assessments.

- 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 more 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.

Key Findings and Recommendations Concerning the State-of-the-Practice of Ecological Risk Assessment for Product Health and Safety Decision-making

- For product health and safety decision-making, guidance is needed on the use of models to conduct population level effects assessments, particularly for terrestrial ecological risk assessment.

- Many tools are currently available to conduct accurate screening level risk assessments for product health and safety in a short period of time. Such tools can be applied in risk assessments. 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 particular risk assessments for product health and safety should be conducted and what should be protected. As currently described in EPA guidance, the process of problem formulation does not really focus on this important question.

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

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

- Life cycle analysis in ecological risk assessment is not adequately 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 we must now look ahead and correct past mistakes.

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

- 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 must be more closely tied to appropriate assessment endpoints.

- The problem formulation stage of product health and safety risk assessment must 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.

- Ground truthing, follow up to risk assessments and validation should be part of problem formulation in risk assessments for product health and safety decisions. 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.

- Because testable hypotheses may represent "yes/no" answers they may not always be useful in risk assessments for product health and safety decisions. Problem formulation should be designed to provide an evaluation or quantitative description of magnitude of risk along a continuum.

Key Findings and Recommendations Concerning the State-of-the-Practice of Ecological Risk Assessment for Contaminated Site Management

- During the problem formulation stage of an ecological risk assessment for managing a contaminated site 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 must match the scales of sites. Temporal scale must be considering when determining time frames for remediation of contaminated sites.

- The appropriate temporal scale of a contaminated site 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.

- 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.

- 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 for 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 must 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.

- 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 associates with risk management alternatives. More information is needed for valuation of resources and assessment of ecological services and this information must be provided on multiple scales and from the perspective of multiple stakeholders.

- EPA should develop a checklist that can be used to confirm that the necessary ecological risk assessment steps have been completed and explained.

- A rigorous framework should be developed for considering options for remediating contaminated sites early in the process so that the relevancy of the risk assessment can be enhanced without compromising quality.

- For some contaminated site risk assessments, EPA should consider conducting early peer review of the study design. The review should be conducted by external technical experts.

- At large contaminated sites where there is disagreement about the problem formulation it would be useful to include social scientists, and others who have the expertise to address policy questions, on a peer review panel.

- Long term monitoring would provide data that would reduce uncertainty and improve decisions about remedy selection and, perhaps, future risk assessments. EPA, in conjunction with other agencies, should evaluate the effects of clean-up on sites remediated 5-20 years ago. This would build a data base that could be used to reduce uncertainty in new sites.

- Probabilistic risk assessments are not very helpful in communicating uncertainty to managers for CERCLA sites. A summary of the sources and size of major uncertainties would be helpful, however.

- Net benefit analysis may be a cross-cutting issue 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.

Key Findings and Recommendations Concerning the State-of-the-Practice of 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 must 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 such change will influence other changes that might be noted in the system under study

- In natural resources protection, assessors are looking at broad scales but the specific questions addressed by a study can be local or global. This must be clearly addressed in the problem formulation stage of the risk assessment. Decisions can be made at a very small scale, but they must be made in the context of a much broader scale. 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.

- In assessing risks to protect natural resources, it is important to consider using spatial scales that are large enough to see patterns emerging across a landscape. This will provide insight into the assessment of cumulative effects. Examples of emerging effects included declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

- Spatial and temporal scale analysis may help to later 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.

- 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. Tools include geographic information systems, continuous monitors, models, species life history information. If additional spatial resolution is needed to describe species abundance and distribution, this should be included in the uncertainty analysis.

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

- 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 in assessments for protection of natural resources.

- 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., a chemical predisposing trees to diseases)

- Biological scale should be explicit in an assessment endpoint, and it would be useful to develop standard techniques for assessing risks at these higher levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by use of the sediment quality triad (this includes information on: 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.

- It is important to change the way ecological risk assessors think about testable hypotheses. It is important 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. There is a need to move toward more innovative methods such as Baysian analysis and causal argumentation. Hypotheses should focus on causal relationships and weights of evidence.

- 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 must influence how new data are collected in 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 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. 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.

- 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.

- 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.

4.0 Presentations

4.1 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 (See Slides in Appendix G)*

From her perspective as a manager in EPA's Office of Pesticide Programs and Office of Water, Ms. Keehener 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 impacts 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 impacts to 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 must 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 if 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 impacts, 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 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.

4.2 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 (See Slides in Appendix H)*

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 provided funding for the development of probabilistic ecological risk assessment methods and methods manuals. These 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 within EPA has been associated with 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*[2] 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

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 not probabilistic. However it is important to consider uncertainty and probability in risk assessment. Tiered approaches and models have been developed for conducting probabilistic ecological risk assessment. Ecological risk assessors are ahead of their human health risk assessment colleagues in the application of joint probabilities of 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 methods, and they are understandable by decision-makers and the public. When organismal attributes have been used, EPA has been 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 all effects, but they 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

[2] U.S. EPA 1998. *Guidelines for Ecological Risk Assessment.* EPE/630/R-95/002F. U.S. Environmental Protection Agency, Washington, D.C. (http://cfpub.epa.gov/ncea/raf/recordisplay.cfm?deid=12460)

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 endpoints. Representative species and ecosystems and sensitive species and ecosystems are considered in selecting endpoints. Benefits accounting requires estimating all of the ecological effects that are welfare effects and surrogates 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.

4.3 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 (See Slides in Appendix I)*

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.

4.4 Strengths of the Ecological Risk Assessment Process for Use in Decision making - *Dr. Lawrence Barnthouse, President and Principal Scientist, LWB Environmental Service (See Slides in Appendix J)*

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 have 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 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, 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 even better tools to improve future environmental decisions.

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

4.5 Limitations of the Ecological Risk Assessment Process for Use in Decision Making - *Dr. Lawrence Kapustka, Senior Ecotoxicologist, Golder Associates, Ltd. (See Slides in Appendix K)*

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 must 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, certain uncertainty is certain. Risk statements can therefore be easily interpreted as lack of understanding.

- Consideration of space and time scales that may be unrealistic. Space and time scales must 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 play out 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 low 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 NOAEC, LOAEC, and MATC has been widely refuted over the past 20 years. An alternative is to use all of the available data to derive an effects concentration.

- 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 real 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. Real stakeholders are sometimes excluded from the ecological risk assessment process. In such cases decisions may be made in advance of an ecological risk assessment. Data can be manipulated to justify decisions, and there may be little focus on follow-up monitoring to monitor, calibrate, and corroborate the risk assessment.

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.

4.6 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 (See Slides in Appendix L)*

Dr. Bradbury provided an overview of ecological risk assessment conducted to regulate pesticides under the Federal Insecticide, Fungicide, and rodenticide Act. The US EPA Office of Pesticide Programs regulates potential ecological risks of pesticides 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 must 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, and re-registrations for existing products.

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 must be addressed in the context of finite resources and specified, statutory timeframes. To meet its mission, the Program must 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 more fully 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, in 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 impacted 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 must 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 must 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 is 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 the 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 those 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.

4.7 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 (See Slides in Appendix M)*

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 contaminates 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 in separate chapters 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. Lower 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 these receptors had the greatest amount of uncertainty.

Alternatives Considered

The common theme developed in the risk characterization process was that mine waste presents some 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 bank was needed to address terrestrial risks identified in the ecological risk assessment.

It was determined that this remedy 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.

4.8 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 (See Slides in Appendix N)*

Dr. Ohanian discussed EPA's the 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 revise, criteria for water quality accurately reflecting the latest scientific knowledge. Within the context of their Clean Water Act application, EPA must 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 last 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 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.

5.0 Ecological Risk Assessment in Product Health and Safety Decision Making

5.1 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 B)*

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. It is because that knowledge has not been translated into ecological risk assessment.

- Ecological risk assessment does not currently contribute to cumulative risk assessment (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 because; although ecological risk assessment does not presently consider biological stress (e.g., imposition of an exotic species), product health and safety assessments increasingly must address genetic or biological components of products.

- Time and space issues are particularly challenging in making decisions about many products (e.g., pesticides, plastics, PFOA), yet ecological risk assessment 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. 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, 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 kind of thinking, 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 must address such issues as double cropping in agriculture, production of unique crops, environmental conditions such as annual rainfall of more than 60inches 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, and this 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 waterbodies 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 must be of high quality and must 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. We 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 .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 to be answered. Ecological risk assessment is an iterative process and the information available for an assessment depends upon the statutory authority. Under FIFRA industry must demonstrate that products will not cause harm. Under TSCA, the burden of proof is upon EPA to prove potential harm. Sometimes states must 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 must, 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 really 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 must 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 it there is a need to develop additional tools for evaluating cumulative risks. Contaminants are being released into environmental that are already stressed and regulations do not address cumulative stress. Cumulative risk tools are not available.

- A challenging question that must 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 re-registrations or expanded use registrations. Field data are generated over the lifespan of a chemical and these data must 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 ecosystems 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 deep short term impacts on ecosystems. Newer products are associated with shallower impacts that can be seen over a longer period 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 must 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.

5.2 Product Health and Safety Decision Making Breakout Group Report on Assessing Risks at Different Spatial and Temporal Scales and Levels of Biological Organization

The breakout group participants (Appendix D) discussed how well current ecological risk assessment practices for product health and safety decisions address and explain the following cross-cutting issues:

1. Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments?

2. Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for product health and safety decision making.

Specific discussion questions considered for each of these issues are provided in Appendix E.

The following points were discussed by the breakout group and summarized in the workshop plenary session.

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 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 must be explicitly considered in the problem formulation stage of ecological risk assessments. Problem formulation should be an iterative process. 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)

- 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.

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.

- 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)

A written response to the charge questions was provided by one of the lead discussants and is provided in Appendix F.

5.3 Product Health and Safety Breakout Group Report on Problem Formulation, the Adequacy of Testable Hypotheses, and Decision-making in the Presence of Uncertainty

The breakout group participants (Appendix D) discussed how well current ecological risk assessment practices for product health and safety decisions address and explain the following cross-cutting issues:

1. Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments used in product health and safety decision making?

2. Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments used in product health and safety decision-making?

The following points were discussed by the group and summarized in the workshop plenary session.

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

The group initially discussed whether consideration of the life cycle of a product fits into the problem formulation stage of ecological risk assessment. A number of issues were discussed in this context.

- 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 we must now look ahead and correct past mistakes.

- Life cycle issues must be considered with care. "Front-end" issues must be considered carefully considered in product decisions. It can be dangerous to go too far upstream in assessing risks, but, life cycle considerations are "future oriented." Folding life cycle considerations into ecological risk assessment could be useful for evaluating future technologies.

The group identified a number of broad concerns about problem formulation in risk assessment. The group discussed how problem formulation could be improved and whether additional guidance is needed. The following broad issues were discussed.

- There currently appears to be good guidance available on how to conduct problem formulation. Often, however, generic problem formulation is conducted. Endpoints and exposure pathways are predefined whether they make sense or not.

- 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 EMAP program to establish baselines to determine whether regulatory decisions are making an impact on the environment.

- Assessment endpoints currently used in ecological risk assessment do not currently account for long-term dynamics of populations. This is more a technical problem 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.

The group discussed how ecological risk assessment supports product health and safety decision making, and identified the kinds of ecological risk decisions that are related to product health and safety. Participants expressed the opinion that problem formulation for product health and safety risk assessments must be focused on these kinds of decisions. These decisions include:

- 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.

- NPDES permit decisions to regulate thermal pollution and other non chemical stressors.

- Regulation of compounds falling under multiple agency jurisdiction (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 our 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 Group discussed how well problem formulation addresses the specific kinds of product decisions listed above. 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 must be more closely tied to appropriate assessment endpoints.

- The problem formulation stage of product health and safety risk assessment must 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 it 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 group discussed the incorporation of testable hypotheses into problem formulation for product health and safety risk assessments. 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, hypotheses 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.

The Group discussed the need to broaden the scope of problem formulation in ecological risk assessment in order to include issues that have not been addressed in the past. A number of issues were discussed and improvements were suggested.

- 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 it 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 to 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 must 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

The Group discussed how to address uncertainty in risk assessments for product health and safety decision-making. The following issues were discussed and recommendations to improve the risk assessment process were suggested.

- 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 for 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 must 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 must also provide input on "value" issues. Risk management decisions must 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.

6.0 Ecological Risk Assessment in Management of Contaminated Sites

6.1 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: Ns. 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 B)*

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

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), from the environmental and conservation community (Dr. Michael Fry) , from an EPA ecological risk assessment practitioner (Dr. Mark Sprenger), and from the regulated industries (Dr. Ralph Stahl).

Ms. Meredith's Presentation

Ms. Meredith stated that she is a geologist and contaminated site manager with the Wyoming Department of Environmental Quality (WDEQ). She stated that, given her experience as a geologist and a risk manager, understanding all of the elements of the overall ecological risk assessment process is a challenge for her. 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. 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 that brought together all of the stakeholders to develop the assessment, 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; 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, and problem formulation

and articulation of data quality objectives (DQOs) were done in collaboration with 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, risks to benthic infauna, fish and birds from historic contamination and groundwater discharge to the North Platte River, and risks to fish, birds, and piscivorous mammals from refinery wastewater and residuals that were pumped into a playa lake that was in the central avian 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 were chosen in collaboration with BP/Amoco that removed the sources.

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 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 on would be helpful. It was stated that there were at least four different definitions, but as yet there is no common consensus on what that means.

- The National Research Council (DATE) 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 issue of what constitutes weight-of-evidence should be a subject of further investigation by the SAB.

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, 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 this process there is little to aid the ecological resources that are continued to be exposed 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 stated 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. He stated that 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 that:

- Focusing on the effects of spatial scale relates to the use of small determinations to scale up to a larger scale. This issue is not important in determining whether or not the site is contaminated.

- Focusing on larger populations effects can mask the fact the 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 stated that the main question to be answered is how to remove or control the greatest risks in a timely fashion, and then assess if there is additional environmental contamination that must 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 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 there systems 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 time ecological resources continued to be exposed to DDT.

Dr. Fry commented on the use of probabilistic risk assessment in risk assessments for management of contaminated sites and 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, probabilistic are not a

substitute for field data. However, real field data are needed to make remedial decisions.

- Dr. Fry expressed the view that the environmental community often perceives that good science is circumvented by political decisions. EPA's proposed tissue-based selenium criterion over a well-developed water quality criterion was in his view a good example. 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 longer term monitoring program to determine what else should be done. Another opinion was voiced that it remains important to keep the science in the ecological risk assessment separate from the political process.

A participant offered the observation that for some contaminated sites, ecological risk assessments may not be need to be factored 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 due to any ecological risks.

Dr. Sprenger's Presentation

Dr. Sprenger is an ecotoxicologist with EPA's Office of Solid Waste and Emergency Response (OSWER), and one of the authors of EPA's 1997 ERA Superfund Guidance. Dr. Sprenger stated that his experience is principally with Superfund contaminated sites. Under Comprehensive Environmental Response Compensation, and Liability Act (CERCLA) and the National Contingency Plan, 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 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 further constrains the ERA process in that it may only consider chemical releases (as this is what the CERCLA regulates), that the ecological risks must be evaluated within the confines of the site, and that the protective remedies must be to the standard set in the law.

- Many Superfund sites are relatively small, 2 to 10 acres, and under certain pieces of legislation the remedy must be protective of human health and the environment within the site boundaries. Because of these legislative requirements, the Site investigation including the ecological risk assessment and the remedy must focus on the site, or the investigation is not a legal expenditure of resources under the law. This can preclude then looking at larger spatial, temporal, or even population-level effects that would occur outside the site.

- There is sufficient flexibility written into the ERA guidance documents to consider the issues of scale, time, and populations. However, application of these to contaminated sites are 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. For example, a paradoxical situation arises 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 must protect resources at the point release (i.e., "the site"). While the Agency is open to assessing risks at different scales, the practicalities are 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 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 must 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 before hand 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 really good studies that can influence remedies cost 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 be protective of human health and the environment, while not having to undertake the costly removal of all contaminated soils/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.

- A workshop participant stated that incorporating spatial considerations into an ecological risk assessment is a "slippery slope" in the sense that one must determine how far to go down that path before the site assessment is meaningless.

- The discussion of temporal scale is equally "slippery." Temporal scale is discussed even less than spatial scale. Implicit in remedial decision making for contaminated sites is that we want to return sites to functionality as soon as possible. However, it is 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. He noted that if temporal and spatial boundaries are large enough effects will be lost in the noise.

- A participant pointed out that the problem of assessing effects at a point of maximum exposure (which are often severe) 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[3] 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[4]. For example, if the assessment population is the clapper rails in a marsh treated with pesticides or the 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 stated that he has been involved with ecological risk assessment for DuPont since 1993. Dr. Stahl noted that DuPont has conducted work at 188 sites in the U.S. and others overseas. About 20 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.

- Regarding spatial scales, Dr. Stahl suggested that 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 will be assessed in the future. 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 removing liabilities

[3] U.S. EPA. 2003. *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessmen*t. EPA/630/P-02/004B. Risk Assessment Forum, Washington, DC.
[4] 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.

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. Tools are available to conduct population-level studies. However, 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 get their needs articulated so

they could be addressed, 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 responded 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 the risks need to be mitigated and the level of certainty of 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 a real need to understand the impact to the environment of implementing the remedy. This is generally not done in the ecological risk assessments, but could be part of problem formulation.

6.2 Contaminated Sites Breakout Group Report on Assessing Risks at Different Spatial and Temporal Scales and Levels of Biological Organization

The breakout group participants (Appendix D) discussed how well current ecological risk assessment practices for contaminated site decisions address and explain the following cross-cutting issues:

1. Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments?

2. Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for contaminated site decision-making?

The following points discussed by the breakout group were summarized in the workshop plenary session presentation.

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

The group discussed how spatial and temporal scale issues affect the quality of analyses for ecological risk assessments at contaminated sites. The following issues and recommendations were discussed.

- 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 must match the scales of sites. Temporal scale must be considering 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 the 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 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 must be answered.

- The scale of a study conducted to assess ecological risks at a contaminated site must 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 must be addressed. This would enable adaptive approach 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.

The group discussed opportunities to enhance the analysis and interpretation of spatial and temporal scales for ecological risk assessments at contaminated sites. The following opportunities for enhancement of risk assessments were identified.

- 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.

The group discussed specific data collection, demonstration studies, and research that could enhance the analysis and interpretation of spatial and temporal scales. The following recommendations to enhance ecological risk assessments were identified.

- 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 for 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 must 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

The group discussed how different levels of biological organization affect the quality of analysis in ecological risk assessment for management of contaminated sites. The following points were discussed.

- 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 may not be of high quality.

- Species distributions of LC50's do not relate to protection of communities, and therefore may or may not be protective. There is a high level of uncertainty associated with 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 group discussed how different levels of biological organization affect the utility of analyses in ecological risk assessments for management of contaminated sites. The following points were discussed.

- 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 cases, protecting individuals may protect populations, but this is not always the case. 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 prevent decision-making. An example of this is the Housatonic River risk assessment that focused on minks and kingfishers. 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 group discussed opportunities to enhance ecological risk assessments through analysis and interpretation of information associated with different biological levels of organization. The following points were discussed.

- 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" 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.

The group discussed specific data collection, demonstration studies, or research that could enhance the analysis and interpretation of different biological scales of organization. The following needs for enhancement were discussed.

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

- Life history information must 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 must 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 associates with risk management alternatives. More information is needed for valuation of resources and assessment of ecological services and this information must 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

The group identified a number of overarching recommendations concerning spatial and temporal scale issues in ecological risk assessments at contaminated sites.

- Methods exist to conduct ecological risk assessment at different scales, but more relevant data and explicit guidance is 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 conduct improved outcome assessment (e.g., long term ecological research model). This 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 large 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.

6.3 Contaminated Sites Breakout Group Report on Problem Formulation, the Adequacy of Testable Hypotheses, and Decision-making in the Presence of Uncertainty

The breakout group participants (Appendix D) addressed the issues of problem formulation and the adequacy of testable hypotheses, and uncertainty in decision-making in the context of ecological risk assessment for the management of contaminated sites. Two issues were discussed:

1. Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments for management of contaminated sites?

2. Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for management of contaminated sites?

Issues to be Discussed Concerning Risk Assessments at Contaminated Sites

The session facilitator reviewed questions (Appendix E) that had been posed to all of the workshop breakout groups to facilitate discussion of the issues. The facilitator described the previous discussion of the topic in the Science Advisory Board's Ecological Processes and Effects Committee. He noted that the discussion of the topic initially focused on science, but it was then placed in the context of questions that must be answered by managers. The facilitator identified a number of risk assessment issues that he thought were particularly relevant to the discussion of contaminated sites. These included:

- Clarification of definitions such as the different needs of risk assessment for natural resource goals and for cleanup under CERCLA, RCRA, and state programs. For example, if managers will be making a decision based on human health concerns, should the risk assessment reflect this?

- If some things are quite obvious, such as the fact that nothing grows on the "slickens" in the Clark Fork area, do they really have to be studied. A participant noted that the slickens question may be easy to answer, but in many cases it is more difficult to determine what should be studied.

- Some SAB members, reflecting on the peer review process, feel that a peer review at the end of the problem formulation stage may be more useful than a peer review at the end of the risk assessment.

- What role could, or should, net benefit analysis have in problem formulation. The facilitator expressed the opinion that net benefit analysis compares incremental positive effects caused by remediation with other effects such as disturbing habitat for threatened and endangered species. This kind of net benefit analysis would apply to assessments of ecological effects but not assessments for occupational health and safety decisions.

- When should cost benefit analyses be conducted and how should they be conducted. A participant noted that conducting cost-benefit analyses would require more work than is usually completed. Participants questioned whether cost-benefit issues should be separated from other science-based questions.

Participants discussed the following number of points concerning these issues.

- 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 there decision might be based on effects on a particular species they would not want to invest heavily in other sorts of 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 to 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 difficulty to do this early in the process and that an iterative problem formulation approach might be useful.

Problem Formulation and Incorporation of Testable Hypothesis into the Design of Ecological Risk Assessments for management of Contaminated Sites

The group discussed how problem formulation and the adequacy of testable hypotheses affect the quality of an ecological risk assessment. The following points and recommendations were raised during the discussion.

- Participants discussed whether the testable hypotheses were relevant to problem formulation and expressed the opinion that the term "testable hypothesis" does not belong in the problem formulation step, and actually confuses the issue or creates conflict. The hypotheses that are tested in risk assessments often may not provide the information needed to estimate risk. Estimation of risk is the purpose of the risk assessment. Testable hypotheses are considered because they are needed in a scientific process.

- Potentially Responsible Parties frequently criticize contaminated site risk assessments as being too vague. Removing testable hypotheses from the assessment could make this criticism sharper. However, estimation could be substituted for hypothesis testing. Participants noted that consideration of testable hypotheses could be moved to the data collection step of an assessment. For example, in toxicity testing a dose response curve should be developed.

- 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. An option that might be considered during problem formulation would be to articulate questions that might be as rigorous as testable hypotheses.

The group briefly discussed how problem formulation and the development of testable hypotheses affect the utility of the risk assessment output. Participants agreed that problem formulation affects the utility of the output to a great degree. A number of participants expressed the opinion that testable hypotheses do not have much affect on the utility of the risk assessment output.

The group discussed opportunities to improve problem formulation and enhance the performance of ecological risk assessment. A number of issues were discussed and recommendations were provided.

- The Framework for Ecological Risk Assessment very useful and is "standing the test of time." However there are differences in the practice of ecological risk assessment from site to site.

- 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 made publicly available. The goal of the checklist is to make sure 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.

- There has been a failure to assess whether remediation of contaminated sites has worked. 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. EPA's EMAP program was established to meet the broader goal of demonstrating that the nation's environment is improving.

- There are currently a number of different guidance documents and tools available to risk assessors that were specifically developed for different regulatory programs. There is inconsistency among these guidance documents. Although flexibility is needed it is important to provide consistent recommendations to risk assessors.

- It is important to involve risk managers in problem formulation at an early stage of the risk assessment. A rigorous framework for addressing remedial options at an early stage of the assessment, without compromising the process and precluding important alternatives, would be useful. It may be beneficial to use a conceptual site model for initial analyses needed to facilitate these kinds of discussions.

- 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.

Contaminated Site Decision-making in the Face of Uncertainty

The Group discussed how to address uncertainty in risk assessments for decision-making to manage contaminated sites. The following issues were discussed and recommendations to improve the risk assessment process were suggested.

- 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. This is unlike the case of a human health risk assessment in which a large amount of data are available to assess effects on a single species. Of greater value is a 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. This will build a database that could be used to reduce uncertainty in decision-making.

Net Environmental Benefit

The group discussed the value of conducting net environmental benefit analyses.

- 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.

7.0 Ecological Risk Assessment in Natural Resources Protection

7.1 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, US EPA Region IX; Dr. Jennifer Shaw, Syngenta Corporation; Dr. Terry Young, Environmental Defense (See Panel Biosketches in Appendix B).

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 must often be concerned about stressors other than just chemicals. Such assessments must 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*[5] (Framework). Dr. Young discussed the following points:

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

- The Framework 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 Framework 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. Young referred to Table EF-1 in the Framework document and described how biotic condition could be described using the hierarchy to explicitly focus on 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

[5] 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)

Framework document. 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 Framework 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 very important to informed decision-making. Species location and distribution will drive 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 and 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 consist development of higher quality spatial data layers.

  - There is an opportunity for improved efficiency thorough 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 that

risk assessments can inform decisions that have to be made. Dr. Shaw identified the following opportunity for improved consideration of biological scale.

- An appropriate biological scale must 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 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 must be done to reduce uncertainty and how much the assessment is improved by this work Additional information can provide an understanding of such as factors 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 that may be 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 and in order to determine where risk assessments are inadequate.

Dr. McNaughton's Presentation

Dr. McNaughton discussed an ecological risk assessment example, 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 needed to be drained to provide agricultural land, and 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 this water into vacant land and 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 to north of this areas, and grasslands farmers also moved water into a different site that received drainage 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 very proud of accomplishments. In eight years, the project has met the TMDLs 7 out of 8 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 bioaccumulation has added much complexity to the ecological risk assessment and there is still work to be done – 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. And initially objectives were based on those water quality criteria. However, bioaccumulation occurred, and the ecosystem was impacted.

- Migratory bird species now being found in lesser numbers. Sturgeon in rivers 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 decisions as more monitoring information becomes available. EPA has been unable to look at the larger question of whether the environment benefited from 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 scale are important issues in ecological risk assessments 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 in their risk assessments. 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 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 by some states. 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 do 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 must 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 do not screen things out. The results of analyses conducted using these screening systems may not provide definitive results. The 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 25-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 avoid the completion of 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 revisions 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 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 Framework 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, 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 Framework 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 what they get with 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.

7.2 Natural Resource Protection Breakout Group Report on Assessing Risks at Different Spatial and Temporal Scales and Levels of Biological Organization

The breakout group participants (Appendix D) discussed how well current ecological risk assessment practices for natural resources protection address and explain the following cross-cutting issues:

1. Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments?

2. Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for natural resources protection?

The following points and recommendations discussed by the breakout group were summarized in the workshop plenary session presentation.

Definition of Spatial and Temporal Scales in Ecological Risk Assessments for Natural Resources Protection

The group discussed how spatial and temporal scales affect the quality and utility of an ecological risk assessment.

- 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.

- 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 consider using spatial scales that are large enough to see patterns emerging across a landscape. This will provide insight into the assessment of cumulative effects. Examples of emerging effects included declining condition of small streams and the effects of a myriad of small point sources such as leaking underground storage tanks.

- Large scales bring the interests of more stakeholders into consideration and can also blur details. However, small scales may exclude regional and global trends that affect local conditions. This may leave the process subject to influences of local politics.

- Spatial and temporal scale analysis may help to later 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 this into uncertainty analysis.

The group discussed specific data collection, demonstration studies, and research that could enhance the analysis and interpretation of spatial and temporal scales. The following recommendations to enhance ecological risk assessments were identified.

- 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. Tools include geographic information system continuous monitors, models, species life history information. If additional spatial resolution is needed to describe species abundance and distribution, this 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 b marketed to risk managers.

- Tools for completing common risk assessment activities, such as vulnerability analysis, should be provided to risk assessors.

- An interagency effort should 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 group discussed how different levels of biological organization affect the quality and utility of analyses in ecological risk assessment for natural resources protection. The following points were discussed.

- 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).

- Biological scale should be explicit in an assessment endpoint, and it would be useful to develop standard techniques for assessing risks at these higher levels of biological organization (e.g., common definitions of habitat types and communities). The utility of community level information is demonstrated by use of 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 were the effect is most obvious and then look one level up and one level down.

The group discussed specific data collection, demonstration studies, or research that could enhance the analysis and interpretation of different biological scales of organization. The following needs and opportunities for enhancement were discussed.

- 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, 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 patterns emerging 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

The group discussed the following cross-cutting scale issues concerning ecological risk assessments for natural resources protection.

- Standards of practice are needed for ecological risk assessors and risk managers. These standards of practice should address risk assessment disclosure and methods to assure that spatial and temporal scale issues are appropriately addressed.

- 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 must be rigorously incorporated into risk assessments.

- Findings from reactive risk assessments should be used to inform proactive risk assessments. Scientists must clearly identify with 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.

- The sooner appropriate scales and multiple levels of biological are incorporated into risk assessments, the sooner a record and body of knowledge will be available.

Overview of Points and Issues Concerning Scale and Level of Biological Organization in Ecological Risk Assessments for Natural Resources Protection

The group identified a number of overarching conclusions and recommendations.

- It is of value to incorporate spatial and temporal scale and multiple levels of biological organization into ecological risk assessments. These concepts should be put into practice.

- Problem formulation is a critical step in ecological risk assessment to adequately define appropriate scale and biological organization .

- 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 should be acknowledged "up front" (transparency) and addressed in the uncertainty analysis.

- Practical tools and case studies are needed to demonstrate incorporation of spatial and temporal scales and levels of biological organization into ecological risk assessments.

7.3 Natural Resource Protection Breakout Group Report on Problem Formulation, the Adequacy of Testable Hypotheses, and Decision-making in the Presence of Uncertainty

The breakout group participants (Appendix D) addressed the issues of problem formulation and the adequacy of testable hypotheses, and uncertainty in decision-making in the context of ecological risk assessment for natural resources protection. Two issues were discussed:

1. Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments for natural resources protection?

2. Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for natural resources protection?

Unique Issues Associated with Ecological Risk Assessment for Natural Resources Protection

The facilitator began the discussion by introducing the issues and asking the group to discuss how risk assessments for natural resource protection might differ from other kinds of risk assessments. The following differences were discussed.

- 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 must 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 such 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 must be clearly addressed in the problem formulation stage of the risk assessment. Decisions can be made at a very small scale, but they must be made in the context of a much broader scale. 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

The group discussed how problem formulation and testable hypotheses affect the quality of analyses conducted for natural resources protection. The following points were discussed.

- Both problem formulation and incorporation of testable hypotheses affect the quality of a risk assessment. Paying proper attention to both leads to higher quality decisions, but testable hypotheses can be misused and this can lead to degraded decision-making.

- Natural resources protection should begin with an examination of critical ecological attributes, and then specific endpoints can be established based on specific hypotheses. This 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 things. 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 Baysian analysis and causal argumentation. Hypotheses should focus on causal relationships and weights of evidence.

The group discussed how problem formulation and testable hypotheses affect the utility of analyses in risk assessments for the protection of natural resources. The following points were discussed.

- 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 is necessary to first identify sensitive and realistic measurements. For example, endocrine disrupters do not kill animals often 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.

The group discussed opportunities to enhance problem formulation and testable hypotheses. The following points and recommendations were discussed.

- It is important to build the 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 ones at a population level. This will require more work to identify and assess true links between molecular, cellular, and organismal responses and impacts that can be noted in populations.

- Ecology must 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 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 the effects on populations of 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.

The group discussed specific research that could be conducted as well as data and tools that could be developed to enhance 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 insure that training and guidance is 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 must 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 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 in problem formulation the development of specific linkages that indicate how data will actually be used to inform decision-makers and lead to appropriate decisions.

- 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 has 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.

The group discussed the issue of uncertainty in the face of decision-making and how this affects the quality of risk assessments.

- 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 must decide what level of uncertainty is acceptable. Risk assessors must 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 must therefore communicate effectively and the most profound uncertainties must be identified *a priori*.

The group discussed how uncertainty affects the utility of risk assessments. The following points were discussed:

- 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.

The group discussed opportunities to address uncertainty and improve the risk assessment process. The following opportunities were identified:

- Risk assessors should explore the use of alternative methods of analysis such as the use of 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.

The group discussed a specific research that could be conducted and tools and data that could be developed to enhance ecological 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 should 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.

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. Gregg 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 impact of this issue on ecological risk assessment performance
4. Recommendations for data collection, research, and demonstrations that could mitigate the impact 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. Gregg 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. 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, USEPA**.** 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 stakeholders organizations. Before assuming his current position Dr. Bradbury led and managed ORD's laboratory facilities in Duluth, MN and Grosse Ile, MI. The 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. Larry 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, Larry 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). Larry 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.
Larry 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 Denise 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 Denise was the Director of the Biological and Economic Analysis Division in OPP and also served as the acting Director of the Environmental Fate and Effects Division in OPP. Denise has also held management positions in the Office of Solid Waste and Emergency Response and in the former 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 (USEPA), 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 USEPA 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 USEPA 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 US 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. Peter's expertise includes ecological and human health risk assessment, endocrine disrupting chemicals, coastal eutrophication and public participation. He work 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. Peter has served on the planning committees for a number of SETAC workshops on ecological risk topics. January 2006.

Dr. David L Fischer is currently the Head of Bayer CropScience's Ecotoxicology Section in the US. 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 ecosystems, 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 a SAP panel 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 PhD 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 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 Office in EPA Region 9. 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 DEQ 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 Jennifer 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, Jennifer has served in leadership positions in various industry task forces, trade association committees and expert workgroups including serving as an invited expert on 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 BS in Biology from the State University of New York at Stony Brook, and a MS 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 Stah 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 Dept. 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 PhD 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 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.

Appendix C. Registered Workshop Participants

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Appendix D. Initial Breakout Group Assignments

Breakout Group 1 Overview Session -- Product Health and Safety Decision-Making

Facilitator: Gregory Biddinger, Exxon Biomedical Sciences

Rapporteur: 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

Participants: Thomas Armitage, U.S. EPA
Lawrence Barnthouse, LWB Environmental Services
William Bowerman, Clemson
Kristin Brugger, Dupont
Mark Corbin, U.S. EPA
John Carbone, Rohm and Haas
James Fairchild, USGS
Reinhard Fischer, Bayer Crop Science
Jeffrey Frithsen, U.S. EPA
Jeffrey Giddings, Compliance Services International
Paul Hendley, Syngenta Crop Protection
Diane Henshel, Indiana University
Michael Hooper, Texas Tech University
Wayne Landis, Western Washington University
Gregory Leyes, ISK Biosciences
Josh Lipton, Stratus Consulting
Gregory Masson, U. S. FWS
Charles Menzie, Menzie-Cura & Associates
Dwayne Moore, Cantox
Thomas Mueller, University of Tennessee
Susan Norton, U.S. EPA
Edward Odenkirchen, U.S. EPA
Nicholas Poletika, Dow AgroSciences
Donna Randall
Donald Rodier, U.S. EPA
Dee Ann Staats, Croplife America
Holly Stallworth, U.S. EPA
Ingrid Sunzenauer, U.S. EPA
Kristen Thornton, DNREC

Breakout Group 2 Overview Session -- Management of Contaminated Sites

Facilitator: Michael Newman, College of William and Mary

Rapporteur: 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: Richelle Allen-King
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

Breakout Group 3 Overview Session -- Natural Resource Protection

Facilitator Kenneth Dickson, University of North Texas

Rapporteur 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

Breakout Group 1A - Product Health and Safety Decision-Making Cross-cutting Issues will discuss (1) Effects of Spatial and Temporal Scale; and (2) Assessing Risks at Different Biological Scales (e.g., organism, population, community). If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: Gregory Biddinger, Exxon Mobile Biomedical Sciences

Rapporteur: Wayne Landis, Western Washington University

Participants: William Bowerman, Clemson
Kristin Brugger, Dupont
John Carbone, Rohm and Haas
Mark Corbin, U.S. EPA
Peter Defur, Environmental Stewardship
James Fairchild, USGS
Max Feken, Florida Department of Agriculture
Reinhard Fischer, Bayer Crop Science
Gregory Leyes, ISK Biosciences
Josh Lipton, Stratus Consulting
Gregory Masson, U. S. FWS
Edward Odenkirchen, U.S. EPA
Nicholas Poletika, Dow AgroSciences
Holly Stallworth, U.S. EPA
Leslie Touart, U. S. EPA

Breakout Group 1B - Product Health and Safety Decision-Making Cross-cutting Issues will discuss (3) Problem Formulation and Adequacy of Testable Hypotheses; and 4) Decision Making in the Presence of Uncertainty. If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: Charles Pittinger, BB&L Sciences

Rapporteur: Thomas Mueller, University of Tennessee

Participants: Thomas Armitage, U.S. EPA
Lawrence Barnthouse, LWB Environmental Services
David Fischer, Bayer Crop Science
Jeffrey Frithsen, U.S. EPA
Jeffrey Giddings, Compliance Services International
Paul Hendley, Syngenta Crop Protection
Diane Henshel, Indiana University
Michael Hooper, Texas Tech University
Charles Menzie, Menzie-Cura & Associates
Dwayne Moore, Cantox

Susan Norton, U.S. EPA
Donna Randall, U.S. EPA
Donald Rodier, U.S. EPA
Dee Ann Staats, Croplife America
Ingrid Sunzenauer, U.S. EPA
Kristen Thornton, DNREC

Breakout Group 2A - Management of Contaminated Sites Cross-cutting Issues will discuss (1) Effects of Spatial and Temporal Scale; and (2) Assessing Risks at Different Biological Scales (e.g., organism, population, community). If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: Michael Newman, College of William and Mary

Rapporteur: G. Allen Burton, Wright State University

Participants: Matthew Behum, Integral Consulting
William Creal, Michigan DEQ
Gregory DeCowsky, DNREC
Anne Fairbrother, U.S. EPA
Thomas Forbes, U.S. EPA
Barry Forsythe, U.S. FWS
Laura Haynes, U.S. EPA
Ron Josephson, U.S. EPA
Thomas La Point, University of North Texas
Kevin Reinert, AMEC Earth and Environmental
Keith Sappington, U.S. EPA
Lisa Saban, Windward Environmental
Sean Smith, US Navy
Mark Sprenger, U.S. EPA
Ralph Stahl, DePont
John Wardell, U.S EPA

Breakout Group 2B - Management of Contaminated Sites Cross-cutting Issues will discuss cross-cutting issues (3) Problem Formulation and Adequacy of Testable Hypotheses; and 4) Decision Making in the Presence of Uncertainty. If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: Timothy Thompson, Science, Engineering and the Environment

Rapporteur: Richelle Allen-King, University of Buffalo

Participants: John Bascietto, DOE

Nancy Bettinger, MA DEP
Patricia Casano, General Electric
Carolyn Hammer, U.S. EPA
Michael Fry, American Bird Conservancy
Miranda Henning, Environ International Corp.
Dale Hoff, U.S. EPA
Michael Johns, Windward Environmental
Jeff Margolin, Environ
Vicki Meredith, Wyoming DEQ
Joseph Meyer, University of Wyoming
Anne Rea, U.S. EPA
John Schaffer, Tetra Tech
Glenn Suter, U.S. EPA
Kristen Wandland, ENSR
Randy Wentsel, U.S. EPA
Kathleen White, U.S. EPA

Breakout Group 3A - Natural Resource Protection Cross-cutting Issues will discuss (1) Effects of Spatial and Temporal Scale; and (2) Assessing Risks at Different Biological Scales (e.g., organism, population, community). If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: Kenneth Dickson, University of North Texas

Rapporteur: Judith Meyer, University of Georgia

Participants: Clifford Duke, Ecological Society of America
Bruce Hope, Oregon DEQ
Chester Joy, U.S. Government Accountability Office
Danny Lee, U. S. Forest Service
Deborah Lester, King County Natural Resources
Lawrence Master, NatureServe
Bernalyn McGaughey, Compliance Services International
Eugenia McNaughton, U.S. EPA
Angela Nugent, U.S. EPA
Damian Preziosi, Integral Consulting
Stephanie Sanzone, George Mason University
Rita Schoeny, U.S. EPA
Jennifer Shaw, Syngenta
Michael Slimak, U.S. EPA
Robin Stewart, USGS
Eric Stokstadt, AAAS
Terry Young, Environmental Defense

Breakout Group 3B - Natural Resource Protection Cross-cutting Issues will discuss cross-cutting issues (3) Problem Formulation and Adequacy of Testable Hypotheses; and 4) Decision Making in the Presence of Uncertainty. If time permits, the remaining two cross-cutting issues may be addressed.

Facilitator: James Oris, Miami University

Rapporteur: James Sanders, Skidaway Institute of Oceanography

Participants: Steven Bay, SCCWRP
Pietr Booth, Exponent
Grant Cope, Congress
Robert Frederick, U.S. EPA
Tala Henry, U.S. EPA
Larry Kapustka, Golder Associates
Iain Kelly, Bayer CropScience
Marianne Ottinger, University of Maryland
Joan Pioli, Menzie-Curie and Associates
Amanda Rodewald, Ohio State University
Andy Rowe, GHK International
Vivian Turner, U.S. EPA
Ivor van Heerdon, Louisiana State University
Steven Wharton, U.S. EPA
Rick Ziegler, US EPA

Appendix E. Workshop Questions

Breakout Group 1 -- Ecological Risk Assessments for Product Health and Safety Decision- Making

Overall Breakout Group Objective – Develop information that will allow the EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) to evaluate the current state-of-the-practice of ecological risk assessment. The information will be collated into a workshop proceedings, and used by EPEC to formulate advice and recommendations to the EPA on ecological risk assessment. The breakout group discussions will focus on four cross-cutting issues: 1) effects of spatial and temporal scale; 2) assessing risks at different biological scales (sub-organism, organism, population, community, ecosystem); 3) problem formulation and adequacy of testable hypotheses; and 4) decision-making in the face of uncertainty.

Breakout Group 1A – How well do current ecological risk assessment practices for product health and safety decisions address and explain cross-cutting issues 1 and 2 above. If time permits cross-cutting issues 3 and 4 may also be discussed.

Issue 1 -- Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments used in product health and safety decision-making?

Suggested discussion questions

1. How do spatial and temporal scales affect the quality of analyses for ecological risk assessments used in product health and safety decision-making?

2. How do spatial and temporal scales affect the utility of analyses for ecological risk assessments used in product health and safety decision-making?

3. What opportunities exist to enhance the analysis and interpretation of spatial and temporal scale for ecological risk assessment used in product health and safety decision-making?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of spatial and temporal scales for ecological risk assessments used in product health and safety decision-making?

5. How do different spatial and temporal scales affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 2 -- Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for product health and safety decision-making?

Suggested discussion questions

1. How do different levels of biological organization affect the quality of analysis for ecological risk assessments used in product health and safety decision-making?

2. How do different levels of biological organization affect the utility of analysis for ecological risk assessments used in product health and safety decision-making?

3. What opportunities exist to enhance the analysis and interpretation of different biological levels of organization for ecological risk assessments used in product health and safety decision-making?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of different levels of biological organization in product health and safety ecological risk assessments?

5. How do different levels of biological organization affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Breakout Group 1B – How well do ecological risk assessment practices for product health and safety decisions adequately address and explain cross-cutting issues 3 and 4 above. If time permits the cross-cutting 1 and 2 may be addressed.

Issue 3 -- Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments used in product health and safety decision-making making?

Suggested discussion questions

1. How do problem formulation and testable hypotheses affect the quality of analyses for ecological risk assessments used in product health and safety decision-making?

2. How do problem formulation and testable hypotheses affect the utility of analyses for ecological risk assessments in product health and safety decision-making?

3. What opportunities exist to enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessment used in product health and safety decision-making?

4. What specific data collection, demonstration studies, or research could enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessments used in product health and safety decision-making?

5. How does problem formulation and testable hypotheses affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 4 – Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments used in product health and safety decision-making?

Suggested discussion questions

1. How does decision-making in the face of uncertainty affect the quality of analyses for ecological risk assessments used in product health and safety decision-making?

2. How does decision-making in the face of uncertainty affect the utility of analyses for ecological risk assessments used in product health and safety decision-making?

3. What opportunities exist to enhance the analysis and interpretation of uncertainty for ecological risk assessments used in product health and safety decision-making?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of uncertainty for ecological risk assessments used in product health and safety decision-making?

5. How does decision-making in the face of uncertainty affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Breakout Group 2 -- Ecological Risk Assessment in Management of Contaminated Sites

Overall Breakout Group Objectives – Develop information that will allow the EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) to evaluate the current state-of-the-practice of ecological risk assessment. The information will be collated into a workshop proceedings, and used by EPEC to formulate advice and recommendations to the EPA on ecological risk assessment. The breakout group discussions will focus on four cross-cutting issues: 1) effects of spatial and temporal scale; 2) assessing risks at different biological scales (sub-organism, organism, population, community, ecosystem); 3) problem formulation and adequacy of testable hypotheses; 4) decision-making in the face of uncertainty

Breakout Group 2A – How well do current ecological risk assessment practices for management of contaminated sites address and explain cross-cutting issues 1 and 2 above. If time permits cross-cutting issues 3and 4 may be addressed.

Issue 1 -- Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments used in management of contaminated sites?

Suggested discussion questions

1. How do spatial and temporal scales affect the quality of analyses for ecological risk assessments used in management of contaminated sites?

2. How do spatial and temporal scales affect the utility of analyses for ecological risk assessments used in management of contaminated sites?

3. What opportunities exist to enhance the analysis and interpretation of spatial and temporal scale for ecological risk assessment used in management of contaminated sites?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of spatial and temporal scales for ecological risk assessments used in management of contaminated sites?

5. How do different spatial and temporal scales affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 2 -- Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for management of contaminated sites?

Suggested discussion questions

1. How do different levels of biological organization affect the quality of analysis for ecological risk assessments used in management of contaminated sites?

2. How do different levels of biological organization affect the utility of analysis for ecological risk assessments used in management of contaminated sites?

3. What opportunities exist to enhance the analysis and interpretation of different biological levels of organization for ecological risk assessment used in management of contaminated sites?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of different levels of biological organization in contaminated site ecological risk assessments?

5. How do different levels of biological organization affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Breakout Group 2B – How well do ecological risk assessment practices for management of contaminated sites address and explain cross-cutting issues 3 and 4 above. If time permits the cross-cutting issues 1 and 2 may be addressed.

Issue 3 -- Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments used in management of contaminated sites?

Suggested discussion questions

1. How do problem formulation and testable hypotheses affect the quality of analyses for ecological risk assessments used in contaminated site management?

2. How do problem formulation and testable hypotheses affect the utility of analyses for ecological risk assessments used in contaminated site management?

3. What opportunities exist to enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessment used in management of contaminated sites?

4. What specific data collection, demonstration studies, or research could enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessments used in management of contaminated sites?

5. How does problem formulation and testable hypotheses affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 4 – Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments used in management of contaminated sites?

Suggested discussion questions

1. How does decision-making in the face of uncertainty affect the quality of analyses for ecological risk assessments used in management of contaminated sites?

2. How does decision-making in the face of uncertainty affect the utility of analyses for ecological risk assessments used in management of contaminated sites?

3. What opportunities exist to enhance the analysis and interpretation of uncertainty for ecological risk assessments used in management of contaminated sites?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of uncertainty for ecological risk assessments used in management of contaminated sites?

5. How does decision-making in the face of uncertainty affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Breakout Group 3 -- Ecological Risk Assessment in Natural Resource Protection

Overall Breakout Group Objectives – Develop information that will allow the EPA Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) to evaluate the current state-of-the-practice of ecological risk assessment. The information will be collated into a workshop proceedings, and used by EPEC to formulate advice and recommendations to the EPA on ecological risk assessment. The breakout group discussions will focus on four cross-cutting issues: 1) effects of spatial and temporal scale; 2) assessing risks at different biological scales (sub-organismic, organismic, population, community, ecosystem); 3) problem formulation and adequacy of testable hypotheses; 4) decision-making in the face of uncertainty

Breakout Group 3A – How well do current ecological risk assessment practices for natural resource protection address and explain cross-cutting issues 1 and 2 above. If time permits cross -cutting issues 3 and 4 may be addressed.

Issue 1 -- Can spatial and temporal scales be better defined and incorporated into the design and operational performance of ecological risk assessments used in natural resource protection?

Suggested discussion questions

1. How do spatial and temporal scales affect the quality of analyses for ecological risk assessments used in natural resource protection?

2. How do spatial and temporal scales affect the utility of analyses for ecological risk assessments used in natural resource protection?

3. What opportunities exist to enhance the analysis and interpretation of spatial and temporal scale for ecological risk assessment used in natural resource protection?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of spatial and temporal scales for ecological risk assessments used in natural resource protection?

5. How do different spatial and temporal scales affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 2 -- Can different levels of biological organization be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments for natural resource protection?

Suggested discussion questions

1. How do different levels of biological organization affect the quality of analyses for ecological risk assessments used in natural resource protection?

2. How do different levels of biological organization affect the utility of analyses for ecological risk assessments used in natural resource protection?

3. What opportunities exist to enhance the analysis and interpretation of different biological levels of organization for ecological risk assessment used in natural resource protection?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of different levels of biological organization in ecological risk assessments for natural resource protection?

5. How do different levels of biological organization affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Breakout Group 3B – How well do ecological risk assessment practices for natural resource protection address and explain cross-cutting issues 3 and 4 above. If time permits cross-cutting issues 1 and 2 may be addressed.

Issue 3 -- Can problem formulation and the adequacy of testable hypotheses be better defined and incorporated into the design and operational performance of ecological risk assessments used in natural resource protection?

Suggested discussion questions

1. How do problem formulation and testable hypotheses affect the quality of analyses for ecological risk assessments used in natural resource protection?

2. How do problem formulation and testable hypotheses affect the utility of analyses for ecological risk assessments used in natural resource protection?

3. What opportunities exist to enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessment used in natural resource protection?

4. What specific data collection, demonstration studies, or research could enhance problem formulation and the adequacy of testable hypotheses for ecological risk assessments used in natural resource protection?

5. How does problem formulation and testable hypotheses affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Issue 4 – Can decision-making in the face of uncertainty be more explicitly defined and incorporated into the design and operational performance of ecological risk assessments used in natural resource protection?

Suggested discussion questions

1. How does decision-making in the face of uncertainty affect the quality of analyses for ecological risk assessments used in natural resource protection?

2. How does decision-making in the face of uncertainty affect the utility of analyses for ecological risk assessments used in natural resource protection?

3. What opportunities exist to enhance the analysis and interpretation of uncertainty for ecological risk assessments used in natural resource protection?

4. What specific data collection, demonstration studies, or research could enhance the analysis and interpretation of uncertainty for ecological risk assessments used in natural resource protection?

5. How does decision-making in the face of uncertainty affect or interact with other cross-cutting issues identified for this workshop?

6. Are there other important cross-cutting issues that need to be identified?

Appendix F. Individual Written Responses to Discussion Questions

Discussants were not asked to provide written responses to the discussion questions. However, written responses that were submitted are included in this appendix.

Written responses provided by James Fairchild, U.S. Geological Survey:

How do spatial and temporal scales affect the utility of analyses for ecological risk assessment used in product health and decision-making?

Temporal and spatial scales are the primary platforms for problem formulation, development of theoretical frameworks, and studies in theoretical ecology. We know that different biological, physical, and chemical phenomena occur at different spatial and temporal scales. Therefore it is critical that research, or risk assessments, be conducted at the appropriate scale to answer the question of need. Frequently this is neglected and has been termed the mis-match phenomena, in which we try to answer questions but use information derived at the incorrect scale that is necessary, or try to combine data from different scales that are not compatible. From a risk assessment approach, this is an example of an incomplete problem formulation, and provides outcomes that are confusing or erroneous. This is why we are meeting in separate subgroups, because the various arenas of application of the risk assessment process (site-specific assessments; product health and safety assessment; and natural resource protection) are asking questions directly related to the reality of the importance of using the appropriate temporal and spatial scale.

Risk assessments for product health and safety decision making are commonly conducted using methods best suited for risk analysis at relatively small temporal and spatial scales. This is largely in part due to the approaches taken to develop the risk assessment framework. The risk assessment framework was developed based on the practical fact that when much of the enabling legislation was developed there was an absence of validated, acceptable methods for assessment of exposure and response. In the early 1970s, when the earliest research was directed at the ecological fate and effects of contaminants there was heavy emphasis on small-scale studies developed for early regulatory purposes and rapid generation of information to keep up with the rapidly expanding chemical industry. Large emphasis was placed on the development of toxicity tests with a small suite of species. Test endpoints were, and still are, effects on survival and reproduction of individuals. Chemical fate studies for regulatory purposes have been studied under tightly controlled conditions for estimates of critical fate parameters such as hydrolysis, photolysis, sorption, and biodegradation. Although studies in experimental systems were conducted under simulated terrestrial and aquatic systems, they were also conducted under rather tightly controlled studies with relatively little variation in temporal and spatial scale.

Today, we recognize that this early emphasis on has limited our abilities to predict the fate and effects of chemicals at larger temporal and spatial scales. We do have some comfort level in the endpoints used in toxicity testing (survival and reproduction) because they can be used in population modeling to some extent. However, most population models are limited in the sense that they have certain assumptions such as confined boundaries and stable age distributions that somewhat limit their realism. Difficulty arises when we try to extrapolate population models to larger temporal and spatial scales. Populations in the environment are now more realistically viewed as metapopulations composed of smaller populations distributed in mosaic patterns. Inherent mechanisms of population dynamics, such as immigration and emigration, and the effects of so many other anthropogenic and natural stressors make actual measurement of populations at larger scales difficult. Newer population models have been developed which can be used to evaluate the influence of spatial and temporal factors on chemical fate and effects and this is an active and fruitful research area. However, these models are primarily conceptual as opposed to useful in a regulatory context.

Indeed, the temporal and spatial scales affect the utility of the risk assessment. This is largely due to the uncertainty in extrapolation across biological, temporal, and spatial scales which all have degrees of uncertainty due to variability of the environment; lack of knowledge of critical factors affecting ecological responses to chemical stressors; and errors in the way we apply our science. The degree to which it is affected is dependent on what the need is and how the problem is formulated. Our challenge is to recognize that temporal and spatial scale are critical factors affecting the utility of the risk assessment, and we have a lot to learn in actual consideration of these factors.

New tools for ecological risk assessment include:
Geographic Information Systems
Remote Sensing
Modeling
Data to actually implement the risk assessment at expanded scales
NAWQA: Focus on Fish and Invertebrate communities
EMAP
BEST (Large River Scale of Fish Health at Individual Level)
- Lower Colorado
- Rio Grande
- Upper Mississippi River
- Yukon

Limitations for use of new tools: Time scale of collection; assumption for some monitoring efforts that every 5 years is approximate temporal scale to detect changes at National Level. However, endpoints are not chemical specific, but rather indicators of chemical classes.

What opportunities exist to enhance the analysis and interpretation of spatial and temporal scale for ecological risk assessment in health and safety decision making?

To better get at the real issue here, it may be better to ask the question: "What are impediments to enhance the analysis and interpretation of spatial and temporal scale for ecological risk assessment in product health and safety decision making?" Assessment of risk at varying spatial and temporal scales is not limited by our knowledge of populations, communities, and ecosystems or the lack of conceptual models as to how biological, temporal, and spatial scales may interact to affect to affect the outcome of a risk assessment; rather we are more limited by problems of human thinking and organization. Non-scientists continue to view issues across political boundaries at the state and county levels. State and federal agencies are frequently organized in geographic units that have no relationship to product exposure and ecological response. However, science has influenced the organizational and operational structures of many state and federal agencies that is reducing the impact of temporal and spatial scale in the way they view their individual agency missions and mandates. Barriers are primarily institutional artifacts of human behavior.

Moreover, I am increasingly concerned about the public's concern regarding the process of assessing the health and safety of chemicals. Over the past 5 years, we have seen drastic changes in the public's perception of the concept of risk. Five years ago environmental quality was a primary concern of the public in opinion polls regarding the quality of the human condition. At that time, it was very easy to communicate the concept of ecological risk and the use of science to minimize and manage environmental risk. However, public and political concerns over terrorism have altered the way we view the world; what we value; and how we should spend our resources. This, to some degree, is beginning to diminish research opportunities in environmental protection and is easily seen in Federal and State downsizing of environmental programs. I am interested in the opinions of industry and academia on this trend.

So, having said that, I will start by saying that our best opportunity is to begin to focus risk assessment efforts as inter-agency efforts. We have learned over the past 15 years that ecotoxicology like ecological risk assessment is a an interdisciplinary field that requires input from the field of ecology, toxicology, mathematics, geology, and other fields. There are many opportunities for interagency risk assessment work.

Within USGS there has been a focus on spatial and temporal dynamics and processes at the watershed level. The NAWQA program is working at the watershed level to integrate the disciplines of biology, hydrology, geology, and geography. All are collecting high quality data. Currently, they have a total of 2 cycles at a number of locations that have examined the response of fish and invertebrate communities to land-use at the watershed scale. Data collected are primarily focused on nutrients and pesticides as opposed to organics, metals, or pharmaceuticals. However, they are not necessarily collecting data in a risk assessment context. They are focused on natural

resource assessment in a geographic sense by linking and utilizing data GIS data platforms of geology, soils, climate, hydrology, and ecology. So, the data is available and it can be used in the problem formulation phase. However, the risk assessment components of exposure and response are not necessarily conducted due to the influence of multiple stressors. This represents a tremendous opportunity to work at the watershed scale to conduct risk assessments at larger temporal and biological scales.

Within USDA there has been an incredible contribution through long-term research programs that have led to the development of much of what we know about the environmental fate of agricultural chemicals at the plot and field level. They are now expanding their focus across the country in a new program called the Conservation Assessment and Evaluation Project (CEAP). These are efforts conducted at the watershed level to determine the effects of conservation practices on off-site transfer of agricultural chemicals and nutrients. Sites locations:

Opportunities for cooperation among programs in industry and academia can be identified.

The talks that I have heard at this workshop clearly indicate to me that continued effort at the parameterization, validation, and application of models that incorporate the effects of spatial and temporal scale should continue to be a major research emphasis. Interdisciplinary workshops such as this are good opportunities to get input and advice from experts in industry, academia, and government on evolving research issues and applications. There has been a lot of discussion of changes in the government workforce due to retirements. This may create some opportunity to bring in new expertise in the area of modeling. Every agency appears to be increasing its use of GIS and other techniques. GIS technology can be applied to monitoring efforts of many government agencies. Opportunities will be created for new graduates to enter the public and private sector. Academia seems to be ready to fill the voids!

Over a course of years I have observed the continued success of professional societies in bringing multiple disciplines together for presentation and publication that deal with the issue. Organizations like SETAC are putting major efforts into teaching, short courses. SETAC has recently created a new journal, *Integrated Environmental Assessment and Monitoring* to increase the awareness and application of modeling in risk assessment. As the risk assessment process continues to evolve there will be opportunities for industry and government to assist in research progress being made in modeling capabilities. Certainly, bringing interdisciplinary groups of individuals together in setting such as this will help

How does incorporation of different levels of biological organization into the design and operation performance of ecological risk assessments for product health and safety decision making affect the quality of the risk analysis?

Ecological risk assessments can be conducted at any level of biological organization ranging from the cell, organ, individual, population, community, or ecosystem level. Furthermore, at each level of biological organization we can assess risk using either functional or structural measurement and assessment endpoints. Over the past 30 years there has been much discussion regarding the relative sensitivity and interpretive value of various approaches of study in ecotoxicology. This subject area is again emerging in various circles such as the area of conservation biology, where many are now arguing that we should not focus on management goals of protection of species richness or status of rare species. Rather, many are arguing that we should focus on maintenance of functional diversity and how it relates to the delivery of environmental resources and human services. The Group assigned the topic of natural resource protection, I am sure, will discuss this in great detail.

Many argue strongly that we should focus risk assessments of product safety on these higher level endpoints from a functional view. However, we simply do not have enough agreement on the most valuable, yet practical measurement and assessment endpoints. Currently, we focus on individual-level endpoints such as survival, growth, and reproduction. This emphasis is based on 30 years of research regarding test methodologies that produce data that are repeatable, replicable, and reproducible. The standardization of product testing is necessary to produce data for product testing and registration that are easily used; interpreted; and communicated within the risk assessment framework. In addition, this approach is generally accepted by the public because they in general recognize the importance of protecting populations of economic, recreational, and biological importance. Without the public's understanding and support, it will be difficult to change our current approach in the near future.

What are recommendations for data collection, research, and demonstrations (concerning incorporation of various levels of biological organization into risk assessments)?

More research is needed to explicitly incorporate various levels of biological organization within the risk assessment process. The continuum of levels of biological organization must be considered as it relates to the previous issue of temporal and spatial scale. Although current risk assessment efforts for health and product testing are conducted using individual-level indicators as surrogate estimators of population-level effects, we need to continue to seek opportunities for collaborative, multidisciplinary research at multiple biological, spatial and temporal scales to further evaluate additional indicators of environmental health at the community and ecosystem levels. Both structural and functional approaches should be measured, and compared across multiple temporal and spatial scales.

To do this, we need discussions among various agencies and stakeholders involved in watershed and landscape level assessments to merge resources and disciplines in this effort. One way might be to examine opportunities for cooperation within monitoring

programs such as NAWQA, BEST, and EMAP and state data collection efforts to determine the effect of spatial and temporal scale on our abilities to apply higher level functional and structural endpoints in comparison to the individual and population level assessments currently being applied. This is a daunting task under the current economic and political climate. But to improve the risk assessment process we must continue in our data collection, research, and demonstration efforts.

Appendix G.- Slide Presentation - *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

Appendix H. -Slide Presentation - *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

Appendix I.-Slide Presentation - *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

Appendix J. –Slide Presentation - *Strengths of the Ecological Risk Assessment Process for Use in Decision making* - Dr. Lawrence Barnthouse, President and Principal Scientist, LWB Environmental Service

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

Appendix L. – Slide Presentation - *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 Limitations of the Ecological Risk Assessment Process for Use in Decision Making* – Dr. Steven Bradbury, Director, Environmental Fate and Effects Division, EPA Office of Pesticide Programs

Appendix M – Slide Presentation - *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

Appendix N. – Slide Presentation - *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