United States
Environmental Protection
Agency

PRESORTED STANDARD
POSTAGE & FEES PAID
EPA
PERMIT NO. G-35

U.S. Environmental Protection Agency
Office of Research and Development
Washington, DC 20460

Official Business
Penalty for Private Use
$300

United States
Environmental Protection
Agency

EPA/100/R-10/004 | December 2010
www.epa.gov/osa

Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward

Results of a Colloquium in Response to Science Advisory Board and National Research Council Recommendations

Office of the Science Advisor
Risk Assessment Forum

EPA/100/R-10/004
December 2010

Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward

Results of a Colloquium in Response to Science Advisory Board and National Research Council Recommendations

Risk Assessment Forum
U.S. Environmental Protection Agency
Washington, DC 20460

NOTICE

ABSTRACT

An Intra-Agency Colloquium, convened by a Technical Panel of the U.S. EPA's Risk Assessment Forum, reviewed the state of ecological risk assessment, responded to recommendations by the Science Advisory Board, and recommended actions to improve ecological risk assessment practices in the Agency. The panel and participants recommended an integrated framework that included all types of environmental assessments and focused on solving environmental problems. They reviewed existing guidance and found that, while it is abundant, it is not systematic or readily available. The response to comments found that most of the recommendations were being carried out in some components of the Agency, but practices are not consistent. The panel and participants made policy recommendations including greater attention to Agency-wide ecological protection goals, better communication of ecological issues, and a systems approach to assessment and management including better integration of assessment into the decision making process. They also made technical recommendations for improving assessment practice including the development of guidance on linkage of assessment endpoints to ecosystem services, weighing multiple types of evidence in assessments, and quality assurance for assessments. Finally, the participants strongly recommended that mechanisms and venues be provided for communication, problem sharing, training and mentoring in the community of ecological assessors.

Preferred Citation:

U.S. EPA (Environmental Protection Agency). (2010) Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward. Results of a Colloquium in Response to Science Advisory Board and National Research Council Recommendations. Risk Assessment Forum. Washington, DC. EPA/100/R-10/004

TABLE OF CONTENTS

TABLE OF CONTENTS (continued)

LIST OF TABLES

Page

LIST OF FIGURES

LIST OF ABBREVIATIONS

CADDIS	Causal Analysis/Diagnosis Decision Information System
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
DDT	dichlorodiphenyltrichloroethane
DQO	data quality objective
EO	Executive Order
EPA	Environmental Protection Agency
ERA	Ecological Risk Assessment
ESRP	Ecosystem Services Research Program
FIFRA	Federal Insecticide, Fungicide and Rodenticide Act
GEAE	Generic Ecological Assessment Endpoint
LCA	life-cycle assessment
NAAQS	National Ambient Air Quality Standards
NO_x	nitrogen oxides
NPL	National Priority List
NRC	National Research Council
OAQPS	Office of Air Quality Protection and Standards
OECD	Organization for Economic Cooperation and Development
OPP	Office of Pesticide Programs
OPPTS	Office of Prevention, Pesticides and Toxic Substances
ORD	Office of Research and Development
PCB	polychlorinated biphenyl
PRD	Pesticide Reevaluation Division
RAF	Risk Assessment Forum
RCRA	Resource Conservation and Recovery Act
ROE	Report on the Environment
SAB	Science Advisory Board
SO_x	sulfur oxides
T&E	threatened and endangered
TMDL	total maximum daily load
TSCA	Toxic Substances Control Act
USGCRP	U.S. Global Change Research Program
WQC	water quality criteria

PREFACE

This report was prepared by a Technical Panel of the U.S. EPA's Risk Assessment Forum to document an Intra-Agency Colloquium of ecological assessors. The impetus for the colloquium was a report of the Ecological Process and Effects Committee of the Science Advisory Board (SAB). That report presented the Committee's view of the state of practice of ecological risk assessment in the Agency and made recommendations for improvement. The Forum determined that the best way to respond to the recommendations was to convene ecological assessors from across the Agency to consider the Agency's ecological assessment practices in light of the recommendations. While the colloquium was being planned, the National Academy of Sciences published a report titled *Science and Decisions Advancing Risk Assessment* that contained recommendations concerning environmental risk assessment that were also relevant. Those recommendations were extracted, organized and added to the SAB's recommendations for consideration during the colloquium.

The report was prepared in three stages. First, the Technical Panel reviewed the recommendations, identified topics to be considered during the colloquium and developed white papers to serve as starting materials. Research for those white papers included interviews with ecological assessors in the various programs and regions. One outcome of the Technical Panel's work was a decision to broaden the topic from ecological risk assessment to include all types of ecological assessments performed by the Agency. Second, during the colloquium, working groups considered each of the topics identified by the Technical Panel, edited and added to the white papers, and developed recommendations. In plenary sessions, the recommendations were discussed and expanded. Third, following the colloquium, the Technical Panel reviewed the products of the colloquium and their notes and used them to write this report.

These results of the colloquium are already being used to guide the development of new projects of the Ecological Oversight Committee of the Risk Assessment Forum. The members of the Technical Panel hope that the report will be widely read and that its recommendations will be broadly implemented.

AUTHORS, CONTRIBUTORS, AND REVIEWERS

Anthony Maciorowski (Co-Chairman and Editor)
U.S. EPA,
Science Advisory Board Staff Office,
Washington, DC 20460

Glenn Suter (Co-Chairman and Editor)
U.S. EPA, Office of Research and Development,
National Center for Environmental Assessment,
Cincinnati, OH 45268

Susan Cormier (Group Chairman)
U.S. EPA, Office of Research and Development
National Center for Environmental Assessment
Cincinnati, OH 45268

Kathryn Gallagher (Group Chairman)
U.S. EPA, Office of Science Advisor
Risk Assessment Forum
Washington, DC 20460

Tala Henry (Group Chairman)
U.S. EPA, Office of Chemical Safety and Pollution Prevention
Office of Pollution Prevention and Toxics
Washington, DC 20460

Marc Sprenger (Group Chairman)
U.S. EPA, Office of Solid Waste and Emergency Response
Office of Superfund Remediation and Technology Innovation
Edison, NJ 08837

Mace Barron
U.S. EPA, Office of Research and Development
National Health and Environmental Effects Research Laboratory
Gulf Breeze, FL 32561

Charles Delos
U.S. EPA, Office of Water
Office of Science and Technology
Washington, DC 20460

Kristen Keteles
U.S. EPA, Office of Chemical Safety and Pollution Prevention
Washington, DC 20460

Charles Maurice
U.S. EPA, Office of Research and Development,
Office of Science Policy, Region 5 Superfund Division
Chicago, Illinois 60604

Wayne Munns
U.S. EPA, Office of Research and Development
National Health and Environmental Effects Research Laboratory
Narragansett, RI 02882

Matt Nicholson
US EPA, Region 3
Environmental Assessment & Innovation Division
Philadelphia, PA 19103

Edward Odenkirchen
U.S. EPA, Office of Chemical Safety and Pollution Prevention
Washington, DC 20460

Vicki Sandiford
U.S. EPA, Office of Air Quality Planning and Standards
Washington, DC 20460

Denice Shaw
U.S. EPA, Office of Research and Development
National Center for Environmental Assessment
Washington, DC 20460

Patti TenBrook
U.S. EPA, Region 10
San Francisco, CA

Dana A. Thomas
U.S. EPA, Office of Water
Office of Science and Technology
Washington, DC 20460

Steve Wharton (retired)
U.S. EPA, Region 8
Denver, CO

Risk Assessment Forum Staff
Lawrence Martin
U.S. EPA, Office of Science Advisor
Risk Assessment Forum
Washington, DC 20460

Meghan Radtke (Until 3/30/10)
U.S. EPA, Office of Science Advisor
American Association for the Advancement of Science Fellow
Washington, DC 20460

Seema Schappelle (Until 2/28/10)
U.S. EPA, Office of Science Advisor
Risk Assessment Forum
Washington, DC 20460

EXECUTIVE SUMMARY

BACKGROUND

Both within and beyond the U.S. Environmental Protection Agency (hereafter referred to as EPA, or the Agency), issues have been raised concerning ecological risk assessment practices including interpretation of existing guidance, incorporation of recent science, and the relationship of science and policy (U.S. EPA, 2004a; Tannebaum, 2005; Dearfield et al., 2005; DeMott et al., 2005; Bridgen, 2005; Stahl et al., 2005). More recently, the Science Advisory Board (U.S. EPA, 2008e) offered advice to EPA on improving the application of ecological assessment in environmental decision-making. Shortly thereafter, the National Research Council (NRC) of the National Academy of Sciences (NRC, 2009) provided advice on advancing risk assessment science in EPA environmental decisions. Because the collective advice applied to a number of EPA programs and regions, the development of an appropriate response required broad Agency representation. Therefore, a Technical Panel of the Risk Assessment Forum's Ecological Oversight Committee was formed with scientists from various EPA Program Offices and Regions. The Technical Panel convened an Intra-Agency Colloquium that included over 50 scientists from across the Agency (see Section 2).

AN INTEGRATIVE FRAMEWORK

An integrated framework for environmental assessment (Cormier and Suter, 2008) was used as a major organizing principle for the Colloquium (see Section 2). Because ecological assessments are conceptually and methodologically diverse, Colloquium participants used that framework to organize agency assessment into one of four kinds:

1. *Condition assessments* to determine whether the environment is impaired or trends that will lead to impairment.
2. *Causal assessments* to determine the causes of impairments and the sources of causal agents.
3. *Predictive assessments* to determine the risks and other considerations associated with alternative management actions.
4. *Outcome assessments* to determine whether management actions have adequately resolved the environmental issues.

The Technical Panel found that the integrated assessment framework provides a simple conceptual approach for describing, categorizing, integrating, and harmonizing all EPA assessment types. Condition, causal, predictive, and outcome assessments each have utility for specific objectives. However, each assessment type is limited to answering one type of management question, and no one assessment type can provide the scientific support needed to meet Agency goals. In contrast, the integrated assessment framework delineates the specific objectives of the four assessment types, shows how they can be used sequentially, and offers the option of designing a priori integrated assessments.

Although the integrated framework assessment typology has not been used widely within EPA, the Technical Panel found that it was compatible with current Agency practice and regulatory authorities. This was demonstrated through case examples from the Superfund and total maximum daily load (TMDL) programs and telephone interviews with Agency ecological assessors (see Section 4). In addition, two innovative assessment case examples in the pesticide and air programs (atrazine and nitrogen oxides−sulfur oxides [NO_x–SO_x] National Ambient Air Quality Criteria and Standards) were also compatible with the integrated framework (see Section B.2). The Technical Panel believes that implementation of the integrated framework at EPA would aid communication among assessors, managers, and the general public concerning the scope of a particular assessment or set of integrated assessments. It could also be used to clarify how the different assessment types can be combined and integrated to inform environmental decisions. The integrated framework was developed for ecological assessments but could be used with human health, economic, and engineering assessments.

EXISTING ECOLOGICAL ASSESSMENT GUIDANCE

Cataloging existing Agency science policy and technical guidance (see Section 5) pertinent to ecological assessment was necessary for understanding the status of current Agency practices, and prerequisite for addressing Science Advisory Board (SAB) and NRC advice and recommendations. EPA science policy guidance provides broad principles for conducting risk and other kinds of assessments. Technical guidance, on the other hand, focuses on specific scientific methodologies and procedures to be used during the analytical phase of an assessment. Collectively, Colloquium participants reviewed and evaluated over 90 Agency guidance documents. The Technical Panel also conducted a preliminary review of Agency-wide science policy documents (U.S. EPA, 1997a, 1998a, 2002a, 2003a,b,c, 2004a). This review demonstrated that EPA general risk assessment science policies are well developed (see Section 5.1) and have been heavily influenced by National Research Council reports (NRC, 1983, 1993, 1994, 1996, 2009). The Technical Panel concluded that existing science policy documents provide well-developed guidance on risk assessor-risk manager interactions, roles, and responsibilities; planning and scoping; problem formulation; conceptual model development; specific inputs to analytical phases of risk assessment; and risk characterization. However, the Technical Panel also found that implementation of the foregoing general science policy guidance was highly variable across the Agency. Awareness and implementation by ecological assessors of Agency-wide science policy guidance is inhibited by the fact that the guidance is human health-centric. Therefore, despite its general applicability to ecological assessments, this guidance is not well known in the ecological community within or beyond EPA.

The *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) have remained the primary focus of ecological assessors who are often unaware of Agency-wide science policy guidance. Concomitantly, because human health issues typically dominate Agency-wide science policy development and implementation, many human health assessors and senior decision-makers are unfamiliar with the diversity and scope of ecological assessment approaches and methods. The Technical Panel concluded that these factors have hindered the development of and the fullest application of Agency-wide science policies and their regarding protection of ecological attributes.

The SAB and the Technical Panel agreed that the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) have improved the state of practice. However, ecological risk assessment has become almost synonymous with estimating acute and chronic toxic risk of chemicals to plants, fish, invertebrates, and wildlife. Although the guidelines were designed to cover a wide variety of assessment scenarios, field-based ecologists working on descriptive and causal assessments do not view their work within the ecological risk assessment paradigm. The Technical Panel concluded that additional frameworks (e.g., causal assessment) were necessary, and the integrated assessment framework (Cormier and Suter, 2008) provided an approach for explaining and documenting alternative frameworks and assessment types, whether conducted individually, sequentially, or in an integrated manner.

Cataloging existing Agency guidance for ecological assessment (see Section 5.2, Appendix C) was challenging because it spans nearly two and a half decades. However, within the large and heterogeneous set of documents, a set of core documents was identified that provides general ecological risk assessment policies, principles, and guidance at EPA (U.S. EPA, 1992a, 1997b, 1998a, 2003b, 2004b).

To evaluate the utility of the integrated assessment framework, Colloquium participants categorized existing ecological assessment guidance as condition, causal, predictive, or outcome-based (see Section 5.2, Appendix C). All four assessment types were identified in this exercise, and integration of the four types was evident in selected Agency applications (e.g., Superfund, TMDL, Pesticide, and Air Programs). Generally, laboratory toxicity-based predictive assessments for estimating direct acute and chronic risk of individual chemicals are the most commonly employed assessment type at EPA. However, condition and causal assessments are also conducted by field-based ecologists. Outcome assessments that demonstrate the efficacy of risk management actions are conducted by EPA, but are the least common assessment type currently conducted by the Agency. The Technical Panel believes that outcome assessments are underutilized at EPA, and that linking them with other assessment types would enhance environmental assessment and decision-making.

The categorization of guidance (see Section 5.2, Appendix C) revealed several issues. General guidance for major steps in the ecological risk assessment process (planning and scoping, conceptual model development, assessment endpoints, measurement endpoints, effects assessment, exposure assessment, risk characterization) was found to be well developed. However, technical guidance was found to be inconsistent. Although not often explicitly stated, elements of newer guidance and practice supersede older guidance and practice. Guidance documents reflect the state of science and science policy at the time they were written. Guidance did not develop in a sequential or coordinated way for the Agency as a whole but reflects individual historical programmatic or regional needs and mandates with little consideration of other EPA programmatic or regional practice. In fact, an underlying rationale for the development of the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) and later general risk characterization guidance (e.g., U.S. EPA, 2003b) was to promote more consistent terminology and practices at EPA.

Second, the guidance is not available in any organized manner. The guidance needed for a particular issue can be found in various documents in various locations. It might be in an Agency-wide, programmatic or regional document, and the title may not be a good or complete guide to the contents.

Third, the guidance might not be in a useful form. Rather than a traditional report, guidance may be more useful if it takes the form of examples, responses to frequently asked questions, short state-of-practice white papers, exemplary case studies, expert systems, decision support systems, or other forms.

Finally, some important topics still have not been adequately addressed. For example, many Agency assessments weigh multiple lines of evidence to derive a value, categorize a chemical, or even derive a final conclusion concerning conditions, causes, or risks. However, no guidance has been provided for that inferential process. Similarly, general guidance for important but peripheral issues such as stakeholder involvement, risk communication, and risk management is less well developed.

Technical guidance, on the other hand, is often program specific and old. Based on the number of documents identified (>90), one Colloquium participant observed—"we are drowning in guidance that is neither easily obtained nor interpreted."

The Technical Panel agreed that a single compendium of available guidance needs to be developed. This proposed compendium would be most useful as a publicly available web-based resource. The Risk Portal and the Risk Assessment Forum (RAF) Web sites were suggested as possible platforms for a compendium.

RESPONSE TO SAB AND NRC COMMENTS

The SAB and NRC comments were summarized, yielding 46 discrete recommendations (see Section 6). The recommendations included issues directed to the Agency as a whole and to specific program offices. They included broad suggestions to transform thinking about ecological assessment and decision-making, as well as suggestions for incremental process and technical improvements. Each SAB and NRC recommendation was discussed at the Colloquium, grouped into categories, and ranked as being: (a) investigatory; (b) in initial implementation in one or more program offices or regions; or (c) fully implemented in one or more programs or regions. These determinations were made by comparing the recommendations with existing science policy and technical guidance (see Section 5) and the collective experience of Agency scientists at the Colloquium. The accompanying text (see Section 6) demonstrates that there are relatively few gaps between Agency practice and the SAB and NRC advice. However, practices are in different stages of development and highly variable among programs and regions. Many recommendations were found to be investigatory, in initial application stages, or already implemented in one or more program offices. None of the recommendations were considered to be fully implemented Agency-wide.

The Technical Panel and Colloquium participants focused on developing general responses to the transformative issues (e.g., spatial, temporal, and biological scales; global change; ecosystem services and benefits, adaptive management). The Technical Panel believed that advancing ecological concepts and incorporating them into Agency science policies has the greatest potential benefit for future Agency practice and ecological protection. They also believe that incorporating transformative scientific principles into Agency practice will help to resolve the apparent confusion surrounding variable Agency practice and the risk assessment-risk management interface. The Technical Panel strongly recommends that these issues be more fully considered by the EPA Science and Technology Policy Council.

Colloquium participants and the Technical Panel concurred with the SAB observation that clear Agency-wide science policies concerning what ecological attributes the Agency strives to protect have not been established. Some 15 years ago, a report by the Office of Policy, Planning, and Evaluation (Troyer and Brody, 1994) stated that more than three fourths of EPA programs interviewed expressed the need for ecology policy guidance within EPA. That report surveyed Agency legislative authorities, and specific ecological endpoints that EPA Program Office and Regions had used in risk management decisions. These results were updated in an appendix to *Generic Ecological Assessment Endpoints for Ecological Risk Assessment* (U.S. EPA, 2003b). Although the science and Agency precedents for using ecological attributes in decision-making have improved, no science policy "bright lines" akin to 1×10^{-6} for cancer risk exists for ecological risk. The variety of endpoints that the Agency uses in ecological assessments is a contributing factor to the frustration over perceived inconsistencies in practice, variable interpretation of existing guidance, the need to incorporate more recent science into ecological risk assessment, and the intermingling of science and policy (U.S. EPA, 2004a;

Tannebaum, 2005; Dearfield et al., 2005; DeMott et al., 2005; Bridgen, 2005; Stahl et al., 2005; U.S. EPA, 2008e)

RECOMMENDATIONS

The Colloquium was the first Agency-wide gathering of ecological assessors since finalization of the *Guidelines for Ecological Risk Assessment* in 1998. Accordingly, the Colloquium participants took the opportunity to develop recommendations for improving ecological assessment (see Section 7). Five overarching recommendations were identified. Additionally, the Technical Panel identified a number of specific recommendations to enhance ecological assessment at EPA.

Summary of Overarching Recommendations

The Technical Panel believes that the quality, scope, and application of ecological assessments in environmental decisions would be improved by the development and implementation of Agency-wide science policies in five potentially transformative areas and recommends that the Science Policy Council undertake their development.

Develop Science Policies that Promote Agency-Wide Ecological Protection Goals

Colloquium participants repeatedly expressed concern that many Agency decision and policymakers are less familiar with and are less focused on ecological issues and associated environmental protection goals than human health protection-related goals and issues. The Technical Panel acknowledged that human health issues remain critical in overall Agency decisions. However, many emerging environmental issues facing the Agency cannot be addressed within conventional human health or ecological risk assessment paradigms. Broader science policies are necessary for categorizing and contextualizing existing ecological assessments, as well the design and conduct of complex large-scale assessments currently facing EPA (e.g., global change, sustainability, estuarine and coastal hypoxia, integrated nitrogen control, biofuels, hydraulic fracturing of deep geologic formations for methane extraction, mountain top mining, deep sea oil spills, etc.).

The Technical Panel also noted that that senior science advisor positions in the program offices, regions, and Agency-wide science policy coordinating bodies are almost exclusively filled by human health risk assessors. This disciplinary and structural imbalance has had the unintended effect of weighting Agency-wide science policy priorities toward the many human health risk assessment issues facing EPA. If the Agency is to successfully incorporate important and well-developed ecological science principles (e.g., systems analysis, landscape ecology, ecosystem services and benefits, adaptive management) into its science policy framework, it must consider ways to elevate representation and influence of ecological scientists as senior science advisors in its programs, regions, and Intra-Agency science policy development and coordinating bodies.

Apply Systems Approaches to Ecological Assessments

Ecological assessors, particularly those in the regions, are concerned that the focus on medium-specific and chemical-specific assessments have inhibited ecological protection by not adequately recognizing that pollutants move among media, that multiple sources cause combined exposures, that multiple pollutants affect multiple receptors, and that effects on one ecological receptor have consequences for other ecological receptors and for humans. The Technical Panel recommends that the Agency begin to employ system approaches in ecological assessments. This is particularly important for broad scale environmental assessment issues discussed above.

Enhance Communication of Ecological Assessment Issues and Results

The strongest and most consistent recommendation of the Colloquium participants was that methods be developed for better communication with decision-makers and stakeholders. This applies to communicating both ecological assessment issues during planning of assessments and results at the conclusion. In part, this is a matter of inability of assessors to communicate the significance of the loss of species, changes in community structure, and other endpoints. In addition, it involves the lack of standard bright lines for acceptability like those in human health assessment, the plethora of assessment methods employed, and difficulties in conveying variability and uncertainty. Currently there is no guidance for communicating ecological risks.

Consider Ecosystem Services and Benefits in Assessment Scenarios as Methods and Tools Become Available

Quantification of ecosystem services and benefits is in its infancy but represents a significant research program at EPA. This program is potentially transformational for environmental sciences and decision-making. Ecosystem services can be used to describe quantitative outcomes for ecological assessments that can be more effectively communicated to decision-makers and the public.

Explore Adaptive Management as a Formal Science Policy for EPA

Adaptive management is a process that determines the outcome of actions and uses that information to improve assessments that inform decisions and improves the efficacy of those decisions. Adaptive management has not been adopted as a science policy at EPA. However, it is conceptually well developed and has been widely adopted in numerous federal and state agencies charged with ecological, fisheries, and wildlife management. The Technical Panel recommends that the Science and Technology Policy Council and the Risk Assessment Forum explore the use of adaptive management for testing and revising risk management actions.

Integrate Different Types of Assessments to Solve Broad Environmental Problems

The Colloquium participants found a need for the Agency to move beyond conventional risk assessment and to consider additional frameworks and assessment types to better inform decisions and the efficacy of risk management decisions. The Technical Panel also believes that conventional risk assessments, systems approaches, and adaptive management are inherent to the integrated assessment framework (Cormier and Suter, 2008). Additionally, in certain applications, the Agency is already conducting integrated assessments.

The Technical Panel believes that working toward Agency-wide science policies in the preceding five transformative areas will benefit ecological assessment at EPA in several ways. Most notably, it has the potential for applying new and innovative science and assessment approaches across the range of the Agency's existing authorizing legislation to better inform management decisions. The process of transforming ecological assessment science policy and practice would also assist in resolving the perceived confusion concerning ecological assessment which has been expressed by U.S. EPA (2004a) external observers (Tannebaum, 2005; Dearfield et al., 2005; DeMott et al., 2005; Bridgen, 2005; Stahl et al., 2005) advisory bodies (U.S. EPA, 2008e; NRC, 2009), and Colloquium participants in the following ways.

- *Communication, dialogue, and understanding among risk assessors and risk managers and the public concerning conditions, causes, predictions, and outcomes would be enhanced.*

- *Planning and scoping between risk assessors and risk managers would be improved.*
- *Problem formulation, including conceptual model development and the analytical plan would be improved for each assessment type whether they are conducted independently, sequentially, or in an integrated manner.*
- *Communication with risk managers and stakeholders during assessment planning and the presentation of assessment results would be improved by clear a priori documentation of the type, scope, and scale of ecological assessments.*

Specific Issues and Recommendations

Although Colloquium participants emphasized broad transformative science policy needs for ecological assessment, the Technical Panel understands that its foregoing recommendations are visionary and will require significant time and effort to accomplish. The call for transformative thinking regarding ecological assessment is not intended to diminish the need for incremental improvements in specific ecological assessment applications. As such, a number of specific recommendations for improving technical practices also surfaced. Many of the issues are of longstanding concern in ecological assessment and would benefit from additional development. The following list is long and ambitious and requires prioritization and flexibility. The Technical Panel recommends that the following list be referred to the Risk Assessment Forum Ecological Oversight Committee for further discussion and action.

Increase Training and Awareness for Ecological Assessment—Colloquium participants, particularly newer staff, stated that not enough training was available for them or the managers and stakeholders with whom they interact.

Quality assurance and data quality objectives (DQOs) for ecological assessment—The available quality assurance and DQO guidance for assessments emphasizes human health issues and techniques. For example, the DQO guidance presumes that risk characterization is performed by determining the probability of exceeding a bright line. Few ecological assessments have a priori bright lines, and risk characterization often involves multiple lines of evidence.

Weight of evidence—Although ecological assessments often involve multiple lines of evidence, there is no guidance on how to weigh those lines of evidence to make inferences.

Multiple stressors—The existing guidance documents for assessing the effects of mixtures is based on the types of data that are available for human health assessments and are limited to chemicals.

Receptor-specific guidance—While assessment methods are well developed for some taxa and assemblages such as fish and benthic invertebrates, few data and no assessment guidance are available for others such as amphibians, reptiles, and mollusks.

Stressor-specific guidance—Some stressors, such as nanomaterials, are not well addressed by current assessment guidance.

Life-cycle analysis for product safety evaluations—A life-cycle approach to the assessment of new chemicals and other products could improve the completeness and quality of assessments and decisions.

Uncertainty characterization and communication—The analysis of uncertainty, other than Monte Carlo analysis of transport and exposure models, has not been addressed by Agency guidance. Uncertainties in ecological assessments are particularly ill defined. It should be emphasized that condition, causal, predictive, and outcome assessments represent different modes of investigation and will require different uncertainty characterization procedures.

State-of-science or best practices reports—Rather than developing guidance, *per se*, the RAF might develop reports based on workshops or Technical Panels that summarize the best practices with respect to an assessment problem.

Case studies—Case studies of good assessment practices are a useful adjunct to training. They could include large scale assessments, assessments that reach no-effect conclusions in a defensible manner, or assessments that use new types of data or methods of data analysis.

Success stories—Create a document showing how actions based on ecological risks have resulted in improvements in the environment. This would encourage both assessors and managers. Also because ecological successes are more apparent, they can help to justify the Agency's actions. For example, by banning DDT, the Agency saved bird species and may have headed off effects on humans.

Cumulative assessment—The RAF should continue developing Agency guidelines on cumulative assessment, including a discussion of consideration of ecosystem services and benefits.

1. INTRODUCTION AND OBJECTIVES

Every technical practice must periodically step back, evaluate itself, and determine its path forward. For ecological assessors in the U.S. Environmental Protection Agency (EPA or the Agency) the impetus for reevaluation was the 10th anniversary of the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a), an EPA Science Advisory Board (SAB) review of ecological risk assessment practices, and a National Research Council (NRC) report on science and decisions in the EPA. This report presents the results of that reevaluation, including an evaluation of current practices and guidance, a path forward for improving ecological assessment, and a rationale for the path forward based on responses to the SAB and NRC recommendations.

The primary source of this document is an Intra-Agency Colloquium to evaluate ecological risk and related environmental assessments at EPA, which was organized by the Risk Assessment Forum (RAF), under the auspices of an Ecological Oversight Committee Technical Panel. The Colloquium afforded an opportunity to catalog the types of ecological risk and related environmental assessment approaches used by EPA and to consolidate existing guidance and technical practices employed at EPA under an integrated framework for environmental assessment (Cormier and Suter, 2008), and provided EPA ecological risk assessors and ecologists a structured forum to offer recommendations on how to improve the application of ecological assessments in Agency decision-making. The program allowed an evaluation of where the Agency has implemented, or is in the process of implementing, SAB and NRC recommendations, as well as gaps between Agency practice and the external science advice. Participants recommended priority science and science policy actions to fill gaps between current Agency practice and the SAB and NRC recommendations.

There has been little deliberate conceptual review of the field of ecological risk assessment as a whole, or of Agency practices, since the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) were finalized. The guidelines were a milestone in the continuing evolution of ecological risk assessment. Beginning in the late 1980s and early 1990s, a conceptual shift began in environmental decision-making from biological assessment and ecological hazard evaluation to ecological risk assessment. The shift was prompted by increased attention to human health risk assessment processes in the federal government (NRC, 1983, 1993, 1994), scientific advances in ecological risk assessment (Barnthouse et al., 1986; Fava et al., 1987; Suter, 1990, 1993; Calabrese and Baldwin, 1993), and greater focus on risk-based approaches to environmental regulation (Ruckleshaus, 1983; Thomas, 1987; U.S. EPA, 1989a,b, 1990a,b,c,d). Recognizing the need for a process that coupled scientific analysis to decision-making, the Agency undertook a 9-year effort, resulting in an ecological risk assessment framework and guidelines (U.S. EPA, 1991a, 1992a,b,c, 1993, 1994a,b,h, 1996a,b, 1998a). The EPA guidelines have been evaluated by several federal agencies (CENR, 1999) and have been found to be useful for related environmental assessments (e.g., agricultural ecosystems, threatened and endangered species, and ecosystem management).

In 2004, the Agency compiled risk assessment principles and practices (U.S. EPA, 2004a), with the purpose of beginning a dialogue with the scientific community to enhance risk assessment practices. It formed the basis of a debate and commentary on ecological risk assessment in the inaugural issue of *Integrated Environmental Assessment and Management* (Tannebaum, 2005; Dearfield et al., 2005; DeMott et al., 2005; Bridgen, 2005; Stahl et al., 2005). Issues raised in the commentaries included inconsistencies in practice, the variable interpretation of existing guidance, the need to incorporate more recent science into ecological risk assessment, and the intermingling of science and policy.

Prompted in part by *Risk Assessment Principles and Practices*, the SAB convened a workshop on the application of ecological risk assessment in environmental decision-making. The workshop results were summarized in a special section of *Integrated Environmental Assessment and Management* (Dale et al., 2008; Suter, 2008; Kapustka, 2008; Barnthouse, 2008). Widespread acceptance and success of the EPA ecological risk assessment framework and guidelines process were acknowledged. However, frustration was also expressed with the application of the *Guidelines for Ecological Risk Assessment*, the lack of Agency-wide policy or guidance defining which ecological attributes to protect (Dale, 2008), and the method of applying ecological risk assessment in risk management decisions.

The SAB used the workshop proceedings as a starting point for further deliberations, resulting in an advisory report to the EPA Administrator (U.S. EPA, 2008e). Nearly concurrently, the NRC released *Science and Decisions: Advancing Risk Assessment* (NRC, 2009). The primary focus of the latter report was to improve human health risk assessment; but, its recommendations have implications for ecological risk assessment, and some were similar to those made in the SAB Advisory.

Taken collectively, the foregoing literature highlights a need for better understanding and transparency of risk assessment in decision-making and policy within and beyond the Agency. Although true for all risk assessment, the need is particularly acute for ecological risk and related environmental assessments, which are conceptually and methodologically diverse. The Colloquium was organized to assess the evolution of ecological assessment thinking and experience in the Agency since 1998, and to address key recommendations found in the 2008 SAB Advisory and NRC Report. The Colloquium approach is described in Section 2, with the following sections addressing an integrative framework for understanding ecological assessment, the diversity in ecological risk practices and its development, and finally, the participants' responses to the SAB and NRC recommendations.

2. COLLOQUIUM APPROACH TO EVALUATING EPA ECOLOGICAL ASSESSMENTS AND THE SAB AND NRC RECOMMENDATIONS

The Colloquium was organized to conduct a thorough review of the Agency's ecological risk assessment practices and guidance in the service of preparing proposals to address the SAB and NRC recommendations. The EPA Science Policy Council was briefed on the proposed Colloquium to solicit comment and cross-Agency representation, and the meeting was approved by the Risk Assessment Forum. A Technical Panel composed of representative scientists from EPA's Office of Research and Development, Program Offices, and Regions was established to organize the Colloquium (see Appendix A).

Preliminary evaluation of the SAB and NRC recommendation revealed that the recommendations were multifaceted, interrelated, and ranged from very general to highly targeted items directed to particular program offices and regulatory applications. Prior to the Colloquium, the Technical Panel advised that the report recommendations should be summarized, with care taken to not introduce bias. Several attempts were made to sort the bulleted text into discrete categories, but many recommendations were inter-related, complicating the task. The recommendations were then clustered, and redundant entries were removed. The final summary yielded 46 recommendations (see Section 6).

Most recommendations focused on broad science policy issues and suggested future risk assessment directions for EPA. The need for greater clarity, understanding, and communication of the design and application of ecological assessments at EPA seemed paramount. This was evidenced by the call for clearer a priori science policies, environmental protection goals, and guidance, particularly at the risk assessment-risk management interface. Several longstanding issues were also raised, including weight of evidence, cumulative risk, uncertainty analysis, and hypothesis development in risk assessment. Finally, SAB and NRC recommended increasing science resources, management, and training in support of risk assessment. A third of the recommendations called for the development of additional EPA guidance. Colloquium participants reviewed the summarized recommendations and ranked their degree of implementation at EPA as (a) *investigatory*; (b) *initial stages of implementation*; or (c) *implemented* based on current Agency practice. These responses were grouped, and Colloquium participants offered additional comments on the recommendations in the individual breakout groups. The collective comments from Colloquium participants were collated into the responses provided in Section 6.

The Agency has published a significant number of science policy and technical guidance documents for risk assessment, in general, and ecological risk assessment, in particular. However, these guidance documents have been developed by different EPA offices, are dispersed, and are not available in a single comprehensive source. Although ecological risk is often addressed in Agency-wide guidance, these documents often remain little known in the ecological community at large. Therefore, the Technical Panel viewed consolidation of existing guidance for use by Colloquium participants as a necessary next step after summarizing the SAB and NRC recommendations.

The Technical Panel believed that responding to the SAB and NRC recommendations necessitated a review of the available guidance for the various types of ecological assessments conducted by the Agency. Over 90 documents covering science policy, technical methods and tools, and ecological risk and related assessment applications for different decision-making contexts were identified. Many of these documents were reviewed at the Colloquium to determine if they provided Agency-wide or program-specific guidance. They were also evaluated to determine if they addressed problem formulation elements (conceptual model development, assessment endpoints, measurement endpoints); analysis elements (effects assessment, exposure assessment); corollary issues (stakeholder involvement, risk communication, risk management, ecosystem benefits or services, uncertainty; risk integration); or issues of scale (biological and spatial). They were also sorted by type of assessment (condition, causal, predictive or outcome).

The integrated framework for environmental assessment (Cormier and Suter, 2008) was selected as a mechanism to clarify the relationship between the ecological risk assessment framework and guidelines, and the diversity of approaches to ecological assessments applications at EPA. The integrated framework was effectively used to categorize and differentiate the diverse ecological assessments used at EPA. Colloquium participants were introduced to the integrated framework by applying it to several EPA assessment scenarios, and discussing EPA frameworks, guidance, and practice relative to the four assessment types identified in the integrated framework (condition, causation, prediction and outcome).

Colloquium participants (see Appendix A) were assigned to breakout groups to discuss

- Existing EPA science policy guidance for planning and scoping, problem formulation, and risk assessor-risk manager interactions;
- The utility of the integrated framework for environmental assessments for cataloging EPA ecological assessment types;
- EPA ecological assessment approaches – by comparing existing technical guidance and practice with the integrated framework for environmental assessment; and
- The summarized SAB and NRC recommendations – to evaluate where the Agency has fully or partially implemented them and to identify gaps between the recommendations and Agency practice.

Composition of the breakout groups (see Appendix A) was fluid, collaboration between workgroups was encouraged, and many participants contributed to more than one group. Preliminary materials developed by the Technical Panel were expanded during breakout group and plenary sessions to develop the Colloquium proceedings. Unstructured discussions occurred during the Colloquium and particularly during the closing plenary session, which expanded the scope of the Colloquium beyond the agenda. The conclusions from the breakout groups and from those plenary discussions are summarized in Appendices E and F.

The enthusiasm of the discussions showed that the Colloquium was having an unplanned benefit. The strong cross-Agency collaborative networks established throughout the 1990s during the guidelines development have not been maintained, and ecological risk assessors have been increasingly compartmentalized within specific EPA program office and research applications. The Colloquium reinvigorated communication and clarified the need for collaboration across a broad range of Agency ecological and environmental activities.

3. THE INTEGRATED FRAMEWORK FOR ENVIRONMENTAL ASSESSMENT

Although the ecological risk assessment framework and guidelines were designed to meet all ecological assessment needs, their limitations soon became apparent. Risk assessment estimates the likelihood of undesired effects from alternative actions, but the Agency's decisions require a variety of input implying other types of assessments. As a result, frameworks for implementing the Total Maximum Daily Load provisions of the Clean Water Act, the development of criteria, the Superfund process, and other programs often bear little relationship to the Ecological Risk Assessment (ERA) framework. This disconnect has resulted in some frustration among practitioners, and resentment of the implication that they were not performing assessments correctly if they did not follow the ERA framework. These issues were expressed by some participants in the Colloquium. This concern is reinforced by the NAS's 2008 Science and Decisions report. It emphasizes that assessments should be designed to meet the needs of decision-makers rather than following a standard process. While the ERA framework was intended to be flexible, it has not been flexible enough to meet all of the Agency's needs for ecological assessment.

Until the Colloquium, the question of how the existing ERA framework corresponds to different environmental statutes and environmental decision-making contexts remained largely unarticulated. The integrated framework for environmental assessment (Cormier and Suter, 2008) was employed by the Colloquium Technical Panel to bring organization to the ecological risk assessment universe, and it became an overarching organizing principle during the Colloquium. The integrated framework offered a compelling conceptual model for clarifying, categorizing, integrating, and potentially harmonizing ecological assessment approaches and terminology across the Agency. The integrated framework set the stage for subsequent Colloquium discussions.

Regardless of scope, scale, objective, type, or methodology, virtually all EPA assessments can be described using a simple lowest common denominator process (see Figure 3-1). An assessment is typically initiated to address a regulatory or policy need to provide information for an environmental decision or action. The process proceeds through three steps: *planning* that determines the assessment scope and objectives; *analysis* that analyzes data and information on underlying causal relationships (e.g., an exposure-response relationship and an exposure estimate); and *synthesis* that evaluates analytical evidence, considers uncertainties, identifies implications of the analysis, and interprets the assembled information to develop conclusions or recommendations. Assessment results may lead to additional assessment, or to a management decision or action. This generic process is a useful model for showing relationships between different assessment types, and for illustrating how the ecological risk assessment framework has been adapted for different assessment purposes (Cormier and Suter, 2008).

A comparison of the generic assessment process with the ecological risk assessment framework and guidelines process (see Figure 3-2) demonstrates that the latter incorporates and expands upon the *planning*, *analysis*, and *synthesis* steps. *Planning* is divided into *planning* and *problem formulation* steps.

Similarly, *analysis* is defined further as a characterization of exposure and effects—a cause and effect relationship that can be modeled empirically, experimentally, or by using existing knowledge. *Synthesis* becomes *risk characterization*, where the probability of a defined effect occurring at the characterized exposure is calculated.

Many EPA program offices and regions routinely employ the ecological risk assessment framework and guidelines to assess the toxic risk of chemicals. This specific application is so commonplace, that, in some quarters, "conventional ecological risk assessment" is synonymous with estimation of direct acute and chronic risk of chemicals to organisms and populations. This narrow view is unfortunate and clearly limits the original intent and design of the framework and guidelines. Yet, it also reflects the reality that many ecologically oriented assessors often judge their work to lie outside of what they see as a toxicology-oriented paradigm, more akin to human health risk assessment than ecology. Two case examples illustrate the conceptual and practical difficulties in characterizing certain Agency assessments as "conventional ecological risk assessment."

Assessments to derive criteria, standards, or other benchmark values can be conceptualized as a variant of risk assessment that does not fit the standard framework (see Figure 3-3). Both conventional ecological risk and criterion assessments incorporate the planning, analysis, and synthesis steps of the basic assessment process. However, there are important differences in their underlying conceptual bases. Unlike conventional risk assessment, which estimates the risk of an ecological effect due to an exposure, criterion assessments estimate a level of exposure associated with a type and level of effect that will achieve an environmental goal (Suter and Cormier, 2008). The operational distinction between conventional risk assessment and criterion assessment can be understood by considering the role of the exposure-response relationship in the two assessment types. For conventional risk assessment, an exposure-response relationship is solved for the predicted exposure level to estimate risk (red [chronic] and blue [acute] arrows in Figure 3-4). For criterion assessment, the exposure-response relationship is used to estimate a protective environmental concentration (acceptable exposure level) based on prescribed effects (dashed orange arrow in Figure 3-4).

Another assessment scenario difficult to place within the conventional risk assessment view is The Causal Analysis/Diagnosis Decision Information System or CADDIS (http://www.epa.gov/caddis/). Originally developed in a guidance document (U.S. EPA, 2000b) and updated in a Web-based application (http://www.epa.gov/caddis) the CADDIS Stressor Identification framework (see Figure 3-5) was specifically designed for causal assessments. This causal assessment framework differs from conventional risk assessment in that effects have been found to have occurred, but the causative agent or agents are unknown. Causal assessments begin with an observed effect and proceed to the identification of a cause or source and are, therefore, epidemiological investigations. Note that in causal assessments, the initiator is a condition assessment, and the decision is to perform predictive assessments to determine how to remediate the identified cause.

These examples demonstrate that while some ecological risk and related ecological assessments fit the conventional ecological risk assessment framework, others do not because they are not intended to predict the environmental effects of an agent or action. Some assessments represent modifications of the ecological risk assessment framework. Others require new investigative frameworks to meet emerging or programmatic needs. The essential point is that regardless of the assessment form or framework, key components of ecological assessments at EPA remain *planning*, *analysis,* and *synthesis* directed toward environmental problem resolution.

Conventional ecological risk assessment of chemicals and contaminants is deeply embedded in EPA's mission and authorizing legislation (e.g., Toxic Substances Control Act [TSCA], Federal Insecticide, Fungicide and Rodenticide Act [FIFRA], Comprehensive Environmental Response, Compensation, and Liability Act [CERCLA], Resource Conservation and Recovery Act [RCRA], Clean Air Act, etc.) and will remain an important aspect of EPA's work for the foreseeable future. However, the last decade has also witnessed increased calls for integrated multidisciplinary environmental research, as well as more formal scientific integration of all the issues that go into environmental decision-making (U.S. EPA, 2008e; NRC, 2008). The underlying basis for integration resides in the fact that many environmental issues (e.g., estuarine and oceanic hypoxia, global warming, reactive nitrogen, fossil fuel extraction, biofuels development, sustainability, ecosystem services, etc.) are not resolvable by sole reliance on conventional risk assessment of pollutants.

The value of an integrated framework is that it allows conceptualization and categorization of different assessment types, it builds on current EPA practice and experience, and it can be sufficiently flexible to address emerging and future environmental issues. The framework by Cormier and Suter (2008) appears to offer all these advantages. It appears that all assessment types conducted by EPA can be conceptualized within a 2 × 2 matrix consisting of condition, causal, predictive, and outcome assessments (see Figure 3-6). The assessment types may be integrated in different ways, depending on programmatic needs and objectives. In the left column, environmental problems are detected by condition assessments that monitor the biological, chemical, or physical conditions of a site or system, or by outcome assessments that evaluate the adequacy of a former management action. In the right column, problems may be solved by causal assessments that identify impairment causes and sources, and by predictive assessments, such as conventional ecological risk assessment. Any individual assessment type may lead to any of the other three to investigate and resolve a particular environmental problem. Therefore, the top row (condition and causal assessments) identifies causes, while the bottom row (outcome and predictive assessments) manages causes. In any event, the four assessment types share a common process and can be linked within the integrated framework (see Figure 3-7).

Condition assessments are performed by analyzing environmental monitoring results (see Figure 3-7). These assessments determine whether the physical, chemical, or biological conditions constitute an impairment that should be addressed. A simple condition assessment would compare ambient chemical concentrations to ambient water quality criteria to determine whether the criteria are exceeded. If no criteria are exceeded, no further action is necessary until the next monitoring period. Otherwise, exceeding criteria would lead to a causal assessment.

Causal assessments determine the probable cause of the impairment and the source of the causal agent (see Figure 3-7). For example, if a stream is biologically impaired based on a state bio-criterion, the causal assessment might determine that the cause is ammonia toxicity. A subsequent source assessment might apportion the nitrogen loading among publicly owned treatment works, confined animal feeding operations, etc. If the cause is natural or outside the Agency's authority, no further action is taken by the Agency. Otherwise, the causal assessment results would lead to a predictive assessment.

Predictive assessments estimate risks and predict the effects of alternative management actions (see Figure 3-7). They include conventional risk assessments, as well as management assessments that may integrate ecological risks, health risks, feasibility, costs, policies, and other considerations. Predictive assessments are intended to inform an environmental management decision concerning remediation, permitting, or other actions. They may be prompted by prior assessments that have determined the cause of an observed impairment. More often, they are performed de novo, as in assessments of new pesticides and industrial chemicals. Predictive assessments end with a decision to take an action that may resolve the problem.

Following a predictive assessment, an outcome assessment may be used to determine if the action taken successfully resolved the environmental problem (see Figure 3-7). For example, outcome assessments are performed at Superfund sites to ensure that the contaminants are removed or destroyed. Similarly, grants for nonpoint-source remediation awarded by the Office of Wetlands, Oceans, and Watersheds require outcome assessments. Outcome assessments may demonstrate problem resolution or may prompt additional risk and management assessments to identify additional actions.

Within the integrated framework (see Figure 3-7), any of the four assessment types may serve as a starting point. However, the process typically begins with either a condition or a predictive assessment. Shortcuts through the process can also occur. In extreme cases, a simple condition assessment may be sufficient. For example, a causal assessment is not needed when a major oil spill is detected, and rather than performing a risk assessment, a response plan can be implemented.

For this report, the integrated assessment framework provides a simple conceptual approach for describing, categorizing, integrating, and harmonizing all EPA assessment types. Condition, causal, predictive, and outcome assessments were each found to have utility for specific objectives. However, the increasingly complex environmental assessment questions facing EPA suggest that their characterization and resolution can be enhanced by integrating different assessment types. The integrated framework is also an aid to communication among risk assessors, risk managers, and the general public concerning the scope of a particular assessment or set of integrated assessments. It can be used to clarify how the different assessment types may be combined and integrated to inform environmental decisions. During the Colloquium, the integrated framework provided a basis for understanding common assessment problems and needs across programs. Finally, it can be used to inform how the four assessment types might be designed to optimize integrated assessments for environmental decision-making. For example, an assessment may begin with a condition assessment to define a problem, followed by problem-solving causal or predictive assessments, and culminate with an outcome assessment.

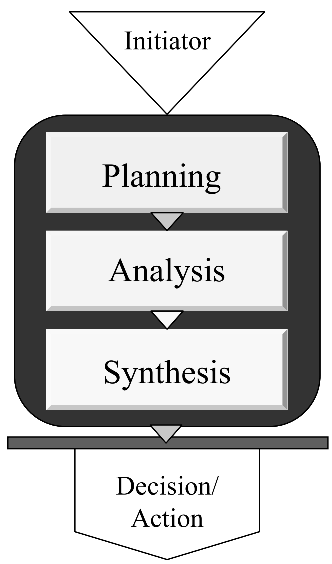

Figure 3-1. A common process for performing environmental assessments (Cormier and Suter, 2008).

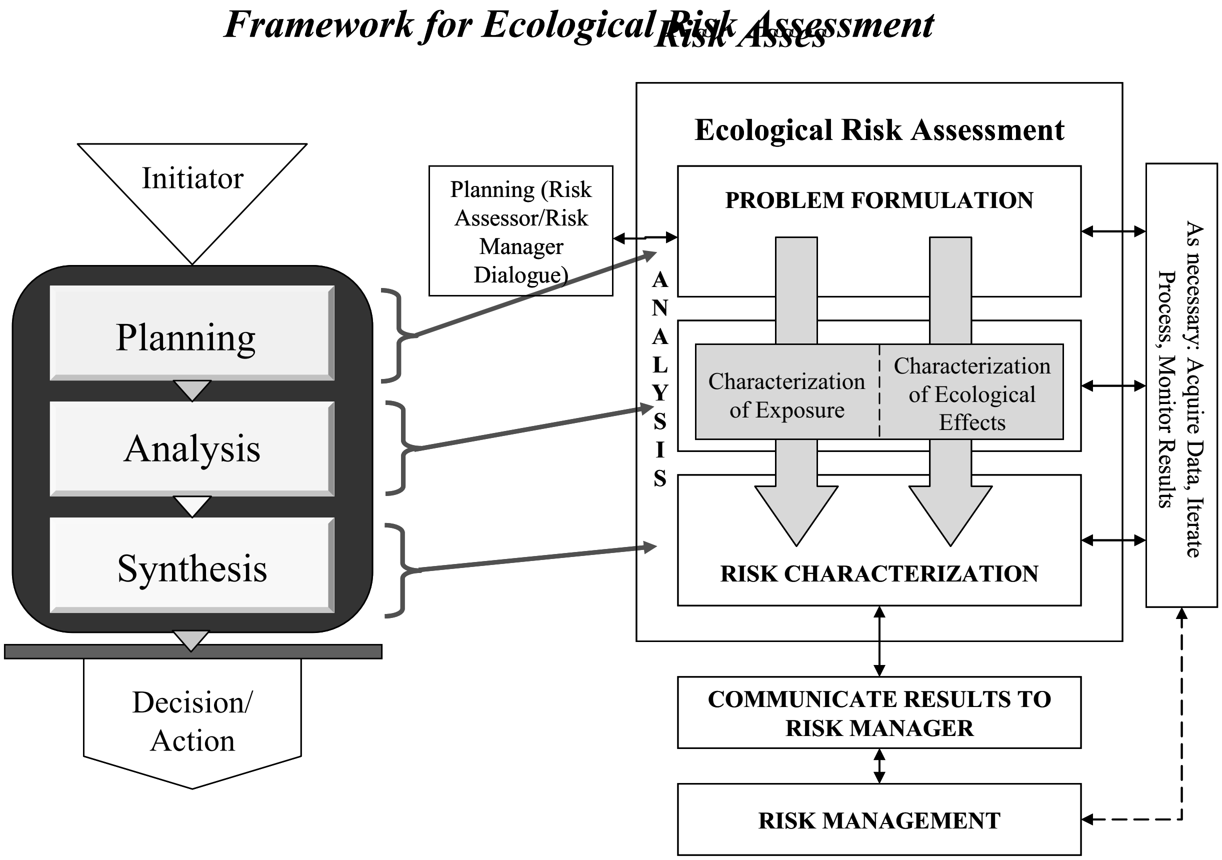

Figure 3-2. Identification of the planning, analysis, and synthesis activities as depicted in the Ecological Risk Assessment Framework.

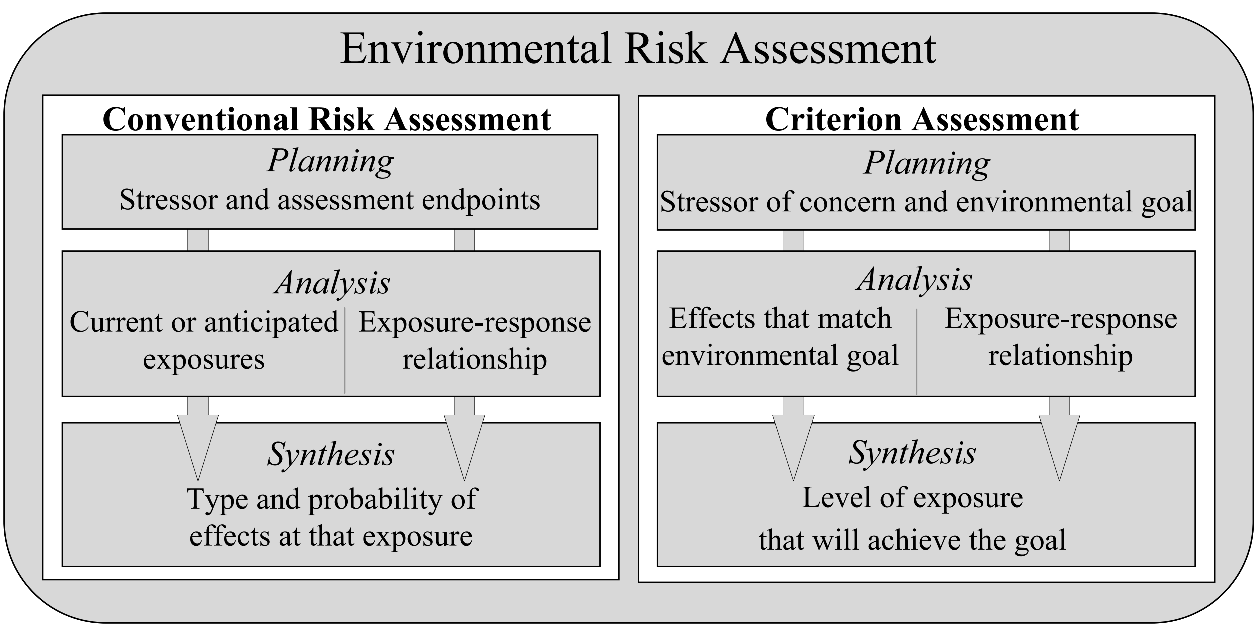

Figure 3-3. Comparison of conventional risk assessment and criterion assessments (Suter and Cormier, 2008).

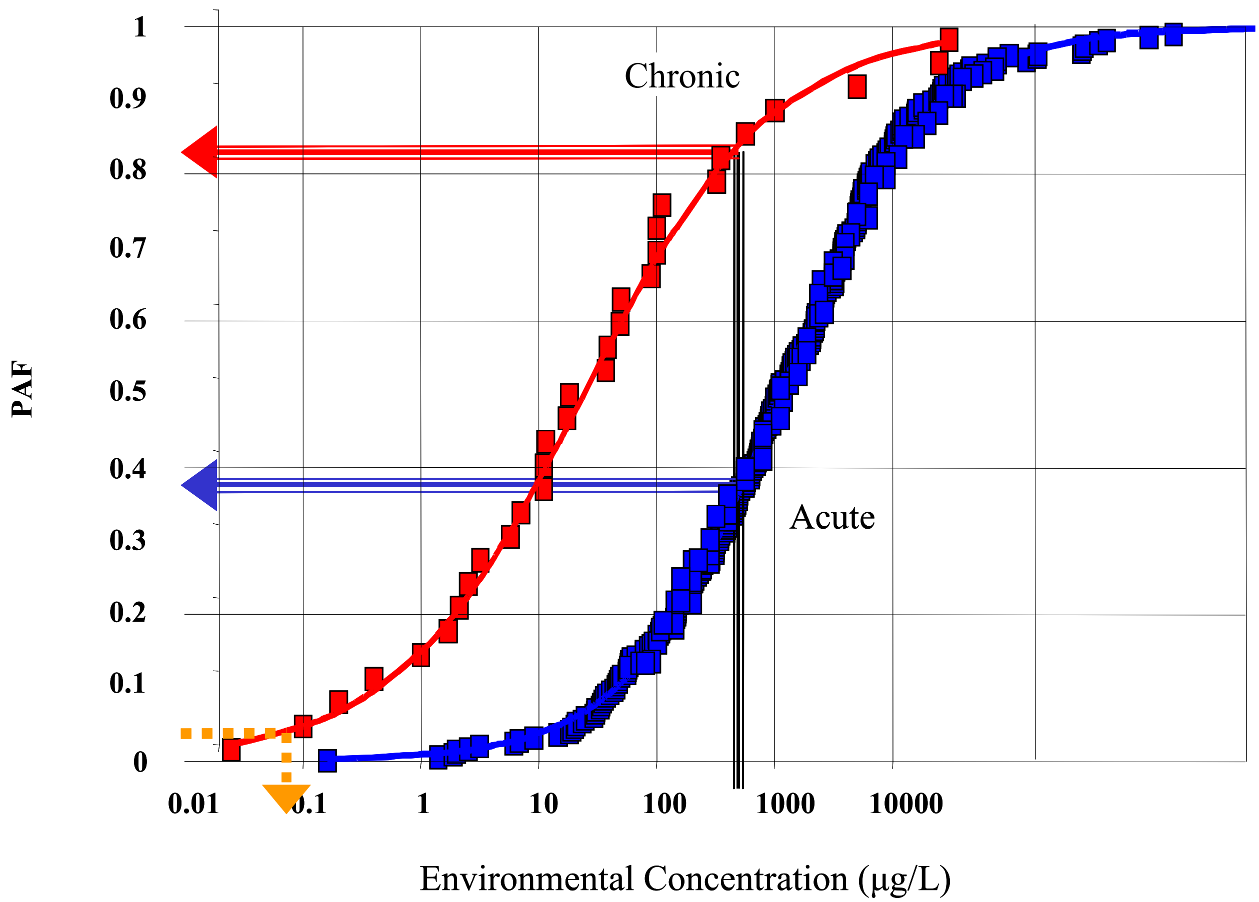

Figure 3-4. The acute (blue) and chronic (red) species sensitivity distributions are examples of exposure-response models. In conventional risk assessment, the red and blue arrows from the concentration axis (exposure) to the potentially affected fraction (PAF) axis (effects) provide estimates of risks. That is, at an exposure value of 500 µg/L, an estimated 39% of species would experience acute lethality, and 83% would exceed their chronic effects levels. In criterion assessments, the dashed orange arrow from effects to exposure determines that the concentration that is below the chronic effects value for 95% of species is 0.04 µg/L (Suter and Cormier, 2008).

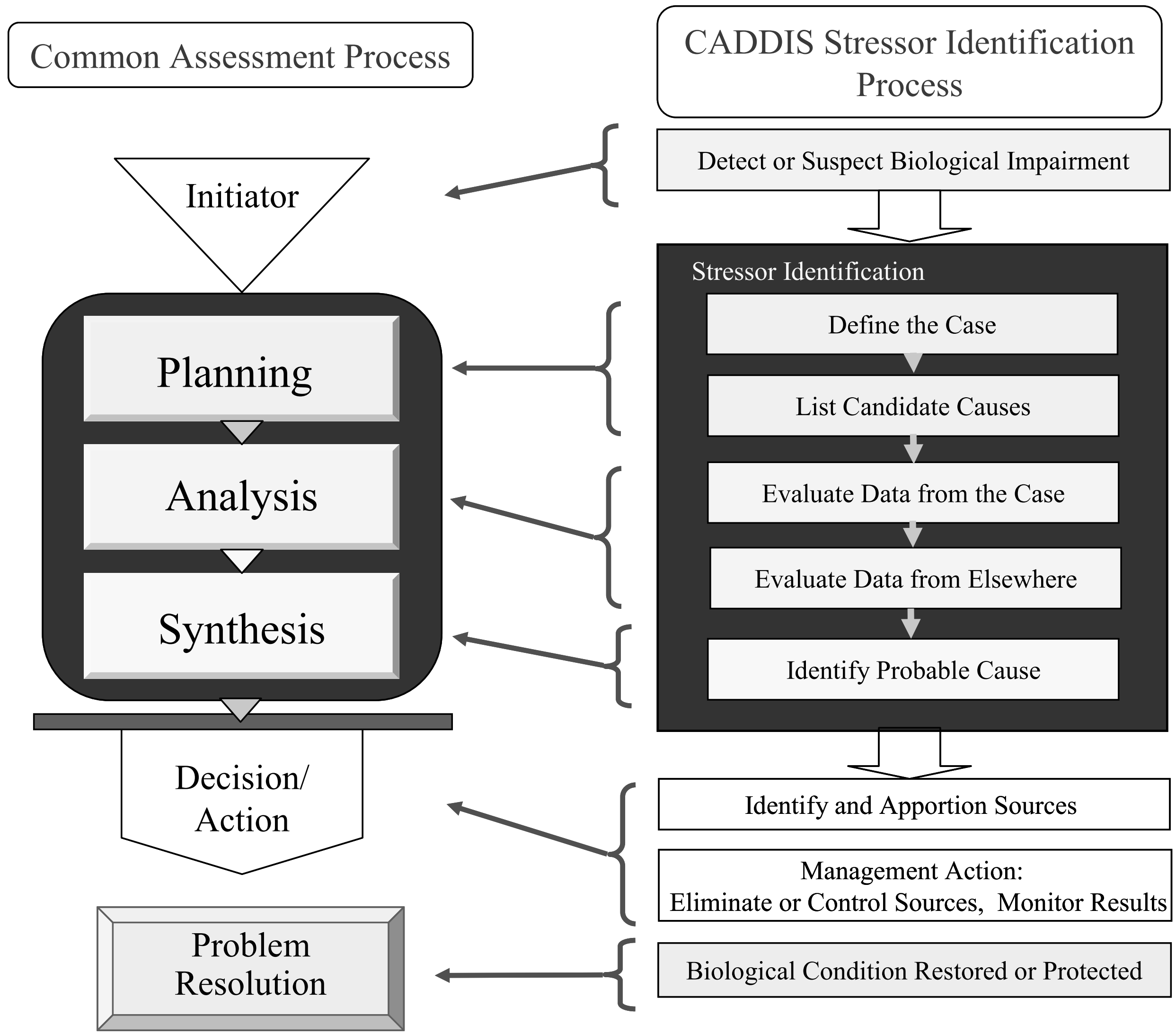

Figure 3-5. Identification of the planning, analysis, and synthesis activities as depicted in the Stressor Identification Framework from www.epa.gov/caddis.

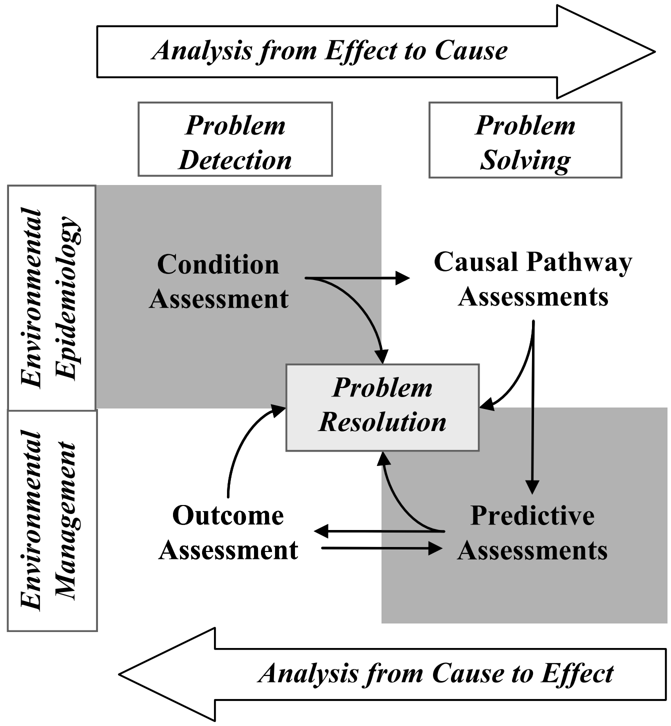

Figure 3-6. The basic structure of an integrated framework for environmental assessment (Cormier and Suter, 2008).

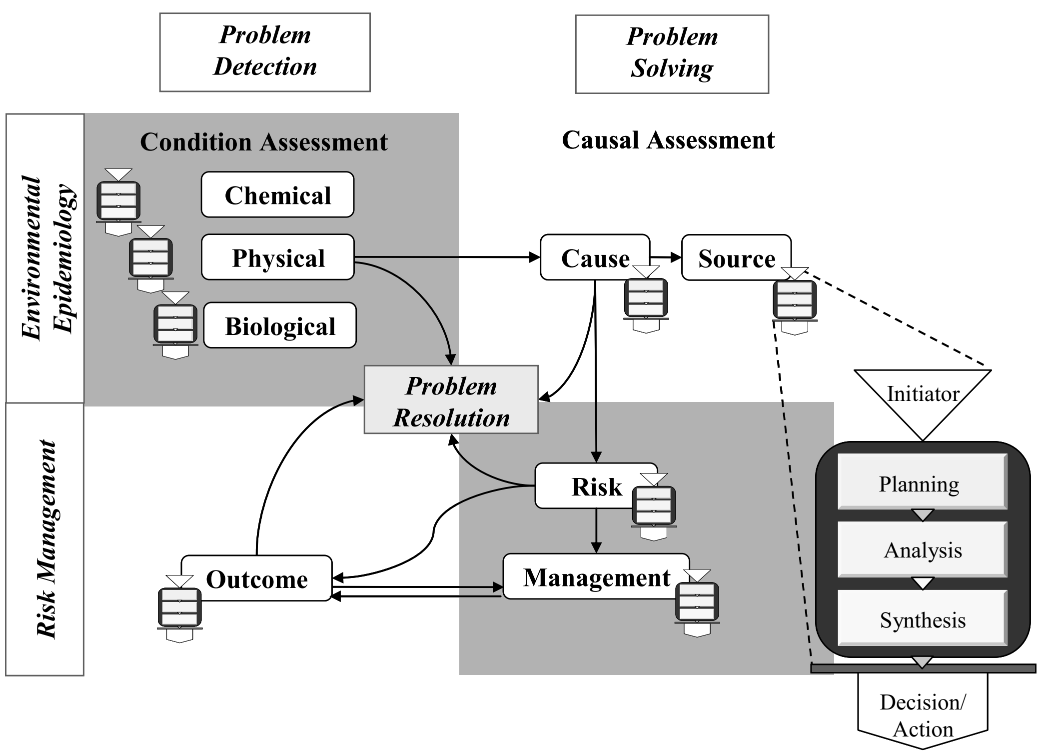

Figure 3-7. Specific assessment types within the integrated framework showing the shared common assessment process (Cormier and Suter, 2008).

4. CATEGORIZING EXISTING AGENCY PRACTICE AND GUIDANCE WITHIN THE INTEGRATED ASSESSMENT FRAMEWORK

The foregoing conceptual overview of the integrated framework asserts that all Agency assessments include common planning, analysis, and synthesis components, and can be categorized as condition, causal, predictive, or outcome assessments. While it may not be readily apparent, EPA already conducts integrated assessments. Two examples are the Superfund and total maximum daily load (TMDL) programs (Cormier and Suter, 2008).

CERCLA, commonly known as Superfund, was passed in 1980. Following its passage, federal agencies developed assessment and management processes to address different provisions of the Act. EPA and state regulatory agencies perform a condition assessment to determine if the site has been sufficiently contaminated to occur on the National Priority List (NPL). If a contaminated site is listed, the agency and state prepare two risk assessments: a baseline risk assessment during the remedial investigation to estimate risks from no action; and a feasibility study to estimate risks from alternative remedial actions (U.S. EPA, 1998b). The record of decision presents the results of a management assessment that selects the remedial action (see Figure 4-1). An outcome assessment is a component of the Operation and Maintenance Plan that re-evaluates the site after 5 years and may lead to the deletion of the site from the NPL.

The TMDL process is another example of a program that integrates multiple types of assessments. Every year, EPA files a Report to Congress listing all water bodies that states have identified as impaired, the *303(d) List of Impaired Waters*. The Clean Water Act requires that steps be taken to restore 303(d)-listed bodies of water to acceptable, useful conditions. To accomplish restoration, the Agency mandates that states determine the TMDL of the pollutant that can be safely discharged, while maintaining “acceptable use” of the body of water. The TMDL rule also requires states to develop a restoration implementation plan. Figure 4-2 depicts the sequence of assessments involved with 303(d) listing and the TMDL determination. Although different in form, the diagram contains all the components of the integrated environmental assessment framework in a similar sequence. The corresponding components of the assessment and management framework are indicated in grey oblongs: condition assessment (listing process), causal assessment (problem/pollutant identification), risk assessment of effects from exposure (target analysis), source assessment, risk assessment of sources (linkage of sources and target), management assessment (allocation to sources), and outcome assessment (update next listing cycle).

The CERCLA and TMDL examples demonstrate that the integrated assessment framework is already implicit in at least two Agency processes. However, the Technical Panel and participants were interested in further evaluating the applicability of the integrated assessment framework concepts to existing EPA processes. The evaluation was conducted in two stages. First, interviews with Agency ecological assessors were preformed prior to the Colloquium, and they were supplemented by review of frameworks and guidance processes publicly available on the EPA Web site (see Appendix B). Second, at the Colloquium, a matrix was developed that compared the integrated framework assessment types with the existing Agency guidance documents (see Appendix C).

The first stage was initiated by interviewing practitioners in representative program offices and regions to identify different assessment frameworks or processes used at EPA. References obtained from interviewees, supplemented with publicly available information from the EPA Web site were evaluated to determine what assessment types were currently being used (see Appendix B). If one of the four assessment types was not performed, the U.S. Code for the pertinent environmental law was consulted to determine if the salient act implied intent or authorized or required the assessment. Table 4-1 presents a summary of the results.

The composite results indicate that the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) are widely used throughout EPA. Additionally, ecological epidemiology assessments sometimes use the Stressor Identification (CADDIS) framework. The Superfund, Air, Water, and Pesticide Programs integrate all four assessment types in certain applications. Threatened and endangered (T&E) species assessments are also integrated, but Agency responsibility is limited to risk assessment for pollutant exposures. Still other programs depend on other groups to initiate or complete a sequence of assessments. For example, the Office of Water sets water quality criteria (WQC) that are used by states, tribes, and territories to assess the condition of surface waters. Some programs depend on the regulated entities to supply the information and even perform the assessments upon which they will be regulated. In rare cases, ecological assessments are initiated by citizen complaints or suits.

Although preliminary, the evaluation revealed some notable trends. Programs that involve remediation rather than prevention are more likely to routinely use an integrating framework or process with different assessment types. In particular, programs that estimate chemical and product safety do not routinely conduct outcome reviews, even where they seem to be allowed under existing legislative authority. The relative rarity of outcome assessments is scientifically problematic. Without them, the efficacy of risk management actions cannot be demonstrated; and without monitoring, ecological perturbations from an environmental insult will not be identified. Without timely detection and action, ecological damage and concomitant remediation costs are increased. If impacts are severe, remediation may become impossible.

Three overarching assessment issues were identified by the interviews. First, overlapping authorities were viewed as problematic for the Agency's overall mission of protecting the environment. Independent decisions in one part of the Agency may impact the ability of other programs, regions, or states to realize their mission. Overlapping authorities seem to create two kinds of constraints: (1) no individual program may see a particular issue as being within its area of responsibility; and (2) different expectations and assumptions embedded in different frameworks, processes, or technical methods may lead to conflicting assessment results or decisions. A common integrated framework for assessment and decision-making could provide the conceptual basis for linking across programs and regions. Second, all interviewees recognized the importance of involving stakeholders in assessment processes. Regional scientists, in particular, recounted various situations where success or failure was determined by stakeholder engagement and involvement. The current ecological risk assessment framework (U.S. EPA, 1998a) suggests stakeholder involvement before and after the assessment process. However, regions and states often engage stakeholders throughout the assessment process. Third, all interviewees voiced a preference for transparent processes and assessments. They suggested that stakeholder involvement could be strengthened by documenting and publishing assessment and decision-making processes.

Additional challenges were noted by multiple participants in the interviews and Colloquium. Certain assessments could be made more transparent if their non-sensitive aspects could be released while still protecting confidential business and proprietary information. The recognition by EPA assessors of the importance of stakeholders and transparency is consistent with the recommendations of review panels (NRC, 2009).

At first glance, frameworks and guidance for ecological risk assessment among different EPA programs often appear to be dramatically different. However, it was found through the interviews and Colloquium that the assessment needs are similar, and virtually all Agency assessments can be categorized as condition, causal, predictive, or outcome assessments. More importantly, the four assessment types can be used individually or integrated for different applications. Clearly, a common framework and terminology for ecological risk assessment has fostered communication among risk assessors. Similarly, broader Agency adoption of the integrated assessment framework and its terminology could improve communication and understanding among risk assessors, risk managers, and stakeholders. Improved communication could also assist the development of Agency-wide best practices between risk assessors and risk managers and help teams understand the respective roles of each contributor. Finally, adoption of the integrated assessment framework and terminology would promote deliberate thinking about the strengths and limitations of the four assessment types, assist in promoting integrated assessments for complex assessment scenarios, and, ultimately, provide an iterative feedback loop between scientists and decision-makers, resulting in better environmental decisions.

Importantly, integrated assessments are already practiced in some EPA programs (e.g., Water, Air, and Superfund) for certain issues. More importantly, they have demonstrated that integrated assessments can effectively resolve environmental problems under their purview. However, the differences among the four types of assessments may remain unrecognized by both practitioners and decision-makers. Broad Agency adoption of the integrated assessment framework would provide more opportunities to refine and integrate assessments; more frequent application of outcome assessments; and improve knowledge concerning the environmental performance of risk management actions. Directly coupling technical assessments with outcome assessments through feedback loops would also promote wider application of adaptive management (i.e., a structured process for implementing policy decisions as an ongoing activity that requires monitoring and adjustment) into environmental problem-solving and decision-making.

Table 4-1. Composite summary of interviews and EPA Web site review to survey available guidance for each type of environmental assessment.

Program	Framework or Guidance	Condition	Causal	Predictive	Outcome
OSRTI	P	Cn	C,S	R,B,M	O
R6 CERCLA, RCRA	P, Rg, St	Cn	C,S	R,B,M	O
OAR/OAQPS	A	Cn	C,S	R,B,M	O
OPPTS/OPPT	P	Cn		R,B,M	
OPPTS/OPPE	P			R,B,M	
Reg PPCP	A	Cn	C,S		O
Reg TMDL, NPDES	BPJ	Cn	S	R,B	
Reg Landscape	R			R,B,	
RoE	BPJ	Cn			
OW-T&E	A			R,B	
OW WQC	A			B	
OW Drinking	A		S	M	6-yr review

Letter with grey-fill is performed by the program.
Letter with white-fill is performed by others.
Grey-fill alone is part of regulatory authority, but not usually performed.
White-filled alone is not performed and not part of the regulatory authorities for the mission of this program.

programmatic (P), regional (Rg), state (St), agency (A), best professional judgment (BPJ) condition (Cn), cause (C), source (S), risk (R), benchmark/criteria (B), management (M), outcome (O).

OAQPS = Office of Air Quality Protection and Standards; OAR = Office of Air and Radiation; OPPT = Office of Pollution Prevention and Toxics; OPPTS = Office of Prevention, Pesticides and Toxic Substances; OSRTI = Office of Superfund Remediation and Technology Innovation; OW = Office of Water; PPCP = pharmaceuticals and personal care products; RoE = Report on the Environment.

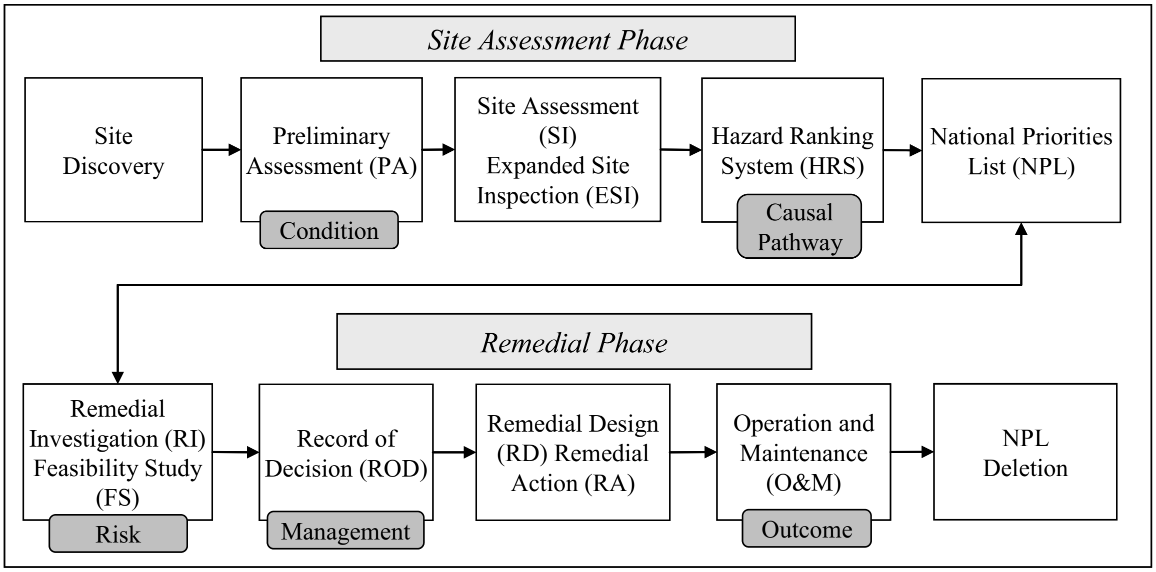

Figure 4-1. Superfund process and integrated assessment (U.S. EPA, 1998b).

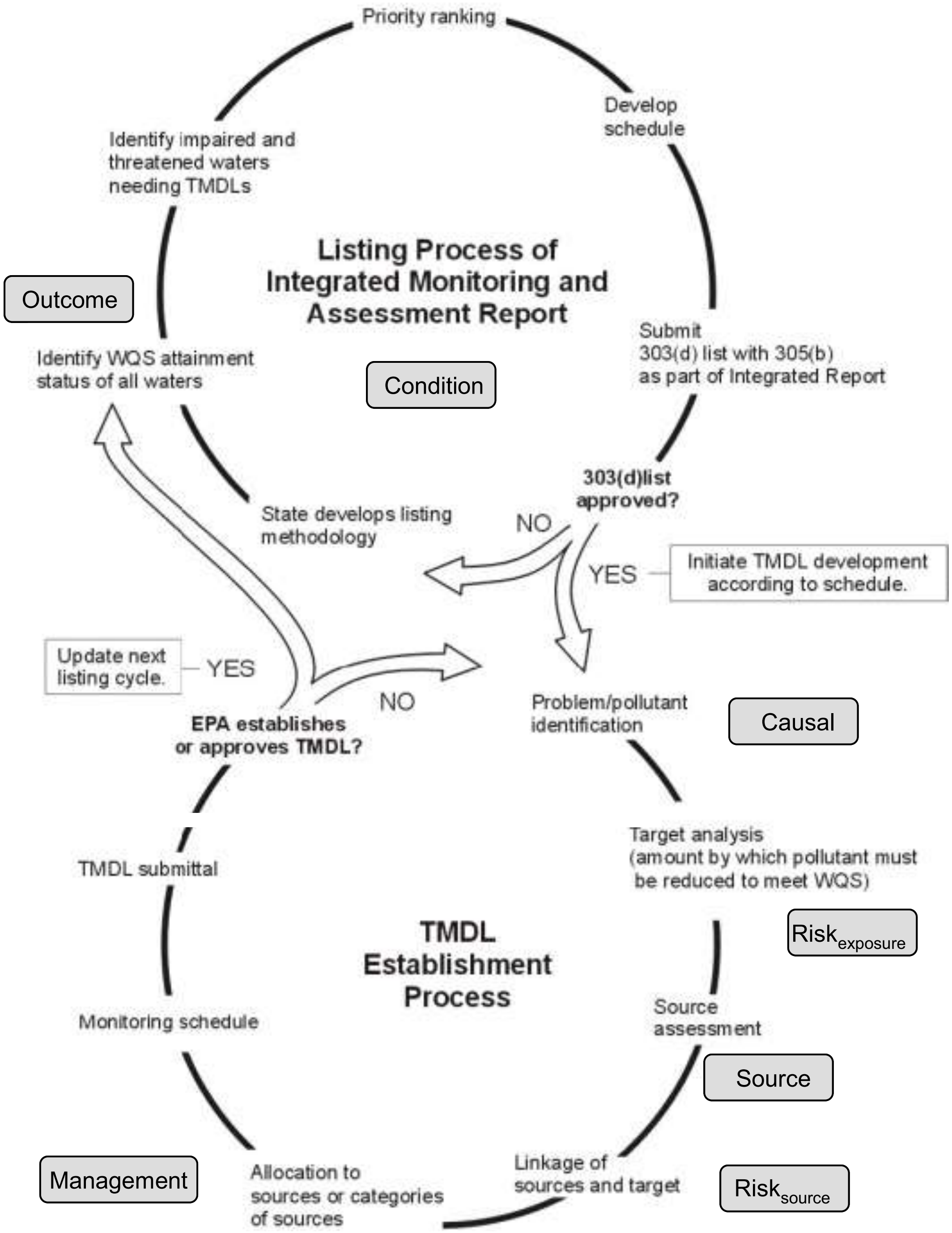

Figure 4-2. Process for listing impaired waters and determining total maximum daily loads (U.S. EPA, 2002b).

5. EXISTING GUIDANCE FOR ECOLOGICAL ASSESSMENTS AT EPA

The large body of guidance for ecological risk assessment and environmental risk assessment in general is not as helpful as it might be. Several factors may account for this problem. First, the guidance spans nearly two and a half decades. Although not often explicitly stated, elements of newer guidance and practice typically supersede older guidance and practice. Additionally, individual guidance documents reflect the state-of-science policy and science at the time they were written. Early guidance did not develop in a sequential or coordinated way by the Agency as a whole but reflects individual historical programmatic or regional needs and mandates with little consideration of other EPA programmatic or regional practice. In fact, an underlying rationale for the development of the *Ecological Risk Assessment Guidelines* (U.S. EPA, 1998a) and later general risk characterization guidance (e.g., U.S. EPA, 2003b) was to promote more consistent use of terminology and practice at EPA.

Second, the guidance is not available in any organized manner. The guidance needed for a particular issue may be found in any one of various documents in various locations. It may be in an Agency-wide, programmatic, or regional document, and the title may not be a good or complete guide to the contents.

Third, the guidance may not be in a useful form. Rather than a traditional report, guidance may be more useful if it takes the form of examples, responses to frequently asked questions, short state-of-practice white papers, exemplary case studies, expert systems, decision support systems, or other forms.

Finally, some important topics still have not been adequately addressed. For example, many Agency assessments weigh multiple lines of evidence to derive a value, categorize a chemical, or even derive a final conclusion concerning conditions, causes, or risks. However, no guidance has been provided for that inferential process. Similarly, there is no guidance for communicating ecological issues when interacting with decision-makers or stakeholders.

This section begins to address these issues. First, a conceptual and historical review of relevant guidance is presented. Second, relevant guidance is listed and organized in terms of properties that are indicative of its utility.

5.1. A CONCEPTUAL AND HISTORICAL REVIEW

The collective body of guidance can be viewed from various perspectives (e.g., technical issues, objectives, authorizing legislation and regulatory applications, research applications, etc.). Documents like the *Ecological Risk Assessment Guidelines* (U.S. EPA, 1998a), *Risk Characterization Handbook* (U.S. EPA, 2000d), the *Framework for Cumulative Risk Assessment* (U.S. EPA, 2003a), and *Risk Assessment Principles and Practices* (U.S. EPA, 2004a) are considered science policy guidance rather than technical guidance. Typically, science policy guidance provides broad EPA-wide concepts and principles for conducting risk and other kinds of assessments. Technical guidance, on the other hand, focuses on specific scientific methodologies and procedures to be used during the analytical phase of an assessment.

The development of science policies, techniques, and applications is a dynamic, often little known, processes. The distinction between science policy and technical guidance is important for understanding how ecological risk practices have evolved differently across the Agency. Generally, EPA programs and regions must meet different legislative mandates and legal requirements under their respective purviews. In practice, this means that programs and regions have developed targeted regulatory policies, science policies, and technical guidance independently and in keeping with their individual regulatory missions.

In cases where science policies or technical practices of one program office significantly impact that of another program office, Agency coordination vehicles come into play. An example is the collaboration between the Office of Pesticides and the Office of Water to share data and harmonize ecological risk assessment approaches for registration of pesticides and the development of pesticide ambient water quality criteria for the protection of aquatic life. Several major Agency science coordinating bodies exist. The Science Policy and Technology Council develops, reviews, and approves Agency-wide science and science policy guidance, whereas the RAF initiates the development of primarily Agency-wide technical, scientific guidance. Science coordination and review for rulemaking may also occur through the Office of Policy or the Office of Research and Development's Office of Science Policy.

The following highlights of developments in science policy for ecological assessments dispel the perception by some that the variability of ecological risk assessments across the Agency is disorderly. Biological and ecological assessments are longstanding in pollution impact studies (e.g., Cairns et al., 1972) and predate the hazard evaluation process (e.g., Cairns et al., 1978), which, in turn, predates the ecological risk assessment process. Ecological risk assessment at EPA arose and coevolved with human health risk assessment in a diverse regulatory decision-making context (Suter, 2008).

Several NRC reports (NRC, 1983, 1993, 1994, 1996, 2008) have heavily influenced the development of Agency-wide risk assessment science policy guidance at EPA (U.S. EPA, 1997a, 1998a, 2001a,b, 2002a, 2003a,b). With the exception of the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) and related documents, the primary focus of the NRC and EPA documents is on human health risk. As a result, the former documents may not be as well known in the ecological risk and broader ecological assessment communities. Nevertheless, they provide the necessary background for understanding risk assessment science and science policy at EPA.

From its inception, risk assessment has been recognized as a scientific process that informs risk management decisions. *Risk Assessment in the Federal Government: Managing the Process* or the Red Book (NRC, 1983) recommended that regulatory agencies

> take steps to establish and maintain a clear conceptual distinction between risk assessments and consideration of risk management alternatives; that is, the scientific findings and policy judgments embodied in risk assessments should be explicitly distinguished from the political, economic and technical consideration that influence the choice of regulatory strategies.

Some 10 years later, *Issues in Risk Assessment* or the Blue Book (NRC, 1993) proposed a paradigm for environmental risk assessment. It recognized the need for two-way communication between risk assessors and risk managers, and the utility of involving the public while preparing risk assessments to ensure effective communication. The Blue Book recommended

> communication between modelers, risk assessors, and managers should be mutual, iterative, timely and flexible. Risk assessment will be valuable as support to the risk management process only if the assessments address the right problem and if the managers who are the users of the products of risk assessment understand them.

The Blue Book reiterated maintenance of a clear conceptual distinction between risk assessment and risk management alternatives. However, a year later, Science and Judgment in Risk Assessment (NRC, 1994) seemed to reverse that recommendation by stating

> A more subtle and less widely recognized impediment to good decision-making on risk arises from a rigid adherence to the principle of separating risk assessment from risk management…The purpose of separation, however, was not to prevent any exercise of policy judgment at all when evaluating science or to prevent risk managers from influencing the type of information that assessors would collect, analyze, or present. Indeed the Red Book made it clear that judgment (also referred to as risk assessment policy or science policy) would be required even during the phase of risk assessment. The present committee concludes further that the science-policy judgments that EPA makes in the course of risk assessment would be improved if they were more clearly informed by the Agency's goals and priorities in risk management.

The NRC publications demonstrate movement away from the distinct separation of risk assessment as a stand-alone scientific exercise to one that seeks information from risk managers prior to beginning analyses. More importantly, they differentiate between science and science policy. Neither science nor science policy represent environmental decisions *per se*; rather, they represent the assumptions, objectives, data, estimates, data interpretation, and judgments concerning the risk that may occur for the defined conditions specified in a particular risk assessment design.

The ecological risk assessment framework and guidelines represent a significant developmental effort at EPA. In 1990, the EPA RAF initiated a program to develop ecological risk assessment guidelines to support environmental statutes. The effort began with a series of workshops that were intended to build upon information from the broader scientific community (U.S. EPA, 1991a, 1992a,b,c). The workshops resulted in broad scientific endorsement for an ecological risk assessment framework that envisioned (1) planning discussions between risk assessors and risk managers prior to problem formulation and additional discussions following completion of risk characterization and (2) an assessment process consisting of problem formulation, analysis, and risk characterization.

The framework provided a consensus foundation for further development of the *Guidelines for Ecological Risk Assessment*. Also, over several years, the framework was increasingly accepted by the scientific community, federal agencies, and international organizations. The framework was followed by the development of case studies (U.S. EPA, 1993, 1994h) and issue papers (U.S. EPA, 1994b,c) that examined the utility of the framework in various EPA program office and regional applications. The case studies were evaluated to determine if they (1) effectively addressed general components of the ecological risk assessment framework (problem formulation, analysis, risk characterization); (2) addressed some but not all of the components; or (3) provided an alternative approach to assessing ecological effects. The case studies were subsequently used with the framework report to provide a foundation for the draft (U.S. EPA, 1996a,b) and final (U.S. EPA, 1998a) *Guidelines for Ecological Risk Assessment*. Case studies were also evaluated to demonstrate the utility of the guidelines to a range of applications across several federal agencies (CENR, 1999) that included regulatory applications for chemicals (e.g., TSCA, FIFRA, CERCLA), and ecological evaluation of non-indigenous species, agricultural ecosystems, endangered and threatened species, and ecological assessments in ecosystem management.

Conceptually, there is widespread agreement that risk assessors, who develop scientific information and analyses for use in decision-making, and risk managers, who use such information in the decision-making process, both need to be involved in planning ecological risk assessments. This issue is clearly addressed in the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a), which state

> Both risk managers and risk and risk assessors should be involved in planning activities for ecological risk assessment. Risk managers charged with protecting the environment can identify information they need to develop their decision, risk assessors can ensure that science is effectively used to address ecological concerns, and together they can evaluate whether a risk assessment can address identified problems. However this planning process is distinct from the scientific conduct of the risk assessment. This distinction helps ensure that political and social issues, while helping to define the objectives for the risk assessment, do not introduce undue bias.

In practice, however, roles of risk managers and risk assessors in the planning, problem formulation, conduct of a risk assessment, and risk communication remain ambiguous. Various authors have attempted to characterize ecological risk assessor and risk manager relationships (Maki and Slimak, 1990; U.S. EPA, 1994d, 1995b, 2001a; De Pyster and Day, 1998; Barbour et al., 2004; Swindoll et al., 2000; Stahl et al., 2001). However, the existing literature typically provides an ecological risk assessor's perspective of risk management and addresses environmental decision-making in specific applications.

At EPA, risk assessment (evaluation of science) and risk management (decision-making, setting of policy) are distinct but not separate. EPA's *Risk Characterization Handbook* (U.S. EPA, 2000d) describes in detail the roles of the risk assessor and risk manager in the risk assessment process. The NRC report *Understanding Risk* (NRC, 1996) supports the concept that risk assessment is conducted for the purpose of supporting risk management, and risk management consideration shapes what is addressed in the risk assessment. Suter (2008) credited the framework's primary innovation as the identification of planning and problem formulation steps. Barnthouse (2008) stated that the problem formulation phase was a key innovation that recognized that the scope and content of an ERA depended on the problem at hand and needed to be discussed with the risk manager and stakeholders before initiation of the assessment. The NRC (2008) recently conducted a detailed review of its earlier recommendations (NRC, 1983, 1993, 1994, 1996) as well as existing EPA guidance concerning science policy and the risk assessment and risk management interface (U.S. EPA, 1997a,b, 1998a, 2001b, 2002a, 2003a,b, 2004a). They recommended EPA "focus greater attention" on planning and scoping and problem formulation as described in ecological and cumulative risk assessment guidance. In keeping with EPA guidance, the NRC (2008) discusses planning and scoping (U.S. EPA, 2003a, 2004a) and problem formulation (U.S. EPA, 1998a, 2003a, 2004a) as discrete aspects of risk assessment design. It further states that both planning and scoping stages are necessary to ensure that the form and content of a risk assessment are determined by the nature of the decision to be determined. The NRC (2008) concisely defined planning and scoping as *a deliberative process that assists decision-makers in defining a risk-related problem*, and problem formulation as *a technically-oriented process that assists assessors in operationally structuring the assessmen*t. The NRC also acknowledged that incorporation of these stages in the risk assessment process is inconsistent.

The Agency document *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (U.S. EPA, 1997a), although devoted to human health, is applicable to all assessments conducted by EPA. The document defines planning and scoping as follows:

> During planning and scoping, risk assessors, such other technical experts as ecologists, toxicologists, economists and engineers, and risk managers work together as a team, informed by stakeholder input, to develop the rationale and scope for the risk assessment and characterization, specifically to determine the following:
> - purpose and general scope of the risk assessment;
> - products needed by management for risk decision-making;
> - approaches, including a review of the risk dimensions and technical elements that may be evaluated in the assessment;
> - relationships among potential assessment end points and risk management options;
> - an analysis plan and a conceptual model;
> - resources (for example, data or models) required or available;
> - identity of those involved and their roles (for example, technical, legal, or stakeholder advisors); and
> - schedule to be followed (including provision for timely and adequate internal, and independent, external peer review).

The *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) were specifically designed to improve the quality and consistency in ecological risk assessments among the many and varied Agency program office and regions. They do not provide detailed guidance, nor are they proscriptive. They provide a flexible process to organize and analyze data, information, assumptions, and uncertainties to evaluate the likelihood of adverse ecological effects. The guidelines make an explicit distinction between planning and problem formulation. Planning is identified as a phase that precedes the development of the risk assessment and is described as the stage in the risk assessment process where agreements are made about the management goals, the purpose for the risk assessment, and the resources available to conduct the work. These guidelines identify problem formulation as the first phase in the risk assessment process proper. The document notes that during problem formulation

> The purpose for the assessment is articulated, the problem is defined, and a plan for analyzing and characterizing risk is determined. Initial work in problem formulation includes the integration of available information on sources, stressors, effects, and ecosystem and receptor characteristics. From this information two products are generated: assessment endpoints and conceptual models. Either product may be generated first (the order depends on the type of risk assessment), but both are needed to complete an analysis plan, the final product of problem formulation.

EPA's *Risk Characterization Handbook* (U.S. EPA, 2000d) also provides in-depth discussion of planning and scoping and was intended for all scientific assessments at EPA. Specifically, it recommends that during the planning and scoping phase of the risk assessment process, risk assessors and risk managers should engage in dialogue to identify and characterize the following issues

- Motivating need for the risk assessment (e.g., regulatory requirements, public concern, scientific findings, other factors
- Management goals, issues, and policies needing to be addressed
- Context of the risk
- Scope and coverage of the effort
- Current knowledge
- What and where are the available data
- An agreement about how to conduct the assessment including identification of
    - resources available to do the assessment
    - participants in the process
    - plans for coordinating across offices, other agencies, and with stakeholders
    - schedules (e.g., milestones and time frame)
- Plans for how the results will be communicated to senior managers and the public
- Information and data needs for other member of the "team" to conduct their analyses (e.g., economic, social, or legal analyses).

The *Risk Characterization Handbook* also includes several important insights concerning planning and scoping effort. Foremost, planning and scoping discussions should focus on the needs for the assessment effort, not the assessment results. Products that can emerge from planning and scoping process are the conceptual model and its associated narrative and the analysis plan.

The Agency also released *Lessons Learned on Planning and Scoping for Environmental Risk Assessments* (U.S. EPA, 2002a), which was meant to be a catalyst for encouraging agency managers to adopt formal planning and scoping as part of EPA's culture, especially when conducting significant or unique environmental assessments. The document provided lessons learned from case studies after release of *Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping* (U.S. EPA, 1997a). The *Lessons Learned* document identified the following key lessons learned from the case studies

1. Early and extensive involvement of the risk manager (decision maker) helped focus the process toward a tangible product.

2. Purporting that planning and scoping will be quick and easy is likely to be counterproductive; it is a lot more work than people assume. However, it ultimately saves time by helping to organize everyone's thinking and should result in a better quality assessment.

3. Stakeholder engagement is essential at the beginning, because their patience is directly proportional to their sense of influence in the process. They have been helpful in identifying important public health endpoints that were not initially considered by EPA in the process of developing a conceptual model.

4. Conceptual models are helpful in demonstrating how one program relates to other regulatory activities as well as the relationships between stressors and effects beyond traditional regulatory paradigms.

5. Debate over terminology and brainstorming sessions was necessary to reach a consensus in the practice. A clear set of definitions would aid this process.

6. The planning and scoping process cannot be prescriptive, because the context of each situation is different. Planning and scoping is particularly valuable when the assessment will be complex, controversial, or precedential. At this time, planning and scoping should precede cumulative risk assessments.

7. Clear objectives, resource commitments, and estimated schedules from management will drive the approach and level of detail that can be considered.

8. Explaining uncertainty to stakeholders is critical despite a hesitancy to reveal all that is known and not known about chemicals risks. While revealing these uncertainties may lead to criticism and political ramifications, it can also develop a sense of trust, credibility, and support for the decision making process.

The *Framework for Cumulative Risk Assessment* (U.S. EPA, 2003a) further discussed planning, scoping, and problem formulation. A key point made in this document is that…

> During planning and scoping, risk experts (including those involved in assessing risk, such as ecologists, toxicologists, chemists, and other technical experts such as economists and engineers), and decision makers work together as a team, informed by stakeholder input, to develop the rationale and scope for the risk assessment and characterization.

Several of the EPA guidance documents that describe planning, scoping, and problem formulation make the point that although steps are frequently described as a sequence, each step may go through several iterations as additional information is gathered.

In summary, EPA general guidance for risk assessment (see Table 5-1) has evolved over a period of years. Interestingly, planning and scoping and problem formulation were introduced in guidance for specific applications (i.e., ecological risk assessment, cumulative risk, aggregate exposure) prior to inclusion in more general assessment guidance. Nevertheless, guidance for risk assessor and risk manager roles and responsibilities; stakeholder involvement in planning, scoping, and problem formulation; and general risk characterization principles are well developed and relevant to all assessments conducted throughout EPA. In addition to Agency-wide guidance, several other documents address risk assessor-risk manager interactions. The Office of Prevention, Pesticides, and Toxic Substances published *Ecological Risk: A Primer for Risk Managers* (U.S. EPA, 1995b). *Ecological Risk Assessment and Risk Management Principles for Superfund Sites* (U.S. EPA, 1999a) and *Role of the Ecological Risk Assessment in the Baseline Risk Assessment* (U.S. EPA, 1994d) specifically address risk management within the Superfund Program.

A set of six guidance documents provide the basis for the ecological risk assessment process and practice at EPA (see Table 5-2). These documents are in conceptual harmony and provide a general paradigm for ecological risk assessments within EPA, approaches toward specific ecological risk assessment applications (e.g., cumulative and probabilistic risk), development of ecological assessment endpoints, and EPA program-specific ecological risk assessment guidance (Superfund, pesticides, and air programs). The latter documents contain information and guidance to promote the application and use of ecological risk assessment in risk management decision-making, risk assessor and risk management interactions, problem formulation, and specific inputs to the components phases of ecological risk assessment (e.g., hazard or toxicity assessment). The general documents mentioned above are often supplemented with additional program office-specific guidance and guidelines.

Although the concept of risk implies uncertainty concerning outcomes and uncertainty is quantified as probability, there is little Agency guidance on probabilistic risk assessment (see Table 5-3). However, this is an active area for the RAF.

The Superfund program has a number of program-specific guidance documents that address process and data needs (see Table 5-4). Guidance documents for the analysis phase address data to be used in ecological risk assessments, as well as the evaluation of data quality within data quality objectives, and the use of "qualified" analytical data.

While not risk assessment methods *per se*, the Office of Prevention, Pesticides and Toxic Substances (OPPTS) harmonized test guideline library provides numerous study guidelines used to generate data on pesticides and industrial chemicals. The harmonized test guidelines specify methods that EPA recommends be used to generate data that are submitted to EPA to support the registration of a pesticide under the FIFRA (7 U.S.C. 136), or the decision-making process for an industrial chemical under the TSCA (15 U.S.C. 2601). Data submitted to EPA using the harmonized guidelines are used by the Agency to perform risk assessments and to make regulatory decisions. The test guidelines are arranged in topical series, including product properties (Series 830), fate transport and transformation (Series 835), ecological effects (Series 850), microbial pesticides (Series 885) and endocrine disruptors (Series 890). These test guidelines are available at http://www.epa.gov/oppts/pubs/frs/home/guidelin.htm.

Another set of guidance addresses methodologies for assessing particular ecological responses to stressors (see Table 5-5). General guidance for stressor identification, assessment endpoint identification, watershed assessments, and population assessments has been developed by the Office of Research and Development or the RAF. Additionally, stressor specific guidance has also been developed.

Guidance for developing chemical and physical (e.g., dissolved oxygen, salinity, etc.) criteria to protect aquatic life (U.S. EPA, 1985) appeared about 25 years ago and has been used to develop over 120 water quality criteria. However, distinctly different approaches and guidance has also been established for nutrient criteria, biological criteria, coastal dissolved oxygen, and suspended and bedded sediments (U.S. EPA, 1996c, 2000c, 2000f, 2006b).

Approximately 30 technical and policy documents have been developed for nutrients (nitrogen and phosphorus) in rivers, streams, lakes, reservoirs, wetlands, and estuaries in different ecoregions of the United States (http://www.epa.gov/waterscience/criteria/nutrient). The ecoregional nutrient criteria represent surface water conditions associated with minimal impacts caused by human activities and may be used as baselines identify problem areas, provide the basis water quality criteria, and assist in evaluating eutrophication reduction programs.

Twenty-seven documents have been developed on biological assessment and biocriteria (http://www.epa.gov/bioindicators/html/publications.html). These documents describe bioassessment methods for studying the structural and functional integrity of aquatic communities (fish, insects, algae, plants, and other organisms) within aquatic ecosystems. Biocriteria are the qualities of the biological communities necessary for a desired condition, and they represent a benchmark against which assessment results are compared. Current documents cover field and laboratory methods for streams and rivers, coral reefs, lakes, wetlands, and estuaries.

The Agency has also developed a framework for suspended and bedded sediments, and procedures and guidelines for deriving equilibrium partitioning sediment benchmarks for nonionic organics, several pesticides, and metal and PAH mixtures (available at http://www.epa.gov/waterscience/criteria/sediment/). Additionally, the Agency has developed frameworks for assessing metals and polychlorinated biphenyls (PCBs), biphenyls and furans, and specific guidance for soil-screening levels (see Table 5-5).

The foregoing discussion demonstrates that existing Agency guidance is fairly extensive and addresses all phases of the Ecological Risk Assessment process (problem formulation, analysis, and risk characterization). More recent guidance and guidance in development tend to focus upon specific technical issue or approaches, rather than core ecological risk assessment elements. However, some broad issues have been neglected such as ecological risk communication, uncertainty, weighing evidence, and assessment types other than risk assessments.

5.2. A COMPILATION AND ORGANIZATION OF EXISTING GUIDANCE

Agency documents covering science policy, technical methods and tools, and ecological assessment applications were identified and reviewed to ascertain their defining attributes. A table of guidance documents was prepared (see Appendix C) characterizing the type of assessment considered (condition, causal, predictive, outcome), whether they provided Agency-wide or program-specific guidance, and if they addressed problem-formulation elements (conceptual model development, assessment endpoints, measurement endpoints); analysis elements (hazard assessment, exposure assessment); corollary issues (stakeholder involvement, risk communication, risk management, ecosystem benefits or services, uncertainty, risk integration); or scale elements (biological and spatial). The table illustrates that Agency guidance for risk assessment, in general, and ecological assessment, in particular, is extensive and needs to be better organized and presented so as to be useful to assessors, decision-makers, and stakeholders.

One of the goals of the effort that generated the table was to categorize the existing guidance so that the quality and quantity of guidance on topic areas could be evaluated. It was successful in doing that, and this resulted in two important findings: (1) that the Agency guidance does already conform to the integrated framework adopted by the Colloquium; and (2) that ecological risk communication guidance is missing.

Table 5-1. EPA-wide risk assessment polices, principles, and guidance

Guidance on Cumulative Risk Assessment. Part 1. Planning and Scoping (U.S. EPA, 1997a)
EPA Risk Characterization Program Memorandum (U.S. EPA, 1995a)
Guidelines for Ecological Risk Assessment (U.S. EPA, 1998a)
Risk Characterization Handbook (U.S. EPA, 2000d)
Lessons Learned on Planning and Scoping for Environmental Risk Assessments (U.S. EPA, 2002a)
Framework for Cumulative Risk Assessment (U.S. EPA, 2003a)
Risk Assessment Principles and Practices (U.S. EPA, 2004a)

Table 5-2. General ecological risk assessment polices, principles, and guidance

Framework for Ecological Risk Assessment (U.S. EPA, 1992a)
Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final (U.S. EPA, 1997b)
Guidelines for Ecological Risk Assessment (U.S. EPA, 1998a)
Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment (U.S. EPA, 2003b)
Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs (U.S. EPA, 2004b)[a]
Air Toxics Risk Assessment Reference Library, Chapter 26: Ecological Risk Characterization (U.S. EPA, 2004c)

[a]http://www.epa.gov/espp/consultation/ecorisk-overview.pdf.

Table 5-3. General probabilistic risk assessment polices, principles, and guidance

Guiding Principles for Monte Carlo Analysis (U.S. EPA, 1997c)
Risk Assessment Guidance for Superfund: Volume III—Part A, Process for Conducting Probabilistic Risk Assessment (U.S. EPA, 2001a)

Table 5-4. Superfund program-specific guidance

Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Parts A-F[a] (U.S. EPA, 1989c, 1991b,c, 2001c, 2004d, 2009c)
Guidance for Data Useability in Risk Assessment (Parts A and B) Final (U.S. EPA, 1992e,f)
Eco Update Supplements to Ecological Risk Assessment Guidance for Superfund (U.S. EPA, 1997d) including: *Using Toxicity Tests in Ecological Risk Assessments* (U.S. EPA, 1994e); *Catalogue of Standard Toxicity Tests for Ecological Risk Assessment* (U.S. EPA, 1994f); and *Field Studies for Ecological Risk Assessment* (U.S. EPA, 1994g)
Screening Level Ecological Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Peer Review Draft (U.S. EPA, 1999b)
Interim-Final Guidance for RCRA Corrective Action Environmental Indicators (U.S. EPA, 1999c)
OSWER Directive: Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities (U.S. EPA, 1994i)
A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information (U.S. EPA, 2003c)

[a] A series document available at http://www.epa.gov/oswer/riskassessment/ragsa/index.htm.
OSWER = Office of Solid Waste and Emergency Response

Table 5-5. Guidance on stressors, responses, endpoints, and benchmarks

Watershed Ecological Risk Assessment (U.S. EPA, 2000a, 2008c)
Stressor Identification Guidance Document (U.S. EPA, 2000b)
Generic Ecological Assessment Endpoints for Ecological Risk Assessment (U.S. EPA, 2003b)
Risk Assessment Forum Technical Workshop on Population-level Ecological Risk Assessment (U.S. EPA, 2009a)
Guidelines for Deriving Numerical National Water Quality Criteria for Protection of Aquatic Organisms and Their Uses (U.S. EPA, 1985)
Nutrient Criteria Documents[a]
Biological Assessment and Biocriteria Documents[a]
Framework for Developing Suspended and Bedded Sediments (SABS) Water Quality Criteria (U.S. EPA, 2006b)
Sediment Benchmark Documents[a]
Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessments (U.S. EPA, 2008c)
Framework for Metals Risk Assessment (U.S. EPA, 2007c)
Guidance for Developing Ecological Soil Screening Levels (U.S. EPA, 2005)

[a]A series of documents only briefly discussed here. Web site addresses are provided in the text.

6. RESPONSE TO THE SAB AND NRC RECOMMENDATIONS

The SAB and NRC called for clearer science policies and processes, environmental protection goals, and guidance, particularly concerning the risk assessment-risk management interface (NRC, 2009; U.S. EPA, 2008e). Several long-standing risk assessment issues were raised including clarification of lines of evidence, weight-of-evidence, cumulative risk, uncertainty analyses, and hypothesis development in risk assessment. A number of recommendations also call for EPA to address broader spatial, temporal, and biological scales; global change; and adaptive management including post-decision auditing and monitoring in its assessments. Finally, recommendations concerning resources, management, and training were offered. These categories of recommendations are presented in tables and responses are discussed in this section.

The recommendations were generally directed to the Agency as a whole. However, as noted earlier, assessments conducted by different program offices or regions can vary significantly. Some of the recommendations are in initial stages of implementation, or are partially or fully implemented within specific program offices or regions. Others are being investigated by EPA research and development programs. As new science develops through research, it moves into programmatic and regional operations as needed, depending upon programmatic mission, objectives, and necessity.

These circumstances make a point-by-point response to each recommendation difficult. Therefore, the Technical Panel and Colloquium participants focused on developing general responses to the substantive cross-cutting recommendations. This approach was based on an understanding that significant science advancements at EPA often occur through shifts in thought, rather than continuous incremental improvements of existing processes. The nature of the recommendations suggested that transformative thinking was more important for advancing the application of ecological assessments in environmental decision-making than incremental process and technical improvements.

6.1. ASSESSMENT PROCESSES

Although the first six NRC recommendations (see Table 6-1) have implications for ecological assessment, they were specifically directed to improving processes for human health risk assessment. Recommendations 2, 4, and 5 relate to the design of risk assessment processes. The Technical Panel was gratified by the NRC recommendation to draw upon ecological risk approaches for human health assessments and to use a framework more in line with the ERA framework to improve risk management decisions. We believe that we are somewhat ahead in recognizing that a decision-focused assessment process requires types of technical assessments other than risk assessments (see Section 3).

All Agency programs and regions strive to use the most relevant data for all of their assessments (Recommendation 1). For emerging issues, filling data needs may start out as investigatory (e.g., endocrine disruptors [U.S. EPA, 1997e], cumulative risk [U.S. EPA, 2003a], nanotechnology [U.S. EPA, 2007a]), move into initial applications, and, ultimately, become operational. In practice, the Agency often relies on existing literature and data or data submissions from the regulated community in it assessment activities. The Agency's authorities, abilities, and resources to generate data de novo for specific applications remain highly variable. Certain programs have broad authority to require data (e.g., new pesticide registration), whereas others rely on existing scientific literature. In many cases, assessments are updated periodically (e.g., ambient chemical criteria for aquatic life) or at predetermined intervals (e.g., national ambient air quality criteria and standards).

Default assumptions (Recommendation 3) are rare in ecological assessments. Because nonhuman organisms and ecosystems are much more diverse than humans and their societies, default assumptions are difficult to apply in ecological assessments. However, where they occur, they should be justified, as the NRC recommends.

Stakeholder involvement in ecological risk assessment (Recommendation 6) is less common than suggested by the framework and guidelines (US EPA 1998a). The Technical Panel concurs that EPA should establish a process for stakeholder involvement to balance participation of stakeholders, including impacted communities and less advantaged stakeholders. This is particularly true for complex environmental issues that primarily involve ecological effects such as mountain top mining, Gulf of Mexico hypoxia, integrated nitrogen control, biofuels, greenhouse gases, carbon sequestration, and hydraulic fracturing of shale for methane extraction. Ecological assessors need to develop their own set of approaches for engaging stakeholders. This is particularly important because the most vocal stakeholders for these issues are typically the responsible parties such as miners and farmers. It has been widely recognized that scientists need to appropriately translate technical information to stakeholders and decision–makers. (see Appendix D.1).

Conclusion—Ecological assessors should continue to innovate in the development of assessment practices that focus on informing decisions. They need to develop strategies for productively engaging stakeholders and decision-makers in ecological issues.

6.2. ENVIRONMENTAL GOALS

The SAB called for greater delineation of Agency science policies concerning environmental protection goals. Specifically, the SAB recommended better definition of what ecological resources EPA is striving to protect and of assessment endpoints for these resources (see Table 6-2). The need for better understanding of Agency-wide ecological concerns was initially broached nearly 15 years ago in *Managing Ecological Risks at EPA: Issues and Recommendations for Progress* (U.S. EPA, 1994c). That document was prepared during the development of the *Guidelines for Ecological Risk Assessment*, and it inventoried environmental laws and policy support for ecological assessment endpoints used across the Agency, and offered eight recommendations for improving ecological considerations at EPA.

The legal and policy support for ecological assessment was reviewed in *Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment* (U.S. EPA, 2003b). Each assessment endpoint consists of an ecological entity and valued attribute. A detailed summary of the GEAE document is beyond the scope of the present effort. However, the document articulates several discrete categories of environmental values that may be used by EPA including consumptive values, informational values, functional values, recreational values, educational values, option (i.e., future environmental use) values, and existence values. The fifteen GEAEs include attributes of organism, population, community, and ecosystem levels of organization; critical habitats; and special places.

More recently, the Agency developed its *Report on the Environment* or ROE (U.S. EPA, 2008a). The ROE is organized around 23 priority questions that EPA considers important and relevant to its mission and believes should be answered. Although specifically developed as indicators to evaluate environmental trends, the priority questions offer another set of policy relevant science questions that articulate what the Agency values. Refer to Appendix D.2 for a list of the 14 ROE questions that include an ecological element. Although quite broad, the ROE questions provide another way to categorize broad ecological attributes valued by EPA. More importantly, the ROE questions have the potential to define ecological attributes EPA considers important for media-specific and ecological condition assessments.

Policy-relevant science questions and ecological protection values and goals have been articulated in the foregoing documents, as well as in Agency and program-specific guidance (see Appendix C). Yet, science policy-relevant questions for ecological assessments remain poorly understood This may be partially explained by the different ecological assessment objectives and decision-making contexts used by EPA. EPA's mission is to protect human health and safeguard the environment (air water, land) upon which life depends (U.S. EPA, 2004a). EPA fulfills this obligation by, among other things, developing and enforcing regulations that implement environmental laws enacted by Congress. See Appendix D.3 for ecological entities specifically targeted by environmental laws. This does not suggest that there are no Agency-wide ecological or natural resource protection goals. However, the goals are often couched in terms of managing risk by eliminating, reducing, or mitigating sources of exposure to protect natural resources rather than direct management of resources.

Conclusion—The Agency has published extensive guidance on ecological assessment endpoints, but individual assessments should include a clearer presentation of endpoint entities and attributes.

6.3. ADAPTIVE MANAGEMENT

Because adaptive management is common practice in fisheries, wildlife, and other ecological and environmental management applications, it is not surprising that the SAB recommended that EPA explore its application in risk assessment and risk management (see Table 6-3).

The SAB has recommended that the Agency use adaptive management to address uncertainties in decision-making (U.S. EPA, 2008e). The NRC (2004) identified six elements of adaptive management that are directly relevant to goal setting and research needs: (1) resources of concern are clearly defined; (2) conceptual models are developed during planning and assessment; (3) management questions are formulated as testable hypotheses; (4) management actions are treated like experiments that test hypotheses to answer questions and provide future management guidance; (5) ongoing monitoring and evaluation are necessary to improve accuracy and completeness of knowledge; and (6) management actions are revised with new cycles of learning. The EPA (2008e) identified the following NRC (2004) statement as perhaps the most important take home lesson of their work.

> Adaptive management does not postpone actions until "enough" is know about a managed ecosystem (Lee, 1999), but rather is designed to support action in the face of limitations of scientific knowledge and the complexities and stochastic behavior of large ecosystems (Holling, 1978). Adaptive management aims to enhance scientific knowledge and thereby reduce uncertainties. Such uncertainties may stem from natural variability and stochastic behavior of ecosystems and interpretation of incomplete data (Parma et al., 1998; Regan et al., 2002), as well as, social and economic changes and events (e.g., demographic shifts, changes in prices and consumer demands) that affect natural resource systems.

While adaptive management is not an explicitly recognized policy at EPA, its basic elements can be identified in the ecological risk assessment framework and guidelines (U.S. EPA, 1998a). Additionally, integrated assessments currently performed in some EPA programs (e.g., Water, Air, Superfund, Pesticides) implicitly contain elements of adaptive management (as discussed in Section 3, above). As such, the Technical Panel judged that adaptive management is both investigatory and in initial application stages at EPA programs. The Technical Panel also believes that directly coupling technical assessments with outcome assessments through feedback loops will promote wider application of adaptive management at EPA.

Conclusion—Adaptive management is potentially a highly useful strategy, but its implementation would require changes in fundamental Agency science policies and practices.

6.4. PLANNING, SCOPING, AND PROBLEM FORMULATION

The NRC recommended the adoption of a framework for risk-based decision-making that included planning, scoping, and problem formulation (Recommendation 5, Table 6-1). The SAB provided eight additional recommendations concerning problem formulation for ecological assessments (see Table 6-4). The specific problem formulation issues raised by the SAB include the need for better definition of risk management goals, risk assessor-risk manager roles, hypothesis development, peer review, scale (spatial, temporal, and biological), uncertainty, and review of case studies to develop standards of practice (see Table 6-4). The Agency has published more guidance on design, planning, scoping, and problem formulation than is suggested by these comments. Planning and scoping for risk assessment are addressed in 13 separate EPA guidance documents, while elements of problem formulation (conceptual model development, assessment endpoints, measurement endpoints, hazard/toxicity assessment) are addressed in 37 separate EPA guidance documents (see Appendix C).

The Technical Panel considered planning, scoping, and problem formulation to be widely implemented across EPA but also recognized that its documentation and external transparency are widely variable. Problem formulation for screening or routine assessments is sometimes assumed to be embedded in program-specific technical guidance. In these cases, risk assessor-risk manager interactions, the various problem formulation elements (conceptual model development, assessments endpoints, measurement endpoints), and the analysis phase elements (hazard, exposure, effects analyses, risk characterization) may be more or less informal. However, as complexity and visibility of an assessment increase, so too does formal and deliberate characterization and documentation of the problem formulation and analytical plan, stakeholder involvement, and peer review.

The SAB recommends obtaining peer review of problem formulation of large risk assessments and use of checklists cataloguing best practices in problem formulation for smaller scale assessments (Recommendation 12 and 13). The Technical Panel supports this approach to enhancing formalization and review of problem formulations as appropriate in Agency risk assessments. Current Agency peer-review policy requires independent peer review for “highly influential scientific assessments.” Peer review of problem formulation prior to implementation is rare and may be difficult for some programs due to regulatory constraints. However, iterative peer review of complex assessments has been conducted by some program offices.

An example of iterative assessment and review steps in a program office is provided by pesticide registration. Office of Pesticide Programs has a mandate to review the registration of all conventional pesticide active ingredients every 15 years under the Registration Review program. The problem formulation for each active ingredient is requested by the responsible management division (Pesticide Reevaluation Division or PRD) according to a predefined schedule. The Environmental Fate and Effects Division drafts a problem formulation, which is subjected to peer review within the division and then is peer reviewed by PRD. The problem formulation is taken as far as the analysis plan stage, and the data call-in needed to complete the risk assessment is drafted and justified. The final Problem Formulation becomes part of a preliminary work plan, which is published in the Federal Register for public comment and peer review. The problem formulation is modified according to the public comments, if necessary, and becomes part of the final work plan for the Registration Review.

Detailed descriptions of iterative external peer reviews associated with specific regulatory assessments are beyond the scope of this document. However, notable examples include the Office of Pesticides Programs assessment of atrazine and the Office of Air Quality Protection and Standards assessment for the secondary national ambient air quality standards for nitrogen oxides (NO_x) and sulfur oxides (SO_x). The atrazine assessment included consideration of general ecological effects, specific developmental effects on amphibians, and ecological watershed monitoring studies (http://www.epa.gov/pesticides/reregistration/atrazine/atrazine_update.htm#ewmp). The NO_x and SO_x assessment is iterative and has been iteratively reviewed by the Clean Air Scientific Advisory Council since 2007 and includes planning documents, integrated science assessments, risk and exposure assessments, and policy assessments (http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html). It is discussed at greater length in Appendix D.4.

The SAB recommended more dialogue between assessors and managers and more emphasis on supporting the decision (Recommendation 14, 15, and 16). The two preceding examples represent assessments where linkages were made between risk measures, data quality needs, data collection activities, and risk management decisions. They also provide examples where risk assessment questions are directly linked to risk management questions and watershed and landscape scales, and uncertainties are addressed. Both are complex, high priority, data-intense cases; they are certainly not typical. Nevertheless, they demonstrate that the Agency has linked peer review, problem formulation, uncertainty, and risk management questions in ecological assessment.

The SAB recommended moving away from generic problem formulations in the near term (Recommendation 18). However, for certain Agency applications such as routine assessments of industrial chemicals or site screening, the panel concluded that generic problem formulation is useful and should not be abandoned. The panel suggests that such assessment applications are limited in scope and could be documented using a checklist approach.

Five of the eight recommendations on problem formulation (see Table 6-4) mention spatial, temporal, and biological scale. The Technical Panel agrees that the scale of the assessment must be defined and justified during the problem formulation, as discussed in the *Guidelines for Ecological Risk Assessment*. In addition to these recommendations concerning the consideration of scale in planning and problem formulation, the SAB addressed the analysis of spatial, temporal, and biological scale as a separate issue (see Table 6-9). These recommendations broadly overlap and represent longstanding issues in ecological assessments.

Conclusion—Planning, scoping, and problem formulation are well characterized in the *Guidelines for Ecological Risk Assessment*, but individual programs should examine their assessment practices and consider whether additional specific guidance is needed.

6.5. WEIGHT OF EVIDENCE

Two SAB recommendations (see Table 6-5) address the need for guidance, case studies, and standards of practice for weighing multiple lines of evidence to support decision-making. Suter (1993) noted that separate lines of evidence must be evaluated, organized in some coherent fashion, and explained to risk managers so that the decision can be based on the weight of all relevant evidence. Hall and Giddings (2000) illustrated the value and importance of a weight-of-evidence approach using multiple lines of evidence from field and laboratory data to assess the occurrence or absence of ecological impairment in aquatic environments. The Stressor Identification guidance and the CADDIS Web site for determining the causes of biological impairments use a weight-of-evidence approach (U.S. EPA, 2000b). Lines of evidence have been discussed in the Air Toxics Risk Assessment Reference Library (U.S. EPA, 2004c). The latter document states that lines of evidence provide a process and framework for reaching a conclusion regarding confidence in a risk estimate. There are three principal categories of factors to consider when evaluating lines of evidence: data adequacy and quality, relative uncertainty, and relationship to the risk hypothesis.

The Technical Panel agrees, in principle, that case studies or standards of practice may be helpful in weighing multiple lines of evidence for decision-making. In the interim, the Technical

Panel believes that the weighing of evidence should be considered during each problem formulation, and a method for weighing evidence should be included, as appropriate, in the analysis plan. The chosen method for weighing evidence should be used during data analysis and interpretation and fully documented during the risk characterization.

Conclusion—Multiple pieces of evidence are often weighed in ecological assessments without a formal method. Guidance on formalizing inference by weighing evidence could make these assessments more defensible.

6.6. CUMULATIVE AND INDIRECT EFFECTS

The SAB offered two recommendations on cumulative and indirect effects (see Table 6-6). Cumulative risk rose to prominence in EPA risk assessments with the passage of the Food Quality Protection Act in 1996, which required EPA to consider all *aggregate risk* from exposure to a pesticide from multiple sources when assessing pesticide food tolerances; and *cumulative exposure* to pesticides that have common mechanisms of toxicity. This definition is widely used by EPA human health risk assessors, but ecologists typically view cumulative risk more broadly as the sum total of chemical, physical, and biological stressors that may impact a site, watershed, or other ecosystem.

The EPA Risk Assessment Forum is currently developing a cumulative risk assessment framework and guidelines using a sequential process like that used for the ecological risk assessment framework and guidelines (U.S. EPA, 1998a). The *Framework for Cumulative Risk Assessment* (U.S. EPA, 2003a) is an information document that identifies terminology, key issues, and basic elements of cumulative risk as the analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors. As Agency-wide guidance, the framework describes a flexible process without prescribing fixed protocols or procedures. The second phase of development is nearing completion, and a draft document entitled *A Compendium of Illustrative Examples for Cumulative Risk Assessment* is currently in review. This draft document explores key framework issues illustrated by case studies. Development of cumulative risk guidelines, the third stage of the process, began in late 2010.

The SAB recommended that EPA could consider change processes (e.g., climate change) and indirect effects as considerations in risk assessment (see Table 6-6). EPA's Global Change and Ecosystem Services Research Programs are presently looking at these important environmental issues. The Global Change Research Program (http://www.epa.gov/ord/npd/globalresearch-intro.htm) is a stakeholder-oriented research and assessment program in EPA's Office of Research and Development. The program is designed to address the potential consequences of global change, particularly climate variability and change, on air and water quality, aquatic ecosystems, human health, and socioeconomic systems in the United States. The Global Change Research Program emphasizes place-based approaches to investigate change issues particular to given areas. Using this approach, partnerships with locally-based decision-makers are being established to ensure programs are responsive to local scientific information needs and the socioeconomic realities. EPA is 1 of 13 federal agencies and departments that comprise the U.S. Global Change Research Program (USGCRP), which coordinates and integrates scientific research on global change across the federal government (http://www.globalchange.gov/). EPA's research program supports the production of synthesis and assessment products called for in the USGCRP Strategic Plan (http://www.globalchange.gov/about/strategic-plan-2003/2003-strategic-plan) and emphasizes air quality, water quality/aquatic ecosystems, and human health impacts from global change.

Conclusion—Ecological assessors should continue to support and participate in the RAF's efforts in cumulative risk assessment.

6.7. OTHER SOURCES OF GUIDANCE

The SAB also suggested that the Agency evaluate alternative risk assessment methodologies used by other countries and federal agencies and incorporate their valuable aspects in risk assessment guidance (see Table 6-7). Program offices are generally aware of available scientific methods and approaches used by other Agencies and countries and have extensive interactions with them. The OPPTS has been actively involved with the Organization for Economic Cooperation and Development (OECD) for decades to harmonize data requirements, test methods, and data integration methods for pesticide and toxic substances. OPPTS also has working relationships concerning risk assessments approaches with Canada and Mexico under the North American Free Trade Agreement, and other federal agencies including the Department of Interior, Department of Commerce, and FDA. Similarly, the Regions and Programs offices have multiple partnerships with international, other federal, state, and tribal governments and Agencies to address environmental issues of mutual interest and concern. Detailed discussion of Agency international, other federal, and state and tribal partnerships on science and management are too extensive to discuss here. Representative examples with Web site addresses are identified in Appendix D.6.

The Technical Panel believes that the Office of Research and Development, and Agency's programs and regions are fully aware of scientific approaches to ecological risk and environmental assessment used by other countries and federal agencies. Although there are no barriers to employing appropriate scientific approaches used by other countries or federal agencies by EPA, incorporating science and regulatory policies from other countries or agencies is a different matter. Typically, countries and agencies agree that they should use the same scientific data and information to assess the effects of chemicals and other stressors on the environment. However, how the assessments are used and applied in decision-making may differ because of different legal requirements and policy frameworks between countries and agencies. As an example, pesticide and toxic substances test guidelines are harmonized with all OECD member countries. Countries have agreed to harmonize methods because it allows them to share data and information generated by pesticide and chemical companies, which are often global corporate entities. In contrast, water and air quality standards and criteria are specifically developed to protect U.S. territorial water and air. Intergovernmental collaboration certainly occurs for trans-boundary pollution, but collaboration takes the form of bi-lateral or multilateral agreements. EPA's Office of International Affairs is the primary EPA coordinating body for such agreements (http://www.epa.gov/international/about/index.html).

Conclusion—The Technical Panel sees no need for specific actions to increase awareness of assessment methods employed by other agencies and countries.

6.8. BENEFITS AND VALUATION

The SAB's call for a focus on valuation of ecosystem services (see Table 6-8) is being met by research and guidance development on economic valuation and research on quantification of ecosystem services. The principal source of Agency guidance is the *Guidelines for Preparing Economic Analyses* (U.S. EPA, 2000e, 2008b). These guidelines complement ecological risk assessment with a focus on economic analyses in support of policy decisions and meet requirements described by related statutes, Executive Orders (EOs), and regulations. EO 12866 and its recent amendment EO 13422 direct federal agencies to perform a benefit-cost analysis for all economically significant rules (those with an economic impact to society of $100 million or more). The economic analyses guidelines focus on regulatory and non-regulatory management strategies. They describe economic concepts and techniques to address benefits and social costs of policy alternatives. They also describe procedures and analyses for clearly identifying the environmental problem to be addressed and for justifying federal corrective interventions. The guidance recommends that a clear statement of need for policy action should be included in economic analyses of environmental policy prepared for economically significant rules. These considerations include both human health and welfare effects,[1] and are similar to ecological risk assessment planning and problem-formulation activities.

Ecosystem services represent a major research area for the Office of Research and Development. The Ecosystem Services Research Program is designed to improve knowledge for the protection and restoration of nature's services, with an eye toward changing how the type, quality, and magnitude of ecological goods and services can be considered in environmental management decisions. The research is providing the data, methods, models, and tools needed by states, communities, and tribes to understand the cost and benefits of using ecosystem services. The Ecosystem Services Research Program includes major research areas focused on nitrogen, wetlands, coral reefs, and place-based studies (Willamette River Basin, Tampa Bay, Coastal Carolinas, and the Midwest and Southwest Ecosystem Services projects). Further discussion of the use of ecosystem services can be found in Appendix D.7. Details of ongoing research projects may be found at http://www.epa.gov/ecology/index.htm.

SAB also recommended that EPA expand work in support of assessing the net environmental benefits of proposed actions. Although net ecosystem benefits analysis (Efroymson et al., 2004) is largely investigatory at EPA, the Agency has developed the *Ecological Benefits Assessment Strategic Plan* (U.S. EPA, 2006a). This document acknowledges that a new approach is needed to improve the Agency's ability to perform ecological benefits assessments and emphasizes interdisciplinary participation by natural and social scientists. Because ecological risk assessments are designed to address different questions than those of ecological benefits assessments, the immediate value and application of risk

[1]A regulatory term defined by the Clean Air Act in developing National Ambient Air Quality Standards. Welfare effects include, but are not limited to, effects on soils, water, wildlife, vegetation, visibility, weather, climate, as well as effects on materials, economic values, and well being.

assessment results to benefits assessments is often limited. EPA benefits assessments have historically been the purview of economists with limited input from natural scientists. This strategic plan emphasizes that increased collaboration between EPA natural and social scientists will improve ecological benefits assessments at the Agency. Such improvements include identifying appropriate ecological endpoints; collecting the necessary data; and developing and applying the appropriate methods to quantify and value changes in those endpoints.

The *Ecological Benefits Assessment Strategic Plan* recommends a collaborative framework that both builds on the conceptual foundations of ecological risk assessment framework (U.S. EPA, 1998a) and borrows from its terminology. The assessment approach emphasizes collaborative interaction among Agency decision-makers, social scientists, natural scientists, and analysts throughout the process. Such collaboration should begin at the earliest stages of the process, with identification of the need to evaluate alternative policy options for a decision. The options under consideration may be defined partly by the statutory and legal context under which EPA operates, information from existing risk assessments, and technological and socioeconomic considerations. The best science available would then be applied to understand how each policy option would change the environmental stressors they are intended to control, to forecast changes in the affected ecosystems and the services they provide, and to estimate the economic value of the change in those services.

In its review of the *Ecological Benefits Assessment Strategic Plan*, the Science Advisory Board (EPA, 2009b) endorsed the general approach in the strategic plan but suggested an alternative (see Figure 6-1). Although the SAB approach is depicted sequentially, they emphasize that numerous feedbacks should occur with interactions and iterations across steps. Accordingly, the valuation process should always be based on an explicit conceptual model that can be updated or revised. In practice, information about the value of a change in ecosystem services that would result from a given policy option might cause a reformulation of the problem or identification of alternative policy options that could be considered. Also, a predicted ecological effect might suggest social values that were not initially considered.

The SAB framework for ecological valuation process (see Figure 6-1) complements the ecological risk assessment framework and guidance (U.S. EPA, 1992a, 1998a). Although similar, ecological valuation necessarily goes beyond ecological risk assessment. Typically, risk assessments focus on estimating the magnitude and likelihoods of potential adverse effects on ecological entities (species, populations, communities, sites, etc.) but lack information about societal values of the effects. In contrast, ecological valuation characterizes monetary and nonmonetary societal values of the predicted ecological effects, ecological improvements, or ecological losses from environmental degradation. Because of the focus on societal values, ecological valuation more closely resembles risk characterization than risk assessment. Accordingly, the risk characterization principles offered by the NRC (1996) and Agency risk characterization guidance (U.S. EPA, 2000d, 2003a) are pertinent for ecological valuation. Ideally, both are rigorous and transparent analytical processes that integrate scientific information with transparent policy options that reflect societal values.

Conclusion—As methods for quantifying ecosystem services and benefits are developed into reliable assessment tools, they should be integrated into existing ecological assessment guidance.

6.9. SCALES OF ASSESSMENT

The SAB offered several recommendations regarding the consideration of scale and level of biological organization in ecological assessments (see Table 6-9). Spatial scale was discussed in the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a) under management goals that differentiate between national scale (e.g., water quality criteria) and cases where laws and regulations are specifically applied to places or sites. Scale was also addressed within the context of planning and establishing assessment objectives to determine if an assessment is national, regional, or local in scope.

Examples of the consideration of scale are noted briefly here, and elaborated upon in Appendix D.8. The Office of Pesticide Programs conducts ecological risk assessments over a range of spatial scales depending upon uses, fate, transport, and effects of pesticides. These may include the region within which a crop is grown or the range of a potentially-exposed species of concern. The Office of Water develops national ambient water quality criteria as science-based recommendations that EPA considers protective of the aquatic life use, but allows for place-based modifications to account for variation in water chemistry and biology. The Office of Solid Waste and Emergency Response considers scope, boundaries, and scale to be important elements during the development of conceptual site models for ecological risk assessments. Superfund legislation defines the site as the extent of contamination. When the extent of contamination is determined by the remedial investigation, adaptive site management can provide flexibility in the site boundaries as the extent of contamination is characterized.

In EPA regions, risk assessments are generally tied to discrete geographic locations (i.e., place-based assessment) and specific time intervals. In contrast, EPA program office risk assessments are frequently generalized in space and time and, therefore, employ generic assumptions. This dichotomy often results in different approaches and practices. The spatial context profoundly impacts planning and problem formulation of regional ecological risk assessments. Such impacts are illustrated by a case example in northwest Indiana included in Appendix D.8.

The choice of levels of biological organization to be evaluated in regulatory risk assessments is also challenging. The enabling legislation for some EPA programs does not clearly identify a level of organization, using only vague terms such as "the environment" or "aquatic life." Others explicitly or implicitly identify protection of ecological populations as management goals. In either case, conventional ecological risk assessments for chemicals have focused on organismal attributes of assessment populations as assessment endpoints (e.g., survival, growth, or reproduction in a fish population) (U.S. EPA, 2003b; Suter et al., 2005). Organismal attributes are practical and expedient because they can be estimated by toxicity tests. It is often assumed that protection of organismal attributes will protect populations and population-level attributes (e.g., abundance, fecundity, etc.). Additionally, methods and practice are well established for organism-level assessments. In contrast, there are few consensus methods for population-level ecological risk assessment. Consequently, risk to populations has only been occasionally evaluated directly by EPA (e.g., trout populations of Adirondack lakes in the National Acid Precipitation Assessment). This situation results from several factors affecting assessment planning, including the perceived relationships between assessment endpoints and environmental management goals, historical precedence, and importantly, the lack of recognized consensus and guidance about how such assessments should be performed. Examples of the treatment of different levels of organization by the Agency are described in Appendix D.9.

As mentioned earlier in this section, cumulative risk, global change, and ecosystem services, and spatial, temporal, and biological scales are conceptually linked and reflect systems thinking in contemporary ecology and the environmental sciences. As illustrated by the preceding discussion for the SAB recommendations listed in Tables 6-4 and 6-6, current implementation of cumulative risk, global change, ecosystem services, and spatial, temporal and biological scales ranges from investigatory, to initial applications, to implementation in selected program offices. It should be emphasized that integration of these system attributes is far from routine and is not typically encountered in conventional ecological risk assessments of chemicals. However, they are beginning to move into program office applications.

The Office of Air Quality Protection and Standards (OAQPS) has undertaken a complex ecological risk assessment that incorporates elements of cumulative risk, global change, economic benefits, ecosystem services, and broad spatial, temporal biological scale. Importantly, planning and scoping, problem formulation, analysis, and characterization were followed, documented, and conducted in accordance with the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998a). OAQPS is conducting a joint review of the existing secondary (welfare-based) National Ambient Air Quality Standards (NAAQS) for NO_x and SO_x. A joint secondary review of these pollutants was necessary because the atmospheric chemistry and environmental effects of NO_x, SO_x, and their associated transformation products are linked, and because the NRC has recommended that EPA consider multiple pollutants, as appropriate, in forming the scientific basis for the NAAQS. Notably, this assessment is also the first time since the NAAQS were established in 1971, that a joint review of NO_x, SO_x, as well as of total reactive nitrogen, has been considered. A summary of this innovative assessment follows in Appendix D.4.

Conclusion—Scale and level of organization are difficult and controversial issues that are difficult to address Agency-wide. However, the Agency should continue to develop assessment tools and guidance for conducting assessments for larger scales and higher levels of organization. During problem formulations, assessors should be clear about their chosen scales and levels of organization and the rationales for their choices.

6.10. METHODS AND TOOLS

The SAB provided seven recommendations for the development of particular assessment methods and tools (see Table 6-10). Topics included uncertainty, assessment hypotheses, life-cycle assessment, screening, and generic assessments of common pollutants.

The treatment of uncertainty has been a major topic of discussion and consideration among assessors and is frequently addressed by advisory bodies (NRC, 2009). However, quantitative uncertainty analysis is controversial and is inconsistently employed in the Agency. Currently, guidance is limited to Monte Carlo analysis for exposure models (U.S. EPA, 1997c). However, a review of probabilistic risk assessment practices in the Agency is currently in preparation. The SAB recommends an option of categorizing uncertainties and identifying those that are most important to the conclusions (Recommendation 31). This qualitative uncertainty analysis is consistent with common practices in the Agency's ecological assessments.

SAB Recommendations 32 and 33 address the development of assessment hypotheses. These are hypotheses about how sources, pollutants, or actions may cause effects and how those causal relationships might be manipulated to prevent or remediate effects. Hence, conventional statistical hypothesis testing is inappropriate, and other techniques such as estimation of conditional probabilities or logical analysis of the weight of evidence are more appropriate. This issue is largely underappreciated in the Agency.

Product life-cycle assessment (LCA) is distinct from risk assessment in that it is intended to aid in product design by estimating relative environmental impact rather than estimating the acceptability of a product. However, the SAB's comment suggests that ecological risk assessment should adopt some aspects of LCA (Recommendation 34). The Agency has collaborated with industry through the Design for the Environment program to perform some LCAs for products such as solders (http://www.epa.gov/dfe/pubs/solder/lca/index.htm). Although the Agency is not developing guidance on LCA, it has participated in the development of the international consensus system USEtox (http://www.usetox.org/).

Hazard Quotients and Hazard Indices are the primary techniques for risk characterization for both health and ecological risk assessments in the Agency. The SAB recommended that guidance be developed for their appropriate use (Recommendation 35). Individual programs have described their use in general ecological risk assessment guidance such as *The Ecological Risk Assessment Guidance for Superfund* (U.S. EPA, 1997b). Although the interpretation of these simple calculations can be controversial, the Technical Panel does not perceive a demand for Agency-wide guidance.

The SAB endorses the EPI suite (Recommendation 36), which is a set of structure-activity relationships to estimate fate and transport properties of chemicals reviewed by the Office of Pollution Prevention and Toxics (http://www.epa.gov/oppt/exposure/pubs/episuite.htm). The Technical Panel agrees that the range of applicability of these tools could be expanded. However, the data requirements of the European REACH regulations and proposed legislative updates of the Toxic Substance Control Act may reduce the need for such models.

The SAB suggested that the Agency develop generic ecological risk assessments for common pollutants such as PCBs (Recommendation 37). This recommendation is similar to the recurrent calls for an Eco IRIS. However, IRIS is a large effort that has difficulty keeping up with expectations, and it deals with only one species, humans. Currently, precedents (i.e., prior regional or program office assessments) are used in place of generic assessments. They include prior assessments at Superfund sites, water quality criteria documents, and priority air pollutant scientific assessments.

Conclusion—The development of Agency-wide guidance for assessment methods and approaches is a major mandate of the RAF. The Forum must set priorities for the development of such guidance.

6.11. POST-DECISION AUDITING AND MONITORING

The SAB recommended (see Table 6-11) that post-decision monitoring be conducted to determine whether the expected benefits occurred and to provide bases for improving future assessments. The integrated framework (see Section 3) contains this activity as Outcome Assessments. The Technical Panel wishes to emphasize that the point is to perform an assessment of the outcome of a decision, and monitoring is simply a means of gathering data to support the assessment. A well-conducted outcome assessment can provide the basis for adaptive management (see Section 6.3). That is, if the expected benefits of the decision are not realized, the information generated by the outcome assessment can be used to perform new predictive assessments and to make a new, more effective decision.

Monitoring and outcome assessments are seldom performed after the Agency's environmental management decisions. In some cases, as in the Superfund 5-year reviews, monitoring may be performed to determine whether pollutant concentrations have been reduced, but monitoring and assessments are not performed to determine whether environmental benefits have been realized.

Conclusion—The Technical Panel agrees that post-decision monitoring and assessment could be highly valuable. However, it would take a change in policy to make them a part of the Agency's conventional regulatory practices.

6.12. MANAGEMENT, RESOURCES, AND TRAINING

The NRC made several recommendations concerning increasing staffing and training (see Table 6-12). The Office of Research and Development will add staff in new areas, as in the creation of the Center for Computational Toxicology. However, as the NRC wrote, targeted staffing is also needed in programs and regions to employ new assessment science.

In general, training is more important and practical than increased staffing. Training in new assessment science has been irregular. The RAF did a good job of training for the 1992 Framework and 1998 *Guidelines for Ecological Risk Assessment*. Similarly, the Office of Water and Office of Research and Development conducted training of state and regional personnel on biological assessment and stressor identification. However, many guidance documents have no associated training.

Conclusion—Programs to develop new guidance should include plans for training and, if necessary, recommendations for acquiring new expertise.

Table 6-1. NRC broad science policy recommendations

1. (NRC)—Administrator should direct Agency offices to more proactively identify the data most relevant to the current risk assessment needs (related to Recommendations 7, 8, 17, and 18).
2. (NRC)—EPA should pay Increased attention to the design of risk assessment in its formative stages (related to Recommendations 7, 15, 16, 17, 18, 28, and 29).
3. (NRC)—EPA should continue and expand use of the best, most current science to support and revise default assumptions (related to Recommendation 30).
4. (NRC)—EPA should draw on other approaches, including those from ecologic risk assessment and social epidemiology, to incorporate interactions between chemical and nonchemical stressors in assessments; increase the role of biomonitoring, epidemiologic, and surveillance data in cumulative risk assessments; and develop guidelines and methods for simpler analytical tools to support cumulative risk assessment and to provide for greater involvement of stakeholders (related to Recommendations 7, 23, and 36).
5. (NRC)—To make risk assessments most useful for risk management decisions, the committee recommends that EPA adopt a framework for risk-based decision-making that embeds the Red Book risk assessment paradigm into a process with initial problem formulation and scoping, upfront identification of risk-management options, and use of risk assessment to discriminate among these options.
6. (NRC)—EPA should establish a formal process for stakeholder involvement in the framework for risk-based decision-making with time limits to ensure that decision-making schedules are met and with incentives to allow for balanced participation of stakeholders, including impacted communities and less advantaged stakeholders.

Table 6-2. SAB recommendations concerning environmental goals

7. (SAB)—Guidance should be developed to better define what ecological attributes EPA is striving to protect and how to apply risk assessment findings to decisions. In the short term, EPA could make progress toward incorporating such guidance into decision-making processes. Nonchemical stressors alone, and in combination with chemical stressors, should be considered in developing ecological risk assessment guidance, models, and endpoints. Endpoints should reflect elements of ecological conditions such as ecological processes and various levels of biological organization including landscape composition and pattern (related to Recommendation 8).
8. (SAB)—In the short term, EPA could explicitly identify, in the problem formulation phase of the risk assessment, specific ecological resources to be protected, and options for their protection (related to Recommendations 7, 17, and 28).

Table 6-3. SAB recommendations on adaptive management

9. (SAB)—EPEC recommends that EPA explore how adaptive management with iterative triggers for action can be applied in the context of ecological risk assessment and risk management as a way to deal with uncertainties (related to Recommendation 31).
10. (SAB)—In the long term, EPA could develop guidance on the application of adaptive management of ecological resources in contaminated site decision-making.

Table 6-4. Recommendations on problem formulation

11. (SAB)—In the short term, EPA could identify, during problem formulation, those spatial and temporal scales and levels of biological organization of concern that are large enough to capture emerging patterns across a landscape such as effects on local watersheds or migratory pathways (related to Recommendations 17, 18, 21, 26, 28, and 29).
12. (SAB)—For large complex risk assessments, peer review at the problem formulation stage, and again at risk assessment completion, would help assure that the assessment study design and implementation are appropriate for the risk management goals. EPEC recommends that for high priority assessments, problem formulation and study design be reviewed through an independent scientific peer-review process prior to study implementation. For smaller risk assessments, checklists could be used to ensure that management goals are considered in problem formulation and translated into information needs using data quality objectives (DQOs) (related to Recommendation 13).
13. (SAB)—In the short term, EPA could implement an independent, scientific peer-review process for large scale risk assessments to evaluate endpoints, scale, levels of biological organization, uncertainties, and study design outcomes of problem formulation prior to initiating the analysis phase of the risk assessment (related to Recommendation 12).
14. (SAB)—EPEC recognizes that EPA's Framework for Ecological Risk Assessment provides for interaction between risk managers and risk assessors and recommends that EPA further encourage and promote, if not require, problem formulation dialogue between risk assessors and risk managers.
15. (SAB)—To promote a dialogue between risk managers and improve problem formulation, EPEC recommends that EPA compile and develop ecological risk assessment case studies that can provide information for developing standards of practice.
16. (SAB)—EPEC recommends that, during problem formulation, explicit connections be established between risk measures, data quality needs, data collection activities, and risk management decisions. The gap between risk management and risk assessment can be bridged by developing guidelines and examples to (1) connect risk management with risk questions or testable hypotheses and (2) address scientific and technical issues such as the appropriate scale of the risk assessment and communication of uncertainty.
17. (SAB)—EPEC recommends that during the problem formulation phase of ecological risk assessments, EPA explicitly define the extent and resolution of the pertinent spatial and temporal scales and levels of biological organization (related to Recommendations 8, 11, 18, 22, 26, and 30).
18. (SAB)—In the short term, EPA could move away from generic problem formulation that is focused on levels of concern and risk quotients toward broader consideration of the appropriate spatial, temporal, and biological scales in the context of the decisions being made (related to Recommendations 11, 16, 17, 22, 26, 28, 29, 30, and 35).

Table 6-5. Recommendations on weight of evidence and lines of evidence

19. (SAB)—In the long term, EPA could develop guidance for improved weight-of-evidence decision-making that decreases "best professional judgment" and increases statistically-based quantification. Guidance should contain examples of typical sites covering major eco-regions, hydrologic types, and chemical and nonchemical stressors (related to Recommendations 12 and 32).
20. (SAB)—EPEC recommends that EPA develop case studies and/or standards of practice for interpreting lines of evidence, with an emphasis on application in decision-making (related to Recommendations 19 and 32).

Table 6-6. Recommendations on cumulative and indirect effects

21. (SAB)—In the long term, EPA could develop tools for cumulative risk assessments. Contaminants are often released into stressed environments, and risk assessments should consider the combined effects of stressors (related to Recommendations 11, 22, and 26).
22. (SAB)—In the short term, EPA could consider ongoing change processes (e.g., global climate change) and indirect effects, that are often revealed at different levels or scales of biological organization, as part of the risk assessment. Such processes and indirect effects can be particularly important in ecological risk assessments for natural resources protection (related to Recommendations 17, 18, 21, 28, and 29).

Table 6-7. Recommendations on other sources of guidance

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

Table 6-8. Recommendations on valuation and benefits

24. (SAB)—EPEC advises EPA to maintain a long-term focus on research to develop methods for valuation of ecosystem services.
25. (SAB)—EPEC also finds that advancing net environmental benefit tools may be a useful check to fit a specific process such as the remediation of chemically contaminated sites. These approaches may also be useful to other types of applications (such as natural resource management).

Table 6-9. Recommendations on spatial temporal and biological scale

26. (SAB)—In the long term, EPA could determine how large scale spatial, temporal, or population-level effects (and the cumulative effects of several sites within a small area) could be investigated in light of legal and regulatory requirements that may limit the spatial and temporal scale of contaminated site assessments (related to Recommendations 11, 16, 17, 18, 21, 28, 29, and 30).
27. (SAB)—In the long term, EPA could continue to investigate how biomarker and mechanistic data might best be used in exposure and risk assessments.
28. (SAB)—It would be useful to develop standard techniques for assessing risks at pertinent spatial, temporal, and biological scales. The SAB Framework for Assessing and Reporting on Ecological Condition could be used to guide the choice of scale (related to Recommendations 8, 11, 18, 22, 26, and 30).
29. (SAB)—EPEC recommends that EPA promote the evaluation and use of statistical and geospatial data analysis tools (such as time series and spatial data analysis methods) in identifying the appropriate spatial and temporal scales to be considered in ecological risk assessments (related to Recommendations 11, 18, 22, 26, and 30).
30. (SAB)—In the long term, EPA could develop standard techniques for assessing risks at specific scales and levels of biological organization and better define associated uncertainties (related to Recommendations 17, 28, 29, 18, and 26).

Table 6-10. Recommendations on assessment methods and tools

31. (SAB)—In the short term, EPA could categorize uncertainties in the ecological risk assessment according to their sources and sizes, and in the final assessment, identify and acknowledge uncertainties that profoundly affect results and outcomes such as the weight-of-evidence decision-making process (related to Recommendations 9, 20, and 32).
32. (SAB)—EPEC recommends that EPA explore the use of such methods as Bayesian analysis and causal augmentation to develop hypotheses or risk questions focused on causal relationships and weight of evidence (related to Recommendations 20, 31, and 33).
33. (SAB)—In the long term, EPA could explore ways to focus hypothesis development on causal relationships and weight of evidence instead of traditional hypothesis testing with null models (related to Recommendation 32).
34. (SAB)—EPEC recommends that EPA develop guidance for risk assessment practitioners on the application of life-cycle analysis.
35. (SAB)—In the long-term, EPA could take the initiative to develop guidance on the appropriate and acceptable use of such screening tools as hazard quotients (HQs), hazard indices (HIs), and similar environmental benchmarks, especially with regard to their utility in setting actionable environmental protection goals. As EPA addresses recommendations related to appropriate use of screening tools such as HQs and the need to reduce uncertainty, the Agency will need to explore a range of risk calculation methods that represent better and more certain approaches to estimating risk (related to Recommendation 18).
36. (SAB)—In the short term, EPA could use currently available tools for rapid screening-level assessments, such as EPA's Estimation Programs Interface (EPI) Suite, to assist in determining whether chemicals are biodegradable, toxic, or bioaccumulative. The limitations of such tools must be taken into consideration. For example, the EPI Suite tools are generally applicable only to nonpolar organic compounds of relatively low molecular weight. Inorganic compounds, metallo-organic compounds, polar organic compounds, polymers, and surfactants cannot be addressed by most of the EPI Suite tools.
37. (SAB)—In the short term, EPA could increase efficiency by developing "programmatic-level" assessments for contaminants, such as polychlorinated biphenyls, commonly found at many contaminated sites. Such assessments would be similar to programmatic environmental impact statements, which are described in the National Environmental Policy Act and are typically prepared with the intention of describing the impacts of actions that are repeated over time. This approach would decrease the number of redundant risk assessments for contaminants commonly found at contaminated sites.

Table 6-11. Recommendations on postdecision auditing and monitoring

38. (SAB)—EPEC recommends that EPA more fully describe the beneficial ecological consequences resulting from risk management decisions in terms that the public can understand and then follow the risk management decisions with postdecision audit programs can be implemented in the short term, but a longer period of time would be required to complete and document such audits (related to Recommendations 39 and 40).
39. (SAB)—In the long term, EPA could develop a process to provide an interface between risk assessment and monitoring programs so that monitoring data can be used to improve future risk assessments (related to Recommendations 38 and 40)
40. Recommendation S-F5: In the long term, EPA could conduct multigenerational analysis or other retrospective ground-truthing analyses for prospective risk estimates and re-evaluate and validate levels of concern with monitoring studies (related to Recommendations 32 and 39).

Table 6-12. Recommendations on science management, resources, and training

41. (NRC)—Additional staff will be needed in fields that are now lightly staffed, and new staff in fields that are generally understaffed.
42. (SAB)—In the short term, EPA could take stronger leadership in training Agency personnel and those of state regulators on the appropriate use of ecological risk assessment methods and data and explicitly make regulators aware of how such methods and data can be misused. The Agency should consider how to effectively integrate and weight the importance of modeled estimates of risk in the presence of ecological observations from the field, which are assessing ecological integrity or biological performance.
43. (NRC)—Agency leaders should give high priority to establishing and maintaining risk-assessment and decision-making training programs for scientists, managers responsible for risk-assessment activities, and other participants in the process.
44. (NRC)—Revitalize and expand interoffice and interagency collaboration through existing structures and by joining scientists from other agencies (related to SAB Recommendations 15 and 23).
45. (NRC)—Administrator should give special attention to expanding the scientific and decision-making core in the regional offices to ensure that they have the capacity to use improved risk-assessment methods and to meet their obligations for interaction with stakeholders, local agencies, and tribes.
46. (NRC)—EPA should initiate a senior-level strategic re-examination of its risk-related structures and processes to ensure that it has the institutional capacity to implement the committee's recommendations for improving the conduct and utility of risk assessment for meeting the 21st century environmental challenges.

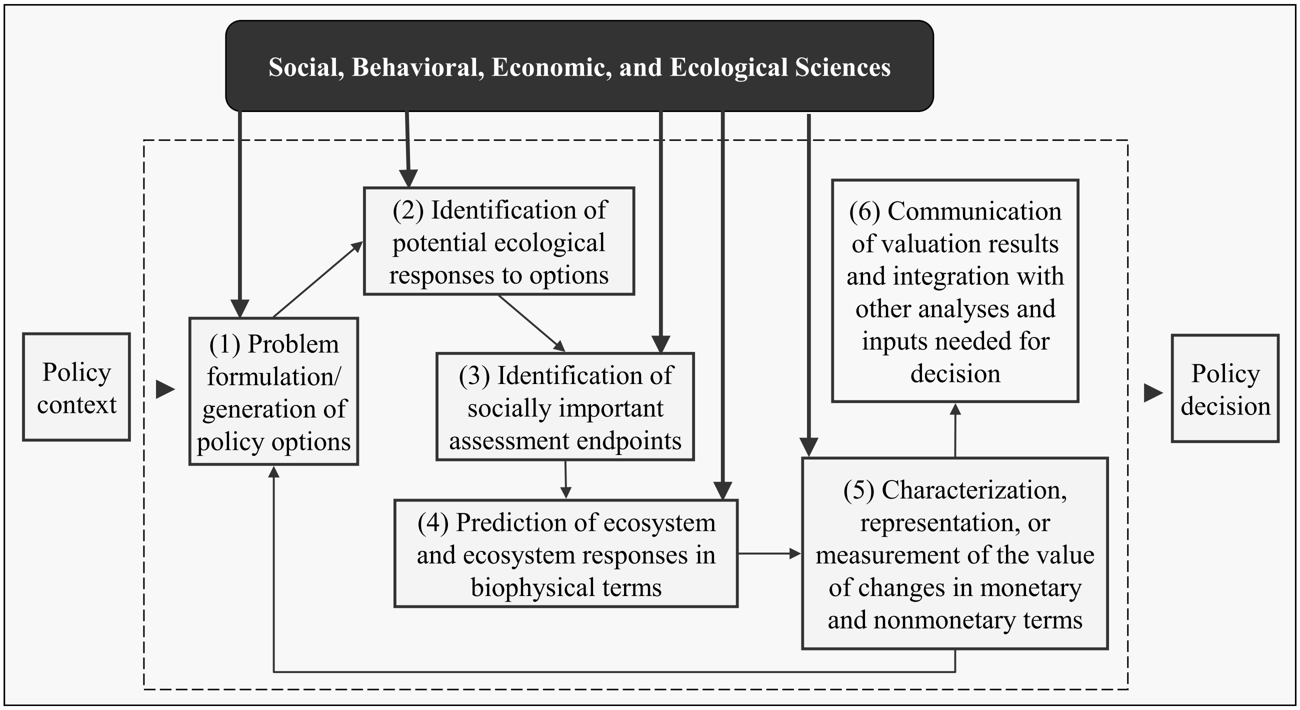

Figure 6-1. Process for implementing an expanded and integrated approach to ecological valuation (U.S. EPA, 2009b).

7. TECHNICAL PANEL RECOMMENDATIONS FOR AGENCY CONSIDERATION

This section presents the Technical Panel's summary compilation of the recommendations of the participants in the Colloquium for advancing ecological assessment. Although they were informed and inspired by the SAB's and NAS's recommendations, the participants also brought other issues to the meeting. Ten years after the publication of the *Guidelines for Ecological Risk Assessment*, the concerns and recommendations of the Agency's ecological assessors involve issues of policy and practice more than with technical methods. In general, they feel that the science of ecological assessment is stronger than the policies and practices that turn their scientific findings into Agency actions. Hence, many of the general recommendations are addressed most directly to policy makers. The relevance of those recommendations to the Office of Research and Development (ORD), Science and Technology Policy Council (STPC), regional offices and program offices is identified. The specific recommendations are more amenable to conventional technical guidance.

7.1. GENERAL RECOMMENDATIONS

7.1.1. Strengthen Policies to Achieve Ecological Protection Goals

Colloquium participants repeatedly expressed concern that many Agency decision and policymakers are less familiar with and are less focused on ecological issues and associated environmental protection goals than human health protection-related goals and issues. Some colloquium participants believe that some in leadership positions operate with the belief that by protecting human health, they also protect the environment. It would seem that they believe that humans are not affected by the loss of biodiversity or ecosystem processes. Ecological scientists at the Colloquium disputed the scientific foundation for these beliefs.

ORD—The Ecosystem Services Research Program (ESRP) is providing one basis for correcting the misunderstandings.

STPC—This body should include more representatives with expertise in ecological/environmental science and should devote more attention to environmental as well as human health protection.

Programs and Regions—These organizations should rededicate themselves to ecological protection goals.

7.1.2. Enhance Communication of Ecological Assessment Issues and Results

The strongest and most consistent recommendation of the Colloquium participants was that methods be developed for better communication with decision-makers and stakeholders. This applies to communicating both ecological assessment issues during planning of assessments and results at the conclusion. In part, this is a matter of inability of assessors to communicate the significance of the loss of species, changes in community structure, and other endpoints. In addition, it involves the lack of standard bright lines for acceptability like those in human health assessment, the plethora of assessment methods employed, and difficulties in conveying variability and uncertainty.

ORD—Conduct research on communicating ecological risks and benefits, possibly in the ESRP.

RAF—Review ecological communication practices in the Agency and identify best practices.

Programs—Develop specific guidance or procedures for communication of ecological issues and assessment results

7.1.3. Strengthen the Risk Assessor-Risk Manager Dialogue

Many participants asserted that they do not receive adequate input from decision-makers when performing ecological assessments. For complex assessments, such as Superfund remedial investigations, this could require days of participation in a data quality objectives (DQO) process, while more routine cases, such as TSCA new chemical reviews, may use standard decision requirements that should be reviewed periodically.

Programs and Regions—These organizations should encourage decision-makers to be more engaged in assessment and to clearly communicate their information needs.

STPC—An Agency-wide policy might require that the decision-maker's information needs be identified in every assessment.

7.1.4. Enhance Problem Formulation

Many participants believe that inadequate attention is paid to problem formulation in their assessments.

RAF—Although problem formulation is addressed at length in RAF documents, specific needs for guidance may be identified by programs and regions. A new framework for assessment and decision-making might be developed in conjunction with human health assessors, as recommended by the NAS. Problem formulation could be enhanced if it is not just "an ecological thing."

Programs and Regions—These organizations should develop specific policies and practices to enhance problem formulation, possibly including checklists of necessary components and peer reviews in some difficult or high profile cases.

7.1.5. Increase Training

Colloquium participants, particularly newer staff, asserted that there is not enough training available for them or for the managers and stakeholders with whom they interact. While formal courses were recommended by some, others recommended online training, training by case studies, or informal methods.

RAF—The forum might develop new training or revive old training materials and courses for Agency-wide assessment methods and processes.

Programs and Regions—These organizations should devote more time and resources to training at all levels.

7.1.6. Apply Systems Approaches to Ecological Assessments

Ecological assessors, particularly those in the regions, are concerned that the medium-by-medium program design of the Agency has inhibited environmental protection by not adequately recognizing that pollutants move among media, that multiple sources cause combined exposures, that multiple pollutants affect receptors, and that effects on one ecological receptor have consequences for other ecological receptors and for humans. While there have been some efforts to bridge gaps, the participants assert that the Agency needs a more systems-based approach to environmental protection.

RAF—The Forum is already developing guidance on cumulative risk assessment, which is a potentially important contributor to solving this problem.

STPC—The major need is for policies that mandate the protection of ecosystems and people as a system.

Programs and Regions—These organizations should extend existing efforts to bridge the gaps between laws and programs to systematically protect the environment.

7.1.7. Integrate Different Types of Assessments to Solve Environmental Problems

The participants found it useful to go beyond risk assessment and consider all of the types of assessments that inform decisions. They include condition assessments that determine whether and in what way the environment is impaired, causal assessments that determine the causes of impairments and their sources, predictive assessments such as risk assessments and management assessments that determine the expected results of alternative actions, and outcome assessments that determine whether the chosen action was effective.

RAF—The forum should develop a document describing the fully integrated assessment framework and explaining how linking different types of assessments can improve decision-making.

Programs and Regions—These organizations should recognize and strengthen the role of assessments other than risk assessments.

7.1.8. Create Forums for Communication

Many ecological risk assessors feel isolated, and assessment concepts and tools are seldom shared among programs and regions.

RAF—The Forum should look beyond this Colloquium and its products to find ways to make communication among ecological assessors more regular and effective. They might include topical interest groups, regular meetings of ecological assessors, and Web sites.

Programs and Regions—These organizations should afford opportunities to their staff to participate in meetings, colloquia, workshops, and details.

7.2. SPECIFIC RECOMMENDATIONS

Although the Colloquium participants emphasized broad policy-related issues, some specific needs for technical guidance were identified in Groups 2, 3, and 4 or were expressed by an individual during plenary discussions.

Quality assurance and DQOs for ecological assessments

The available quality assurance and DQO guidance for assessments emphasizes human health issues and techniques. For example, the DQO guidance presumes that risk characterization is performed by determining the probability of exceeding a bright line. Few ecological assessments have a priori bright lines, and risk characterization often involves multiple lines of evidence.

Weight of evidence

Although ecological assessments often involve multiple lines of evidence, there is no guidance on how to weigh those lines of evidence to make inferences.

Multiple stressors

The existing guidance documents for assessing the effects of mixtures is based on the types of data that are available for human health assessments and are limited to chemicals.

Receptor-specific guidance

While assessment methods are well developed for some taxa and assemblages such as fish and benthic invertebrates, there are little data and no assessment guidance for others such as amphibians, reptiles, and mollusks.

Stressor-specific guidance

Some stressors such as nanomaterials are not well addressed by current assessment guidance.

Adaptive management

Adaptive management is a process that determines the outcome of actions and uses that information to improve the assessments that inform subsequent decisions and the efficacy of those decisions. It is particularly useful when uncertainties are large.

Beneficial ecological consequences from risk management decisions

Guidance should be provided on estimating the expected benefits of actions.

Life-cycle analysis for product safety evaluations

A life-cycle approach to the assessment of new chemicals and other products could improve the completeness and quality of assessments and decisions.

Uncertainty characterization and communication

The analysis of uncertainty, other than Monte Carlo analysis of transport and exposure models, has not been the subject of Agency guidance. Uncertainties in ecological assessments are particularly ill-defined.

State-of-science or best practices reports

Rather than developing guidance, the RAF might develop reports based on workshops that summarize the best practices with respect to an assessment problem.

Case studies

Case studies of good assessment practices are a useful adjunct to training. They could include large scale assessments, assessments that reach no-effect conclusions in a defensible manner, assessments that use new types of data or methods of data analysis, etc.

Success stories

Create a document showing how actions based on ecological risks have resulted in improvements in the environment. This would encourage both assessors and managers. Also, since ecological successes are more apparent, they can help to justify the Agency's actions. For example, by banning DDT, we saved bird species and may have headed off effects on humans.

Cumulative assessment

The RAF should continue developing Agency guidelines on cumulative assessment, including a discussion of consideration of ecosystem services.

REFERENCES

Barbour, MT; Norton, SB; Preston, HR; Thornton, KW. (2004) Ecological assessment of aquatic resources: linking science to decision-making. In: Pellston workshop on ecological assessment of aquatic resources: applications, implementations, and communications, Sept 16−21, 2000. University of Michigan Biological Station, Pellston, MI. SETAC Press: Pensacola FL. 272 pp.

Barnthouse, L.W. and G.W. Suter II (eds.). 1986. User's manual for ecological risk assessment. Oak Ridge National Laboratory, Oak Ridge, TN. ORNL-6251.

Barnthouse. L. (2008) The strengths of the ecological risk assessment process: linking science to decision making. Integr Environ Assess Manag 4:299−305.

Bridgen, P. (2005) Protecting Native Americans through the risk assessment process: a commentary on "An examination of U.S. EPA risk assessment principles and practices. Integr Environ Assess Manag 1(1):83−85.

Calabrese, EJ; Baldwin, LA. (1993) Performing ecological risk assessments. Lewis Press: Chelsea, MI.

Cairns, J, Jr; Dickson, KL; eds. (1972) Biological Methods for the Assessment of Water Quality. ASTM STP 528. ASTM: Philadelphia, PA.

Cairns, J, Jr; Dickson, KL; Maki, AW; eds. (1978) Estimating the hazard of chemical substances to aquatic life. ASTM STP 657. ASTM: Philadelphia, PA.

Cormier, SM; Suter, GW, II. (2008) A framework for fully integrating environmental assessments. Environ Manag 42(4):543−556.

CENR (Committee on Environment and Natural Resources). (1999) Ecological risk assessment in the federal government. National Science and Technology Council, Executive Office of the President, Washington, DC. CENR/5-99/001. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12384.

Dale, VH; Biddinger, GR; Newman, MC; et al. (2008) Enhancing the ecological risk assessment process. Integr Environ Assess Manag 4(3):306−313.

Dearfield, KL; Bender, E; Kravitz, M; et al. (2005) Ecological risk assessment issues identified during the U.S. Environmental Protection Agency's examination of risk assessment practices. Integr Environ Assess Manag 1(1):73−76.

DeMott, RP; Balaraman, A; Sorensen, MT. (2005) The future direction of ecological risk assessment in the United States: reflecting on the U.S. Environmental Protection Agency's "Examination of risk assessment practices and principles". Integr Environ Assess Manag 1(1):77−82.

De Pyster, A; Day, K. (1998) Ecological risk assessment: a meeting of policy and science. SETAC Press: Pensacola FL. 224 pp.

Efroymson, RA; Nicolette, JP; Suter, GW, II. (2004) A framework for net environmental benefit analysis for remediation or restoration of contaminated sites. Environ Manage 34(3):315−331.

Fava, JA; Adams, WJ; Larson; RJ; et al. (1987) Research priorities in environmental risk assessment. Report of workshop held August 16-21, 1987, in Beckenridge, CO, Society for Environmental Toxicology and Chemistry, Washington, DC.

Hall, LW, Jr; Giddings, JM. (2000) The need for multiple lines of evidence for predicting site-specific ecological effects. Hum Ecol Risk Assess. 6(4):679−710.

Holling, CS (ed). (1978) Adaptive environmental assessment and management. Chichester, UK: John Wiley and Sons.

Kapustka, L. (2008) Limitations of the current practices used to perform ecological risk assessment. Integr Environ Assess Manag 4(3)290−298.

Lee, KN. (1999) Appraising adaptive management. Conserv Ecol 3(2):3.

Maki, AW; Slimak, MW. (1990) The role of ecological risk assessment in environmental decision-making. In: Grodzinski, W; ed. Ecological risks: perspectives from Poland and the United States. Washington, DC: National Academy Press. pp. 77−91.

Munns, WR, Jr; Helm, RC; Adams, WJ; et al. (2009) Translating ecological risk to ecosystem service loss. Integr Environ Assess Manag 5(4):500−514.

NRC (National Research Council). (1983) Risk assessment in the federal government: managing the process. Committee on the Institutional Means for Assessment of Risks to Public Health. Washington DC: National Academy Press; 91pp.

NRC (National Research Council). (1993) Issues in risk assessment. Committee on Risk Assessment Methodology. Washington, DC: National Academy Press; 356 pp.

NRC (National Research Council). (1994) Science and judgment in risk assessment. Committee on Risk Assessment of Hazardous Air Pollutants. Washington, DC: National Academy Press; 625 pp.

NRC (National Research Council). (1996) Understanding risk: informing decisions in a democratic society. Committee on Risk Characterization. Washington, DC: National Academy Press; 250 pp.

NRC (National Research Council). (2004) Adaptive management for water resource planning. Committee to Assess the U.S. Army Corps of Engineers Methods of Analysis and Peer Review for Water Resources Project Planning. Washington, DC: National Academy Press; 250 pp.

NRC (National Research Council). (2009) Science and decisions: advancing risk assessment. Committee on Improving Risk Analysis Approaches used by the U.S. EPA. Washington, DC: National Academies Press; 478 pp.

Parma, AM. (1998) What can adaptive management do for our fish, food, and biodiversity? Integr Biol: Issues, News, Rev. 1(1):16−26.

Regan, HM; Colyvan, M; Burgman, MA. (2002) A taxonomy and treatment of uncertainty for ecology and conservation biology. Ecol Appl 12(2):618−628.

Ruckleshaus, WD. (1983) Science, risk, and public policy. Science 221(4615):1026−1028.

Stahl, R; Bachman, R; Barton, AL; et al; eds. (2001) Risk management: ecological risk based decision making. Pensacola, FL: SETAC Press; 222 pp.

Stahl, RG, Jr; Giuiseppi-Elie, A; Bingman, TS. (2005) The U. S. Environmental Protection Agency's examination of its risk assessment principles and practices: A Brief Perspective from the regulated community. Integr Environ Assess Manag 1(1):86−92.

Suter, GW. (2007) Ecological risk assessment, 2nd edition. Boca Raton: CRC Press, Boca Raton, FL.

Suter, GW, II. (1990) Environmental risk assessment/environmental hazard assessment: similarities and differences. In: Landis, WG; van der Schalie, WH; eds. Aquatic toxicology and risk assessment: thirteenth volume. Philadelphia, Pennsylvania: ASTM; p. 5−15.

Suter, GW, II. (1993) Ecological risk assessment. Ann Arbor, MI: Lewis Publishers.

Suter, GW, II. (2008) Ecological risk assessment in the USEPA: a historical overview. Integr Environ Assess Manage 4(3):285−289.

Suter, GW, II; Cormier, SM. (2008) What is meant by risk-based environmental quality criteria? Integr. Environ. Assess. Manag. 4(4):486−489.

Suter, GW, II; Norton, SB; Fairbrother, A. (2005) Individuals versus organisms versus populations in the definition of ecological assessment endpoints. Integr Environ Assess Manag. 1(4):397−400.

Swindoll, M; Stahl, R; Ells, S, Jr. (2000) Natural remediation: it's role in ecological risk assessment and risk management. SETAC Press, Pensacola FL: SETAC; 472 pp.

Tannenbaum, LV. (2005) A critical assessment of the ecological risk assessment process: a review of misapplied concepts. Integr Environ Assess Manage 1(1):66−72.

Thomas, LM. (1987) Environmental decision-making today. Environ Protect Agency J 13:2−5.

Troyer, M.E. and M.S. Brody. 1994. Managing ecological risks at EPA: issues and recommendations for progress. U.S. Environmental Protection Agency, Washington, D.C. EPA/600/R-94/183.

U.S. EPA (Environmental Protection Agency). (1985) Guidelines for deriving numerical National Water Quality Criteria for the protection of aquatic organisms and their uses. PB85-227049. Office of Research and Development, Environmental Research Laboratories, Duluth, MN, Narragansett, RI, Corvallis, OR. Available online at http://www.epa.gov/waterscience/criteria/library/85guidelines.pdf.

U.S. EPA (Environmental Protection Agency). (1988) Guidance for conducting remedial investigations and feasibility studies under CERCLA (Interim Final). PE89-184626. EPA/540/G-89/004. OSWER Directive 9355.3-01. Office of Emergency and Remedial Response, Washington, DC.

U.S. EPA (Environmental Protection Agency). (1989a) Ecological assessment of hazardous waste sites: a field and laboratory reference. Environmental Research Laboratory, Corvallis, OR; EPA/600/3-89/013.

U.S. EPA (Environmental Protection Agency). (1989b) Risk assessment guidance for superfund. Volume II. Environmental evaluation manual. Interim final. Office of Emergency and remedial Response, Washington, DC; EPA/540/1-89/001. Available online at http://www.p2pays.org/ref/36/35513.pdf.

U.S. EPA (Environmental Protection Agency). (1989c) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part A). EPA/540/1-89/002. Office of Emergency and Remedial Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragsa/index.htm.

U.S. EPA (Environmental Protection Agency). (1990a) Reducing risk: setting priorities and strategies for environmental protection. Science Advisory Board, Washington, DC. EPA SAB-EC-90-021.

U.S. EPA (Environmental Protection Agency). (1990b) Relative risk reduction project, reducing risk, Appendix A. The report of the Ecology and Welfare Subcommittee, Science Advisory Board, Washington, DC; EPA SAB-EC-90-021A. Available online at http://yosemite.epa.gov/sab/sabproduct.nsf/8B810983921518588525571BF00496983/$File/ECOLOGY+SUBCOMM++++++EC-90-021A_90021_5-11-1995_205.pdf.

U.S. EPA (Environmental Protection Agency). (1990c) Relative risk reduction project, reducing risk, Appendix B. The report of the Human Health Subcommittee, Science Advisory Board, , Washington, DC.; EPA EPA SAB-EC-90-021B. Available online at http://profiles.nlm.nih.gov/BB/A/Q/K/O/_/bbaqko.pdf.

U.S. EPA (Environmental Protection Agency). (1990d) Relative risk reduction project, reducing risk, Appendix C. The report of the Strategic Options Subcommittee, Science Advisory Board, Washington, DC; EPA SAB-EC-90-021C. Available online at http://yosemite.epa.gov/sab/sabproduct.nsf/AEE0C90214419F8885257330004C0AD4/$File/REDUCING+RISK+APPENDIX+C+++++EC-90-021C.pdf.

U.S. EPA (Environmental Protection Agency). (1991a) Summary report on issues in ecological assessment. Risk Assessment Forum, Washington, DC; EPA/630/R-92/005. Available online at http://www.epa.gov/raf/publications/summary-report-issues-eco-ra.htm.

U.S. EPA (Environmental Protection Agency). (1991b) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part B, Development of risk-based preliminary remediation goals, Interim). EPA/540/R-92/003. Publication 9285.7-01B. Office of Emergency and Remedial Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragsb/index.htm.

U.S. EPA (Environmental Protection Agency). (1991c) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part C, Risk evaluation of remedial alternatives, Interim). Publication 9285.7-01C. Office of Emergency and Remedial Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragsc/index.htm.

U.S. EPA (Environmental Protection Agency). (1992a) Framework for ecological risk assessment. Risk Assessment Forum, Washington, DC; EPA/600/R-92/001. Available online at http://www.epa.gov/raf/publications/pdfs/FRMWRK_ERA.PDF.

U.S. EPA (Environmental Protection Agency). (1992b) Peer review workshop report on a framework for ecological risk assessment. Risk Assessment Forum, Washington, DC; EPA/625/3-91/022. Available online at http://www.epa.gov/raf/publications/peer-review-workshop-rpt-eco-ra.htm.

U.S. EPA (Environmental Protection Agency). (1992c) Report on the ecological risk assessment guidelines strategic planning workshop. Risk Assessment Forum, Washington, DC; EPA/630/R-92/002. Available online at http://www.epa.gov/raf/publications/rpt-eco-ra-guidelines-workshop.htm.

U.S. EPA (Environmental Protection Agency). (1992d) Developing a scope of work for ecological assessments. Office of Solid Waste and Emergency Response, Washington, DC; ECO Update, Publication 9345.0-05I, May 1992. Available online at http://www.epa.gov/oswer/riskassessment/ecoup/pdf/v1no4.pdf.

U.S. EPA (Environmental Protection Agency). (1992e) Guidance for data usability in risk assessment (Part A). Publication 9285.7-09A. PB92-963356. Office of Emergency and Remedial Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/datause/pdf/datause-parta.pdf.

U.S. EPA (Environmental Protection Agency). (1992f) Guidance for data useability in risk assessment (Part B). Publication 9285.7-09B. PB92-963362. Office of Emergency and Remedial Response, Washington, DC. Available online at http://rais.ornl.gov/documents/USERISKB.pdf.

U.S. EPA (Environmental Protection Agency). (1993) A review of ecological assessment case studies from a risk assessment perspective. Risk Assessment Forum, Washington, DC; EPA/630/R-92/005. Available online at http://cfpub1.epa.gov/ncea/cfm/recordisplay.cfm?deid=30819.

U.S. EPA (Environmental Protection Agency). (1994a) Peer review workshop report on ecological risk assessment issue papers. Risk Assessment Forum, Washington, DC; EPA/630/R-94/008 (NTIS PB5252490). Available online at http://www.epa.gov/raf/publications/peer-review-workshop-rpt-eco-ra-papers.htm.

U.S. EPA (Environmental Protection Agency). (1994b) Ecological risk assessment issue papers. Risk Assessment Forum, Washington, DC; EPA/630/R-94/009. Available online at http://www.epa.gov/raf/publications/eco-risk-assessment-issue-papers.htm.

U.S. EPA (Environmental Protection Agency). (1994c) Managing ecological risks at EPA: issues and recommendations for progress. Office of Research and Development, Office of Policy Planning and Evaluation, Washington, DC; EPA/600/R-94/183.

U.S. EPA (Environmental Protection Agency). (1994d) Role of the ecological risk assessment in the baseline risk assessment. OSWER Directive # 9285.7-17. Office of Solid Waste and Emergency Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/pdf/memo.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (1994e) Using toxicity tests in ecological risk assessment. Office of Solid Waste and Emergency Response, Washington, DC; Eco Update, Publication 9345.0-05I, March 1994. http://www.epa.gov/oswer/riskassessment/ecoup/pdf/v2no1.pdf.

U.S. EPA (Environmental Protection Agency). (1994f) Catalogue of standard toxicity tests for ecological risk assessment. Office of Solid Waste and Emergency Response, Washington, DC; Eco Update, Publication 9345.0-05I, March 1994. http://www.epa.gov/oswer/riskassessment/ecoup/pdf/v2no2.pdf.

U.S. EPA (Environmental Protection Agency). (1994g) Field studies for ecological risk assessment. Office of Solid Waste and Emergency Response, Washington, DC; Eco Update, Publication 9345.0-05I March 1994. http://www.epa.gov/oswer/riskassessment/ecoup/pdf/v2no3.pdf.

U.S. EPA (Environmental Protection Agency). (1994h) A review of ecological assessment case studies from a risk assessment perspective. Volume II. Risk Assessment Forum, U.S. Environmental Protection Agency, Washington, DC; EPA/630/R-94/003. Available online at http://www.epa.gov/raf/publications/pdfs/ECORISK.PDF.

U.S. EPA (1994i) OSWER directive: Revised interim soil lead guidance for CERCLA sites and RCRA corrective action facilities. Office of Solid Waste and Emergency Response Washington, DC; OSWER Directive #9355.4-12.

U.S. EPA (Environmental Protection Agency). (1995a) EPA risk characterization program. Memorandum from Carol Browner, Administrator, U.S. EPA, March 21, 1995. Available online at http://www.epa.gov/spc/pdfs/rccover.pdf.

U.S. EPA (Environmental Protection Agency). (1995b) Ecological risk: a primer for risk managers. Office of Prevention, Pesticides, and Toxic Substances, Washington DC; EPA/734/R-95/001.

U.S. EPA (Environmental Protection Agency). (1996a) Proposed guidelines for ecological risk assessment. Risk Assessment Forum, Washington, DC; EPA/630/R-95/002B. Available online at http://cfpub2.epa.gov/ncea/cfm/recordisplay.cfm?deid=15200.

U.S. EPA (Environmental Protection Agency). (1996b) Peer review workshop report on draft proposed guidelines for ecological risk assessment. Risk Assessment Forum, Washington, DC;, EPA/630/R-96/002. Available online at http://www.epa.gov/raf/publications/peer-review-workshop-draft-guide-eco-ra.htm.

U.S. EPA (Environmental Protection Agency). (1996c) Biological criteria: technical guidance for streams and small rivers. Revised edition. Office of Water, U.S. Environmental Protection Agency, Washington, DC, EPA/822/B-96/001.

U.S. EPA (Environmental Protection Agency). (1997a) Guidance on cumulative risk assessment. Part 1. Planning and scoping. Science Policy Council, Washington DC; 18 pp. Available online at http://www.epa.gov/spc/pdfs/cumrisk2.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (1997b) Ecological risk assessment guidance for superfund: process for designing and conducting ecological risk assessments, Interim final. Office of Solid Waste and Emergency Response, Washington, DC; June 1997, EPA/540/R-97/006. Available online at http://www.epa.gov/oswer/riskassessment/ecorisk/pdf/intro.pdf.

U.S. EPA (Environmental Protection Agency). (1997c) Guiding principles for Monte Carlo analysis. Office of Prevention, Pesticides, and Toxic Substances, Washington, D.C; EPA/630/R-97/001. Available online at http://www.epa.gov/raf/publications/pdfs/montecar.pdf.

U.S. EPA (U.S. Environmental Protection Agency). (1997d) Eco Update supplements to Ecological Risk Assessment Guidance for Superfund: Available online at http://www.epa.gov/oswer/riskassessment/ecoup/.

U.S. EPA (Environmental Protection Agency). (1997e) Special report on environmental endocrine disruption: an effects assessment and analysis. Risk Assessment Forum, Washington DC; EPA/630/R-96/012. Available online at http://www.epa.gov/raf/publications/pdfs/ENDOCRINE.PDF.

U.S. EPA (Environmental Protection Agency). (1998a) Guidelines for ecological risk assessment. Risk Assessment Forum, Washington DC; EPA/630/R-95/002F. Available online at http://www.epa.gov/raf/publications/pdfs/ECOTXTBX.PDF.

U.S. EPA (Environmental Protection Agency). (1998b) RCRA, Superfund and EPCRA hotline training module: introduction to: the Superfund response process. Office of Solid Waste and Emergency Response, Washington, DC; EPA/540/R-98/029. Available online at http://www.epa.gov/superfund/contacts/sfhotlne/resp.pdf.

U.S. EPA (Environmental Protection Agency). (1999a) Ecological risk assessment and risk management principles for superfund sites, memorandum from Stephen Luftig, Director OSWER Office of Emergency and Remedial Response. OSWER Directive 9285.7-28 P. October 7, 1999. Available online at http://www.epa.gov/fedfac/pdf/eco_risk_superfund.pdf.

U.S. EPA (Environmental Protection Agency). (1999b) Screening level ecological risk assessment protocol for hazardous waste combustion facilities. Office of Solid Waste and Emergency Response, Washington, DC; EPA/530/D-99/001. Available online at http://www.epa.gov/earth1r6/6pd/rcra_c/protocol/slerap.htm.

U.S. EPA (Environmental Protection Agency). (1999c) Interim-final guidance for RCRA corrective action environmental indicators. Office of Solid Waste, Washington, DC. Available online at http://www.epa.gov/osw/hazard/correctiveaction/eis/ei_guida.pdf.

U.S. EPA (Environmental Protection Agency). (2000a) Workshop report on characterizing ecological risk at the watershed scale. Office of Research and Development, National Center for Environmental Assessment, Washington, DC; EPA/600/R-99/111. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=23760.

U.S. EPA (Environmental Protection Agency). (2000b) Stressor identification guidance document. Office of Water, Washington, DC; EPA/822/B-00/025. Available online at http://www.epa.gov/waterscience/biocriteria/stressors/stressorid.pdf.

U.S. EPA (Environmental Protection Agency). (2000c) Ambient aquatic life water quality criteria for dissolved oxygen (saltwater): Cape Cod to Cape Hatteras. Office of Water, Washington, DC; EPA/822/R-00/012. Available online at http://www.epa.gov/waterscience/criteria/dissolved/docriteria.pdf.

U.S. EPA (Environmental Protection Agency). (2000d) Risk characterization handbook. Science Policy Council. Office of Science Policy, Washingtion, DC; EPA/100/B-00/002. Available online at http://itp-pfoa.ce.cmu.edu/docs/RChandbk_excerpts_re_exposure.pdf.

U.S. EPA (Environmental Protection Agency). (2000e) Guidelines for preparing economic analyses. Office of the Administrator, Washington, DC; EPA/240/R-00/003. Available online at http://yosemite.epa.gov/ee/epa/eed.nsf/webpages/Guidelines.html/$file/Guidelines.pdf.

U.S. EPA (Environmental Protection Agency). (2000f) Nutrient criteria technical guidance manual, lakes and reservoirs. Office of Water, Washington, DC; EPA-/822-B00-001. Available online at http://water.epa.gov/scitech/swguidance/waterquality/standards/criteria/aqlife/pollutants/nutrient/lakes_index.cfm

U.S. EPA (Environmental Protection Agency). (2001a) Risk assessment guidance for superfund: volume III – part A, process for conducting probabilistic risk assessment. Office of Emergency and Remedial Response, Washington, DC; EPA/540/R-02/002. Available online at http://www.epa.gov/oswer/riskassessment/rags3adt/pdf/rags3adt_complete.pdf.

U.S. EPA (Environmental Protection Agency). (2001b) Planning for ecological risk assessment: developing management objectives (external review draft). Risk Assessment Forum, Washington, DC; EPA/630/R-01/001A. Available online at http://cfpub.epa.gov/ncea/raf/pdfs/eco_objectives-sab_6-01.pdf.

U.S. EPA (Environmental Protection Agency). (2001c) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part D, Standardized planning, reporting and review of Superfund risk assessments, Final). Publication 9285.7-47. Office of Emergency and Remedial Response, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragsd/index.htm.

U.S. EPA (Environmental Protection Agency). (2002a) Lessons learned on planning and scoping for environmental risk assessments. Planning and Scoping Workgroup of the Science Policy Council, Washington DC. Available online at http://www.epa.gov/spc/pdfs/handbook.pdf.

U.S. EPA (Environmental Protection Agency). (2002b) The twenty needs report: how research can improve the TMDL program. U.S. Environmental Protection Agency, Office of Wetlands, Oceans and Watersheds, Washington, DC; EPA/841/B-02/002. Available online at http://www.epa.gov/owow/tmdl/20needsreport_8-02.pdf.

U.S. EPA (Environmental Protection Agency). (2003a) Framework for cumulative risk assessment. Risk Assessment Forum, Washington DC; EPA/600/P-02/001F, 109pp. Available online at http://www.epa.gov/raf/publications/pdfs/frmwrk_cum_risk_assmnt.pdf.

U.S. EPA (Environmental Protection Agency). (2003b) Generic ecological assessment endpoints (GEAE) for ecological risk assessment. Risk Assessment Forum, Washington, DC; EPA/630/P-02/004F. Available online at http://www.epa.gov/raf/publications/pdfs/GENERIC_ENDPOINTS_2004.PDF.

U.S. EPA (Environmental Protection Agency). (2003c) A summary of general assessment factors for evaluating the quality of scientific and technical information. Science Policy Council, Washington, DC; EPA/100/B-003/001. Available online at http://www.epa.gov/spc/pdfs/assess2.pdf.

U.S. EPA (Environmental Protection Agency). (2004a) An examination of EPA Risk assessment principles and practices: staff paper. Office of the Science Advisor, Washington, DC; EPA/100/B-04/001. Available online at http://www.epa.gov/osa/pdfs/ratf-final.pdf.

U.S. EPA. (Environmental Protection Agency). (2004b) Overview of the ecological risk assessment process in the Office of Pesticide Programs, U.S. Environmental Protection Agency. Office of Prevention, Pesticides and Toxic Substances. Washington, DC. Available online at http://www.epa.gov/espp/consultation/ecorisk-overview.pdf.

U.S. EPA (Environmental Protection Agency). (2004c) Air toxics risk assessment reference library. Volume 1 technical resource manual. Office of Air Quality Planning and Standards, Research Triangle Park, NC; EPA/453/K-04/001A. Available online at http://www.epa.gov/ttn/fera/risk_atra_vol1.html.

U.S. EPA (Environmental Protection Agency). (2004d) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part E, Supplemental guidance for dermal risk assessment, Final). EPA/540/R-99/005. OSWER 9285.7-02EP. PB99-963312. Office of Superfund Remediation and Technology Innovation, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragse/index.htm.

U.S. EPA (Environmental Protection Agency). (2005) Guidance for developing ecological soil screening levels. November 2003, revised February 2005. Office of Solid Waste and Emergency Response. Washington, DC. OSWER Directive 9285.7-55. Available online at http://www.epa.gov/ecotox/ecossl/pdf/ecossl_guidance_chapters.pdf.

U.S. EPA (Environmental Protection Agency). (2006a) Ecological benefits assessment strategic plan. Office of Policy, Economics and Innovation, National Center for Environment Economics, Washington, DC; EPA/240/R-06/001.

U.S. EPA (Environmental Protection Agency). (2006b) Framework for developing suspended and bedded sediments water quality criteria. Office of Water, Washington, DC; EPA/822/R-06/001. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=164423.

U.S. EPA (Environmental Protection Agency). (2007a) Nanotechnology white paper. Science Policy Council, Office of the Science Advisor, Washington DC; EPA 100/B-07/001. Available online at http://www.epa.gov/osa/pdfs/nanotech/epa-nanotechnology-whitepaper-0207.pdf.

U.S. EPA (Environmental Protection Agency). (2007b) Hypoxia in the Northern Gulf of Mexico: an update by the Science Advisory Board. Washington DC; EPA SAB-08-004. Available online at http://yosemite.epa.gov/sab/sabproduct.nsf/C3D2F27094E03F90852573B800601D93/$File/EPA-SAB-08-003complete.unsigned.pdf.

U.S. EPA (Environmental Protection Agency). (2007c) Framework for metals risk assessment. Risk Assessment Forum, Office of the Science Advisor, Washington DC; EPA 100/B-07/001. Available online at http://www.epa.gov/raf/metalsframework/pdfs/metals-risk-assessment-final.pdf

U.S. EPA (Environmental Protection Agency). (2008a) EPA's 2008 report on the environment. National Center for Environmental Assessment, Washington, DC; EPA/600/R-07/045F. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=190806.

U.S. EPA (Environmental Protection Agency). (2008b) Guidelines for preparing economic analyses. External review draft, September 12, 2008. National Center for Environmental Economics, Washington, DC. Available online at http://yosemite.epa.gov/ee/epa/eerm.nsf/vwAN/EE-0516-01.pdf/$file/EE-0516-01.pdf.

U.S. EPA (Environmental Protection Agency). (2008c) Framework for application of the toxicity equivalence methodology for polychlorinated dioxins, furans, and biphenyls in ecological risk assessment. Risk Assessment Forum, Washington DC; EPA/100/R-08/004. Available online at http://www.epa.gov/raf/tefframework/pdfs/tefs-draft-052808.pdf.

U.S. EPA (Environmental Protection Agency). (2008d) Integrated science assessment (ISA) for oxides of nitrogen and sulfur-ecological criteria. Office of Research and Development, Research Triangle Park, NC; EPA/600/R-08/082F. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=201485.

U.S. EPA (Environmental Protection Agency). (2008e) Advice to EPA on the science and application of ecological risk assessment in environmental decision making: a report of the U.S. EPA Science Advisory Board. Science Advisory Board, Washington, DC: EPA-SAB-08-002. Available online at http://yosemite.epa.gov/sab/sabproduct.nsf/7140DC0E56EB148A8525737900043063/$File/sab-08-002.pdf.

U.S. EPA (Environmental Protection Agency). (2009a) Summary report: risk assessment forum technical workshop on population-level ecological risk assessment. Risk Assessment Forum, Washington, DC, EPA/100/R-09/006. Available online at http://www.epa.gov/raf/files/population_level_era_report_supp_materials.pdf.

U.S. EPA (Environmental Protection Agency). (2009b) Valuing the protection of ecological systems and services: a report of the U.S. EPA Science Advisory Board. Science Advisory Board, Washington, DC; EPA-SAB-09-012. Available online at http://yosemite.epa.gov/sab/sabproduct.nsf/WebBOARD/ValProtEcolSys&Serv?OpenDocument.

U.S. EPA (Environmental Protection Agency). (2009c) Risk assessment guidance for Superfund Volume I — Human health evaluation manual (Part F, Supplemental guidance for inhalation risk assessment, Final). EPA/540/R-070/002. OSWER 9285.7-82. Office of Superfund Remediation and Technology Innovation, Washington, DC. Available online at http://www.epa.gov/oswer/riskassessment/ragsf/index.htm.

White, ML; Maurice, CG; Mysz, A; et al. (2008) The critical ecosystem assessment model (CrEAM) - identifying healthy ecosystems for environmental protection planning. In: Campbell, JC; Jones, KB; Smith, H; et al; eds. North America Land Cover Summit, Chapter 12. Washington, DC: Association of American Geographers; pp. 181−213. Available online at http://www.aag.org/galleries/nalcs/CH12.pdf.

APPENDIX A
COLLOQUIUM PARTICIPANTS

PARTICIPANTS

Hunter Anderson, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, BRAB, Postdoctoral Research Ecotoxicologist, anderson.hunter@epa.gov

Joan Aron, U.S. EPA, Office of Research and Development, Office of the Science Advisor, American Association for the Advancement of Science-Science and Technology Policy Fellow, aron.joan@epa.gov

Mace Barron, U.S. EPA, Office of Research and Development, National Health and Environmental Effects Research Laboratory, Gulf Ecology Division, Branch Chief, barron.mace@epa.gov

Joe Beaman, U.S. EPA, Office of Science and Technology, Ecological Risk Assessment Branch, Branch Chief, beaman.joe@epa.gov

Michael Broder, U.S. EPA, Office of Science and Technology, Biologist, broader.michael@epa.gov

Arden Calvert, Office of the Chief Financial Officer, calvert.arden@epa.gov

David Charters, Office of Superfund Remediation and Technology Innovation, charters.davidw@epa.gov

Susan Cormier, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, Biological Risk Assessment Branch, Senior Scientist, cormier.susan@epa.gov

Charles Delos, U.S. EPA, Office of Water, Office of Science and Technology, Health and Ecological Criteria Division, Environmental Scientist, delos.charles@epa.gov

Laura Dobbins, U.S. EPA, Office of Science and Technology, Ecological Risk Assessment Branch, Physical Scientist, dobbins.laura@epa.gov

William Eckel, U.S. EPA, Office of Chemical Safety and Pollution Prevention, eckel.william@epa.gov

Herbert Fredrickson, U.S. EPA, Office of Research and Development, National Health and Environmental Effects Research Laboratory, Immediate Office, fredrickson.herbert@epa.gov

Jeffrey Gallagher, U.S. EPA, Office of Pollution Prevention and Toxics, NCSAB, Toxicologist, gallagher.jeffrey@epa.gov

Kathryn Gallagher, U.S. EPA, Office of the Science Advisor, Risk Assessment Forum, Acting Director, gallagher.kathryn@epa.gov

Linda George, U.S. EPA, Region 2, Enforcement and Investigations Branch, Risk Assessor, george.linda@epa.gov

Iris Goodman, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, goodman.iris@epa.gov

Michael Griffith, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, griffith.michael@epa.gov

Tala Henry, U.S. EPA, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, henry.tala@epa.gov

Lisa Huff, U.S. EPA, Health and Ecological Criteria Division, Office of Science and Technology, Toxicologist, huff.lisa@epa.gov

Barbara Karn, U.S. EPA, National Center for Environmental Research, Immediate Office, Scientist, karn.barbara@epa.gov

Amuel Kennedy, U.S. EPA, Office of Pollution Prevention and Toxics, Biologist, kennedy.amuel@epa.gov

Kristen Keteles, U.S. EPA, Office of Pollution Prevention and Toxics, Toxicologist, keteles.kristen@epa.gov

Michael Kravitz, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, Environmental Scientist, kravitz.michael@epa.gov

Wade Lehmann, U.S. EPA, Office of Science and Technology, Ecological Risk Assessment Branch, Aquatic Toxicologist, lehmann.wade@epa.gov

Jason Lynch, U.S. EPA, Office of Atmospheric Programs, CMAD, ACB, Ecologist, lynch.jason@epa.gov

Anthony Maciorowski, U.S. EPA, Science Advisory Board, Staff Office, Deputy Director, Staff Office, maciorowski.anthony@epa.gov

Charles Maurice, U.S. EPA, Office of Research and Development, Office of Science Policy, Region 5 Superfund Division, Superfund and Technology Liason, maurice.charles@epa.gov

Mike McManus, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, Environmental Scientist, Ecologist, mcmanus.michael@epa.gov

Wayne Munns, Office of Research and Development, National Health and Environmental Effects Research Laboratory, Atlantic Ecology Division, Associate Director for Science, munns.wayne@epa.gov

Dan Mazur, U.S. EPA, Office of Solid Waste and Emergency Response, Region 5, Ecologist, mazur.daniel@epa.gov

Edward Odenkirchen, U.S. EPA, Office of Chemical Safety and Pollution Prevention, odenkirchen.edward@epa.gov

Edward Ohanian, U.S. EPA, Office of Science and Technology, Health and Ecological Criteria Division, Office of Water, Director, ohanian.edward@epa.gov

Melissa Panger, U.S. EPA, Office of Pollution Prevention and Toxics, Biologist, panger.melissa@epa.gov

Bruce Pluta, U.S. EPA, Biological Techinal Assistance Group, Region 3 Coordinator, Hazardous Site Cleanup Division, pluta.bruce@epa.gov

Sara Pollack, U.S. EPA, Office of Pollution Prevention and Toxics, NCSAB, Environmental Protection Specialist, pollack.sara@epa.gov

Meghan Radtke, U.S. EPA, Office of Science Advisor, Risk Assessment Forum, American Association for the Advancement of Science-Science and Technology Policy Fellow, radtke.meghan@epa.gov

Anne Rea, U.S. EPA, Office of Air Quality Planning and Standards, Environmental Health Scientist, rea.anne@epa.gov

Susan Roddy, U.S. EPA, Superfund Ecological Risk Assessor, Region 6, roddy.susan@epa.gov

Vicki Sandiford, U.S. EPA, Office of Air Quality Planning and Standards, sandiford.vicki@epa.gov

Seema Schappelle, U.S. EPA, Office of Science Advisor, Risk Assessment Forum, schappelle.seema@epa.gov

Anne Sergeant, U.S. EPA, National Center for Environmental Research, Applied Science Division, Environmental Scientist, sergeant.anne@epa.gov

Denice Shaw, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, Immediate Office, shaw.denice@epa.gov

Michael Slimak, US. EPA, Office of Research and Development, National Center for Environmental Assessment, Immediate Office, Associate Director for Ecology, slimak.michael@epa.gov

Mark Sprenger, U.S. EPA, Office of Superfund Remediation and Technology Innovation, sprenger.mark@epa.gov

Glenn Suter, US. EPA, Office of Research and Development, National Center for Environmental Assessment, Cincinnati, Science Advisor, suter.glenn@epa.gov

Patti TenBrook, U.S. EPA, Region 9, Life Scientist, tenbrook.patti@epa.gov

Sharon Thoms, U.S. EPA, Superfund, Ecological Risk Assessor, thoms.sharon@epa.gov

Brett Thomas, U.S. EPA, Superfund Support, Life Scientist, thomas.brett@epa.gov

Philip Turner, U.S. EPA, Technical and Enforcement, Life Scientist/Risk Assessor, turner.philip@epa.gov

Zig Vaituzis, U.S. EPA, Office of Pesticide Programs, Biopesticides and Pollution Prevention Division, Senior Scientist, vaituzis.zigfridas@epa.gov

Sara Waterson, U.S. EPA, Air Toxis and Monitoring Branch, Life Scientist, waterson.sara@epa.gov

Marjorie Wellman, U.S. EPA, Office of Science and Technology, RSTSSB, Ecologist, wellman.marjorie@epa.gov

Randy Wentsel, U.S. EPA, Office of Research and Development, Immediate Office, National Program Director, wentsel.randy@epa.gov

Steve Wharton, U.S. EPA, Region 8, Risk Assessor, wharton.steve@epa.gov

Pai-Yei Whung, U.S. EPA, Office of Science Advisory, Immediate Office, Chief Scientist, whung.pai-yei@epa.gov

Tracy Wright, U.S. EPA, Office of Pollution Prevention and Toxics, Risk Assessment Division, Biologist, wright.tracy@epa.gov

C. Richard Ziegler, U.S. EPA, Office of Research and Development, National Center for Environmental Assessment, Physical Scientist, ziegler.rick@epa.gov

Jean Zodrow, U.S. EPA, OEA, Toxicologist, zodrow.jean@epa.gov

BREAK-OUT GROUP PARTICIPANTS

Break-out Group #1

Joseph Beaman
William Eckel
Herb Fredrickson
Kathryn Gallagher
Lisa Huff
Jason Lynch
Tony Maciorowski
Chuck Mauric
Wayne Munns
Anne Rea
Vicki Sandiford
Anne Sergeant
Denice Shaw
Brett Thomas
Sharon Thoms
Randy Wentsel
Steve Wharton
Rick Zeigler

Break-out Group #2

Hunter Anderson
Mace Barron
Charles Delos
Laura Dobbins
Linda George
Kristen Keteles
Michael Kravitz
Nan Mazur
Melissa Panger
Bruce Pluta
Philip Turner
Marjorie Wellham
Mark Sprenger

Break-out Group #3

Mace Barron
Michael Broder
Arden Calvert
Susan Cormier
Jeffrey Gallagher
Michael Griffith
Barbara Karn
Ameul Kennedy
Wade Lehmann
Bruce Pluta
Sara Pollack
Glenn Suter
Zig Vituzis
Sara Waterson
Jean Zodrow

Break-out Group #4

Joan Aron
Joe Beaman
David Charters
Charles Delos
Iris Goodman
Tala Henry
Tony Maciorowski
Mike McManus
Ed Odenkirchen
Ed Ohanian
Meghan Radtke
Susan Roddy
Mike Slimak
Patti TenBrook
Tracy Wright

APPENDIX B
INTERVIEWS OF ECOLOGICAL ASSESSORS

This appendix presents the results of the 12 interviews of U.S. Environmental Protection Agency (EPA) ecological assessors that were conducted prior to the Colloquium. The primary purpose was to explore the diversity of ecological assessment activities in the Agency and confirm the applicability of the integrated framework (see Section 3) to current assessment practices in the Agency. Thereby, the technical committee was able to confirm that the integrated framework is useful for organizing the Colloquium and report. The interviewees were chosen to represent the Agency's programs and regions. Most of those chosen are relatively senior, so that the answers would reflect a breadth of experience and depth of knowledge.

The interview began by identifying the interviewee's experience and then the regulatory role of their organization and available guidance. The interviewer then proceeded to explain the four types of assessments in the integrated framework and to ask the interviewee about assessments of that type performed by their organization. Then the interviewee was asked about the relationship of ecological assessments to decision-making and to achieving the mandates of their organization. Finally, the interviewer asked about the needs of their organizations with respect to assessment methods and guidance.

The interviews have been extensively edited to be concise, consistent, and on topic.

B.1. COMPREHENSIVE ENVIRONMENTAL RESPONSE, COMPENSATION, AND LIABILITY ACT (CERCLA) AND RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)

Mark Sprenger, PhD
Region 2 Office of Superfund Remediation & Technology Innovation

Professional experience or organizational affiliations relevant to environmental assessment
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 PhD in Environmental Science from Rutgers, the State University of New Jersey. His doctorate research and postdoctorate work focused on alteration in metals availability resulting from acid deposition as well as postdoctorate 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, particularly in sediments; site environmental monitoring; and most recently, on the assessment of innovative remedial technologies and ecological restoration, from an ecological risk perspective, at Superfund and brownfield sites.

Regulations or programs that are informed by assessments
Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA; Superfund)

Guidance
Although there is ample guidance for the assessment process (Fig. B-1 and B-2), it is not always followed. Relevant policy guidance documents can be found at http://www.epa.gov/oswer/riskassessment/policy.htm.

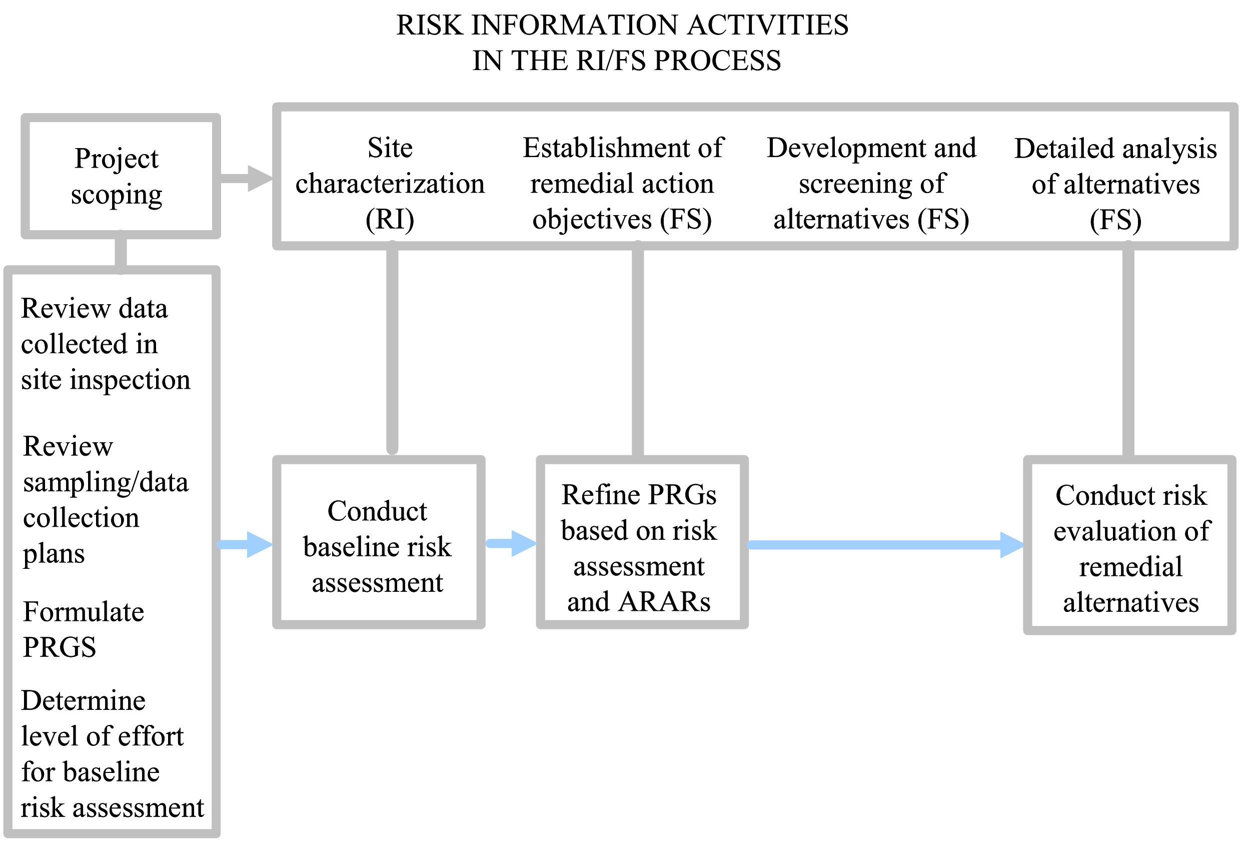

Figure B-1. A diagram of the assessment processes in a CERCLA remedial investigation and feasibility study. Figure by Mark Sprenger.

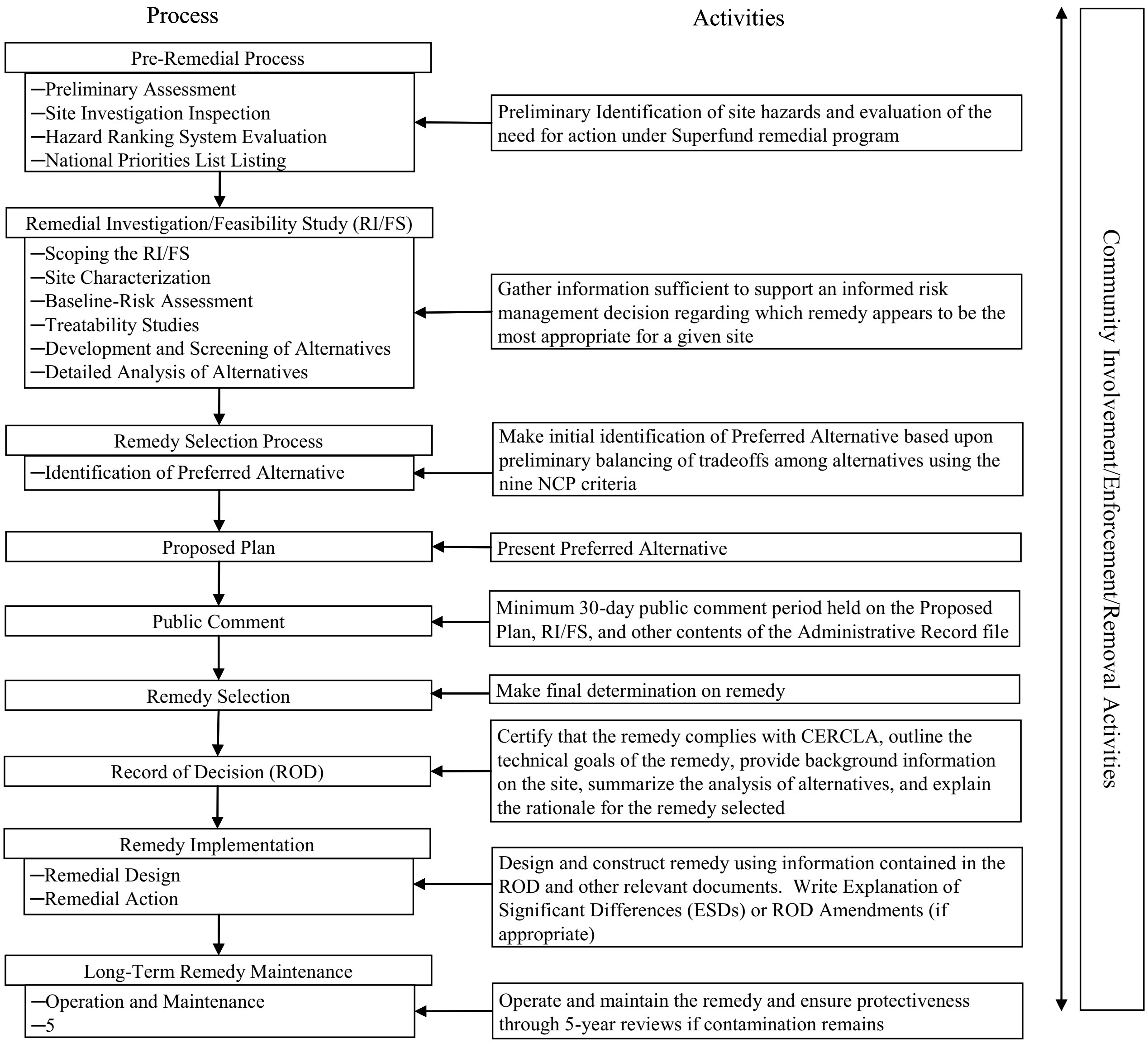

Figure B-2. A diagram of the broader CERCLA remediation process (U.S. EPA, 2005)

Condition Assessments

Site investigations and hazard-ranking-system evaluations are condition assessments that may lead to listing a site as a Superfund site on the National Priority List (NPL) of hazardous sites. Site investigations through CERCLA deal only with regulated chemicals and do not include physical compaction, oil, gas, registered pesticides, petroleum spills. Ostensibly, these pollutants are addressed by other regulations.

Although site investigations use the risk assessment framework, problem formulation is often weak, and stressor identifications (SI) are inconsistent with respect to content. In a screening-level assessment, decision criteria may not be explicitly stated, and, thus, analysis continues until the parties get the answer they wanted rather than an objective assessment. Negotiations occur regarding sampling extent and effort that may not meet the data quality objectives.

Causal Assessments

Causal assessments almost always needed because (1) the biotic communities of the site are often obviously impaired, (2) usually almost nothing is eliminated in screening-level Ecological Risk Assessment (ERA), and (3) the causes are often unclear, creating a need for additional causal assessment. The conventional ecological risk assessment framework has been used to perform causal assessments (see Box B-1).

Box B-1. Superfund assessors use the RA paradigm for causal assessments.
Two examples were illustrative. On the Hudson across from West Point was a nickel cadmium battery manufacturer (Marathon Battery at Foundry Cove, Cold Springs, NY). Yellow cadmium sulfide deposits were highly visible; however, research by Gary Ankley and others at the Duluth laboratory showed that nickel toxicity was the greater threat. For a list of contaminants and more information of this site, which has been remediated, see EPA's Web site. Accessed 20090730.
http://cfpub.epa.gov/supercpad/SiteProfiles/index.cfm?fuseaction=second.Contams&id=0201491

In another case, uranium contamination was suspect, but erosion may have been equally deleterious, or both may have acted together. This is a question of trying to separate out the causative agents. The system was impacted, but if it was impacted from erosion (loss of habitat only), Superfund could not legally take an action in the stream. If it is plausible that an impact would exist from the contamination even if the habitat loss did not exist, then Superfund may take an action. It is a challenge to make those determinations.

At the Palmerton Zinc Pile Site, one area of 2,000 acres was devegetated and was attributed to air and soil contamination resulting from the historic smelting operations. However, it is also possible that fires ignited by coal-fired locomotives during the early part of the 20th century caused the initial damage, and that failure to recover was due to other causes. This is an issue for the Natural Resource Trustees, but it does not mean that the zinc levels are not a risk but more of an issue on what was the initial cause of the system loss. However, that is not a Superfund problem. Accessed 20090730 http://www.epa.gov/reg3hwmd/npl/PAD002395887.htm.

Predictive Assessment—Conventional Risk Assessment

CERCLA assessments are largely not typically predictive because the impact has already happened. However, future effects due to movement of the contaminants must be considered, and the selection of a remedy implies that effects will continue if not remediated. An example is described in Box B-2. Similarly, in a Natural Resource Damage Assessment (NRDA), the damage is assessed for the past loss of the resource (condition assessment) and for future loss of the resource (predictive assessment). Sources and causes are also identified in the NRDA.

Predictive Assessment—Benchmark Determination

On occasion, it might be worthwhile to refine a criterion concentration if there may be a cost saving in the remediation. An example is a New York tannery site contaminated by chromium and other metals. The lowest effect level was 26 ppm; but background was not much lower, and a more reasonable cleanup level was selected. This is becoming a nationwide issue. Typically, promulgated state or federal criteria must be accepted, but states are pushing screening criteria as state standards. Tribes have identified these values as applicable or relevant and appropriate requirements (ARARs) for tribal lands in some cases. The issue is that sometimes we do use the screening values because it is not cost effective for the potential remedy actions to obtain a more accurate number (a higher cleanup goal). The reasons are strictly engineering in nature; for example, a bulldozer can not make a finer cut than 6−12 inches, and dredges are no better and likely a lot worse because you cannot see their work area. If the changes in the "construction" do not change the effort, then the technically better ERA and conclusions drawn from it are of no value to the Program.

Box B-2. Hiteman Tannery, NY.
In mid-1996, a Site Investigation (SI) was performed by EPA. Elevated levels (relative to site reference or regional background levels) of chromium were detected in the surface soil (up to 75,000 mg/kg), subsurface soils (up to 72,000 mg/kg), and surface water (33 µg/L unfiltered; 5.7 µg/L filtered). Several other contaminants detected at low levels and primarily in the soil samples were TAL metals, pesticides, semivolatiles, and volatiles. A structural evaluation determined that most of the buildings and the stack at the site were structurally unsound, and demolition was recommended. The stability of the north bank of the Unadilla River adjacent to the site was determined to be subjected to erosion by high water levels (spring runoff), which may slowly undercut the bank. In November 1996, to stabilize the north bank of the Unadilla River adjacent to the site, 500 linear feet of man-size Rip Rap was installed along the bank.

As part of the RI, a screening-level ERA was conducted. The results indicated the potential for risk to ecological receptors from site-related contaminants. EPA concluded that a more thorough assessment of ecological risk (i.e., a Baseline ERA, or BERA) was warranted. The BERA used a multiple lines-of-evidence approach to evaluate ecological risks, including food chain modeling, site-specific toxicity testing, and field observations (such as the lack of amphibians in the wetland). The BERA focused on both the aquatic communities exposed to contaminants in the Unadilla River and the terrestrial organisms exposed to contaminants in the on-property wetland sediment and upland surface soil at the site. The BERA identified the potential for ecological risks from exposure to chemicals detected in the Unadilla River sediment, wetland sediment, and former tannery property surface soil. Metals drove the risk calculations, showing a high Hazard Quotient (HQ) of 6 attributable to the metals in these media (U.S. EPA, 2006).

New benchmarks are usually derived from databases or the literature. In some cases, an effects-based criterion is determined.

When determining protective levels for cleanup, the selection of assessment endpoints are important because the relevance of tests that are used is not immediately understood by others. For example, if the assessment uses earthworm toxicity tests, and no other, then the decision to remediate a site may appear to be a foolish attempt to save earthworms. In Region 1, such a case arose with respect to a $20 M remediation at a creosote-contaminated site.

Predictive Assessment—Management Assessment
This should be integrated into the assessment endpoints.
There is no value to limiting the number of assessment endpoints.

Use the RA process to evaluate need-for-remedy options (called the Baseline ERA). If a risk is identified a feasibility study is conducted to evaluate remedy options. The feasibility study uses the RA process to evaluate remedy options per the "nine criteria." The feasibility study (FS) is typically an engineering document, and the assessors should use the RA to guide remedy selection. They also do so in concluding whether or not remedy options meet the threshold criteria of protectiveness. The risks associated with the remedy action itself are not as systematically evaluated. That is where net ecosystem benefits analysis (NEBA) could be used effectively. This is all documented in the Decision of Record.

Baseline risk assessments do not look at remedial options.

Outcome Assessment
Assessments are seldom performed to determine whether ecological goals are achieved. The remedy must be "protective," but "protective" is not defined. A 5-year review is performed which could be based on an outcome assessment, but it typically limited to levels of the contaminants rather than effects.

General comments
A risk assessment is a tool to reach an informed decision. When it is done well, clear lines of reasoning lead to a decision. Pure science and knowledge are tools that are applied to these assessments.

The largest dilemma is how to define "protective." For example, protect population or community? Industry often wants community-level protection, because it takes longer, and the results are ambiguous.

Problem formulations are often weak because there are poorly defined assessment endpoints and often no decision criteria. Also, there is a sense that there is just too much paper and information to manage. In some cases, problem formulation becomes an assessment in itself, but without the rigor or protocols to guide the process.

There is no exemption if the "cure is worst than the disease." An option is to apply a risk remedy to monitor natural attenuation processes.

Superfund involves a legal as well as a scientific process. Actions that are required to satisfy the legal process sometimes make the science appear less rigorous than it is. Similarly, some of the analysis may confuse nonscientists because they may not understand the complexity, statistics, or inferences.

The risk assessment community needs to understand that Superfund risk assessment is conducted within a legal and decision-making process. The ERA is not the goal, nor is publishable work the goal; the goal is a justifiable and cost-effective decision.

Suggestions for assuring that scientific information informs and improves decision-making
We need a forum for ERAs with negative results. Such cases help to illustrate that these results do occur and helps to build confidence when others determine similar results.

We also need Eco-Risk training courses for Superfund and hazardous waste sites. The new generation does not have the hard-learned experience.

Jon Rauscher, PhD
Region 6

Professional experience or organizational affiliations relevant to environmental assessment
Jon Rauscher is a Toxicologist in the Superfund Division of U.S. EPA, Region 6. Rauscher has provided technical assistance on human health and ecological risk assessments at over 100 Superfund and Resource Conservation and Recovery Act (RCRA) sites.

Rauscher has been an active work group participant in the development of following risk assessment guidance: Risk Assessment Guidance for Superfund, *Volume 1 - Human Health Evaluation Manual, Part C, Risk Evaluation of Remedial Alternative*; *Risk Assessment Guidance for Superfund, Volume 2 - Environmental Evaluation Manual*; *Guidance for Data Usability in Risk Assessment*; and *Ecological Risk Assessment Guidance for Superfund*. Rauscher is the Region 6 contact for the Integrated Risk Information System (IRIS). Rauscher was a member of the Reference Dose and Reference Concentration (RfD/RfC) Work Group, which verified toxicity values for noncarcinogenic health effects.

In addition, Rauscher is an Adjunct Professor at Southern Methodist University and has taught graduate-level courses entitled “Sources and Nature of Hazardous Waste” and “Risk Assessment and Toxicology.” Rauscher attended the University of Nebraska and Colorado State University.

Regulations or programs that are informed by assessments
Although not an exhaustive list, several programs and regulations that use assessments were noted: Superfund, total maximum daily load [TMDL], Biocriteria, Nutrient impairment (Causal Analysis/Diagnosis Decision Information System [CADDIS] used to address), Louisiana Regional dissolved oxygen.

Guidance

- Primarily rely on the *Ecological Risk Assessment Guidance for Superfund* (IFERAGS) Interim Final (1997)
- Several updates (“Eco-updates”) not explicit in the IFERAGS were valuable additions
- 2001 Role of Screening Level Assessments
- Clarification chemicals of concern from Office of Solid Waste and Emergency Response (OSWER)
- 2008 Ground water-surface water pathways from Eco-forum (Marc Greenberg)
- When he was with the Office of Water, helpful guidance was available for TMDLs. Stressor Identification (CADDIS), and biocriteria

For RCRA, there is not distinct guidance, so states use IFERAGS. Texas has its own Eco-Risk guidance for RCRA.

Condition Assessments
Condition assessments are done as part of the Superfund site assessment but sometimes in conjunction with other programs. For instance, the Houston/Galveston area was listed on the 303(d) list of impaired waters, but when dioxin was found, it was added to NPL. Subsequently, the source was identified as a paper waste pit, and the responsible party was identified. A causal assessment was needed to allocate contribution from the pit and from other water sources.

Preliminary site assessments are condition assessments.

An example of integration is the Calcasieu River in Southwest Louisiana in which a holistic watershed remediation and protection program was implemented. This involved using the authorities and programs from the Clean Water Act, RCRA, Superfund, and Oil Pollution Act.

Causal Assessments
Sometimes causes are known at a Superfund site but not always. In particular, causal assessments are necessary to identify the causal agent for recovering natural resource damages and to identify the potentially responsible party for site remediation. NRDA is the responsibility of the "services" or trustees, Fish and Wildlife Service, and National Oceanographic and Atmospheric Administration. However, the Department of Justice has recommended integrated assessments so that the liabilities based on the NRDA (lost services, fishery closures, etc.) and the Superfund ROD (preferred remedy and cleanup costs) be presented together. This has led to sharing of information between the U.S. Fish and Wildlife Service (FWS), National Oceanographic and Atmospheric Administration (NOAA), and EPA. Coordination between the NRDA and Remedial Investigation (including the risk assessments) has allowed for a more efficient collection of information. The cooperative assessments become parallel processes and may be iterative.

Predictive Assessment—Conventional Risk Assessment
These assessments are part of Superfund activities. Risk assessment is used to identify the media and the remedial goal to be addressed by the FS. The FS uses the nine criteria in the National Contingency Plan to screen the list of potential alternatives.

Predictive Assessment—Benchmark Determination
In the remedial investigation, the cleanup levels are determined depending on the potential future condition. Examples include residential use, industrial use, or ecological habitat. Remedial action objectives (RAO) are identified. They may use the triad of contaminant, toxicity, and biological condition to assess that risk level. The developed level is then used to evaluate remediation alternatives in the FS.

Predictive Assessment—Management Assessment
In the FS, the nine criteria are used to screen out alternatives that will not meet the RAO level. Then the protection of human health and environment and the ARARs (standards and criteria) and the other seven criteria are used to identify the preferred alternative that is described in a proposed plan for remediation. Then the proposed plan is made available to the public for review and to the responsible party. Comments are considered and incorporated into the final

Record of Decision (ROD). Successful management decisions depend on adequate integration of all relevant considerations across all appropriate scales (see Box B-3).

> **Box B-3. Other types of integration.**
> Risk Assessments must be integrated in several ways, (1) across jurisdictions, (2) across regulatory authorities and programs, (3) across receptor endpoints, and (4) across remedial alternatives. An illustrative example is Tar Creek in the lead belt of Kansas, Missouri, and Oklahoma. The aquatic ecological risk assessment required that the entire affected areas be included in the assessment if the remedial action was to be effective. The effort involved three states, two EPA regions, ground and surface water, analyses by contractors (Don McDonald), U.S. Geological Survey (Chris Ingersoll), and EPA (Region 6, Region 7, and HQ [Mark Sprenger]), state agencies, and other integrative efforts. The success of this complex ecological risk assessment was increased by senior leadership's encouragement and understanding of the scale of the assessment.

Outcome Assessment
Although monitoring and assessment of both performance and effectiveness can be specifically directed in the ROD, there is heavy reliance on the required 5-year review. For example, in a Louisiana case in the early 1990s, concerns were raised by the inspector general's office that the remedy had failed. At the time of the original ROD, guidance was not available for modeling the pathways between ground and surface water. In a review of the site, additional sampling was done to enable this analysis. The assessors coordinated the timing of collection of data from several programs including 303(d) State monitoring, EPA-NRMRL-Ada, and Superfund so that the data could be used in modeling. The information collected by these programs will be used to evaluate the remedy effectiveness.

Several examples of periodic monitoring included in the ROD were mentioned. At the Lavaca Bay site in Texas, mercury (Hg) levels in shellfish tissue were not improving as desired. The redeveloped marsh may need to be capped to meet the Hg RAO. This determination will be based on the well-documented food web for the area. Alcoa, the responsible party, has proposed that this would be a reasonable action to interrupt the transfer of Hg through the food web.

Other processes to attain EPA's mission
"Imminent and substantial endangerment" clauses appear in RCRA, 42 U.S.C. §§ 6972(a)(1)(B), 6973; CERCLA (Section 106), and Safe Drinking Water Act §1431a , 42 U.S.C. 301i(a). Guidance on "imminent and substantial endangerment" appears in CERCLA Section 106(a) Unilateral Administrative Orders for Remedial Designs and Remedial Action (OSWER Directive Number 9833.0-1a). Also note that Toxic Substances Control Act (TSCA) has similar language (Federal Pollution Control Act, 1973). In contrast, the Clean Water Act (CWA) and Clean Air Act require evidence of imminent harm.

Strongest aspect of existing processes
The strongest and weakest aspects are when integration is practiced. It is essential to work with the prioritization panel and to convey the importance of ecological risks.

Another strength is that the guidance for Superfund and human health is 20 years old. Familiarity with the guidance by practitioners has a great advantage. The strategic filling of gaps such as probabilistic guidance and inhalation guidance is helpful. The 1997 IFERAGS that superseded the original RAGS Part B guidance has also helped make the process more successful.

Suggestions for assuring that scientific information informs and improves decision-making
Early and continuous involvement with the public is essential. Otherwise, the public will not be supportive. Region 6 relies heavily on open houses on different aspects of the process, such as site investigation, remedial investigation, etc. Region 6 benefits from input from the community, and sometimes the community helps them identify pathways of exposure that were not originally considered. Through this process, the public starts to understand and recognize how toxicity tests and other measurements fit together to enable predictions of risk to an ecosystem.

Regarding the definition of protective—It is important to be very carful to properly articulate and describe the assessment endpoint and to choose appropriate measurement endpoints and hypotheses. The definition of protective is dependent on the acceptable future condition of the site, e.g., residential use, industrial use, or ecohabitat.

Regarding problem formulation—There is often a time limitation, and the problem formulation is short changed. It is important for senior management to have a realistic understanding of the amount of time it takes to do a good problem formulation and that the adage penny-wise, pound-foolish is most apt in this case. To counteract this problem, one approach is to begin the problem formulation even before the responsible party is identified, as soon as an actionable contaminant is identified.

Regarding guidance and project management—Remedial project managers need to value problem formulation, and this can be accomplished by elevating its visibility at the National Association of regional program managers (RPM) meetings and headquarter division director meetings, and then filter to section leads.

Dan Mazur
Region 5

Professional experience or organizational affiliations relevant to environmental assessment
Dan Mazur is an ecologist in the Land and Chemicals Division of EPA, Region 5 and provides technical support on ecological risk assessment for RCRA Corrective Action projects. He is the primary contact for the Region 5 RCRA Ecological Screening Levels and has extensive ecological risk assessment experience with RCRA permits for combustion facilities and wrote a Regional protocol (Example Work Plan to Perform a Screening Ecological Risk Assessment at a Hazardous Waste Combustion Facility) to support the permitting process.

Prior to joining EPA, he was a State Program Manager for both lake restoration and nonpoint source control with the Missouri Department of Natural Resources. Mazur was also involved in applied limnology research and sediment toxicity testing at the University of Michigan Biological Station.

Regulations or programs that are informed by assessments
Hazardous waste site—If there is a release from a RCRA corrective action site, assessments are used to determine impact and to guide cleanup.

When combustion facilities seek a permit to handle hazardous waste, a risk assessment would be conducted to determine how to set their permit limits. For example, cement kilns require very high temperatures; fuel with hazardous organic waste can be converted to a nonhazardous waste. There might be a situation where they are burning a hazardous waste blender mix for energy value, and the mixture contains metals that do not break down. Risk assessments evaluate routine emissions from the cement kiln in addition to fugitive emissions from valves, transport lines, etc. This is a predictive process, very different from Superfund, in which the contamination already occurs. For example, one thing that is different, because the facility is not yet on line, the assessor can require and use trial burns to estimate rate of release when developing risk projections. The assessors do not duplicate efforts, that is, they use the same release values to estimate risk to ecological resources and to human health. The assessment of combustion facilities in Region 5 is guided by an example workplan for combustion facilities developed by Mazur. However, his responsibilities have shifted, and he is no longer involved in the permitting process for combustion facilities. The workplan has been shared—but not widely.

Polychlorinated biphenyl (PCB) cleanup activities have been directed to RCRA, so that the remediation is parallel to the RCRA corrective action. There are a few regulatory differences with PCBs assessments versus other RCRA activities. Regions 5, 6, and 7 have many RCRA sites. The responsibility for some of these sites has been delegated to the states.

Guidance
Superfund and RCRA are under the auspices of OSWER, and much of guidance developed by Superfund is also applicable to RCRA.

- The 1997 Interim Final Ecological Risk Assessment Guidance for Superfund is the primary source of guidance.

- Eco-updates have been a very practical tool for the people in the regions. These are focused white papers/guidance documents.

- Workplan for combustion facilities.

Condition Assessments
Background assessments of soils are required to determine the condition of the site in the absence of contamination. It also provides a limit for cleanup, because the Agency does not normally cleanup below background.

Causal Assessments
Causal assessments determine the source. Sources are not always sure, because highly industrialized area may have several potential sources of the same contaminant.

Predictive Assessment—Conventional Risk Assessment
Described above.

Predictive Assessment—Benchmark Determination
Described above.

Predictive Assessment—Management Assessment
Not as formalized as in a Superfund assessment. Some might do a cleanup until a benchmark is reached.

Outcome Assessment
Not specifically done. But with ground water plumes, pump and treat operations are monitored. Spot check attainment of progress and benchmark. It would be nice to determine if project management's ecological goals were met after the permit was issued.

Strongest aspect of existing processes
Human health goals are not as relevant, e.g., ground water plume into the river, no fishing, no beaches, no withdrawal for potable water, then the driver is ecological, and the project manager is very engaged, then the ecological issues are truly addressed.

Aspects of the process that could be strengthened
The biggest weakness is in the front end, the planning, and scoping. Program managers do not establish their own ecological project goals. They do not go back and look at the contaminants of concern. They do a broad analysis of contaminants rather than targeting the contaminants of concern. Time is wasted and lots of issues are settled by negotiations. A checklist of questions for planning and scoping could be helpful.

Suggestions for assuring that scientific information informs and improves decision-making
We need guidance, communication tools, and decision tools. It would be nice to share them broadly among regions. Establish guidance on the content of assessments, including a uniform format to make review easier. Give it to industry to use to develop their reports. Some reports are an executive summary; everything is in tables, and work is not shown.

B.2. CLEAN AIR ACT

Vicki Sandiford
Office of Air, Office of Air Quality and Planning Standards

Professional experience or organizational affiliations relevant to environmental assessment
Vicki Sandiford is an environmental scientist with EPA's Office of Air and Radiation (OAR)/Office of Air Quality Planning and Standards. She received her BS in Biology from Davidson College in Davidson, NC and her Masters of Environmental Management with a focus on Resource Ecology from Duke University in Durham, NC. Since beginning with EPA in 1990, she has participated in numerous reviews of the Secondary National Ambient Air Quality Standards (NAAQS), including those for sulfur dioxide (SO_2), nitrogen dioxide (NO_2), Ozone (O_3) and particulate matter (PM). Her primary area of expertise is in O_3 effects on vegetation

and ecosystems. In her position, she regularly oversees and/or participates in exposure/risk, policy, and benefits assessments. She works closely with colleagues in Office of Research and Development (ORD)'s National Center for Environmental Assessment in identifying the most policy-relevant research useful in informing the NAAQS reviews. She develops alternative policy scenarios and briefs upper management on the implications of each. She regularly participates in public meetings, including those of the Clean Air Scientific Advisory Committee (CASAC) and reviews and responds to public and CASAC comments on proposed and final rules.

Regulations or programs that are informed by assessments
The Clean Air Act (CAA), which was last amended in 1990, requires EPA to set NAAQS for wide-spread pollutants from numerous and diverse sources considered harmful to public health and the environment. The CAA requires periodic review (every 5 years) of the science upon which the standards are based and the standards themselves. The NAAQS Program continuously reviews and recommends standards for lead, ozone, carbon monoxide, sulfur dioxide, nitrogen dioxide, and particulate matter.

The CAA established two types of national air quality standards.

- Primary standards set limits to protect public health, including the health of "sensitive" populations such as asthmatics, children, and the elderly.
- Secondary standards set limits to protect public welfare, including protection against visibility impairment, damage to animals, crops, vegetation, and buildings. Economic value is considered. Accessed 20090725. http://www.epa.gov/ttn/naaqs/.

The process of review involves a call for information. NCEA-RTP compiles information into an Integrated Science Assessment (ISA). In recent years, the ISA have been more finely tuned to the needs of OAR as required for policy making. The ISA reports on new information since the last assessment and draws attention to what is important for consideration. The documents are peer reviewed and published in the Federal Register. The CASAC reviews the documents and provides independent advice to the EPA Administrator on the technical bases for EPA's NAAQS. Established in 1977 under the CAA Amendments of 1977 [see 42 U.S.C. § 7409(d)(2)], CASAC also addresses research related to air quality, sources of air pollution, and strategies to attain and maintain air quality standards and to prevent significant deterioration of air quality.

Guidance
Some of the guidance used by OAR is listed below.

Guidelines used by OAR are listed on Technology Transfer Network Fate, Exposure, and Risk Analysis (FERA). http://www.epa.gov/ttn/fera/risk_related.html.

Risk Assessment and Modeling: OAR uses EPA Risk Assessment Policy, Guidelines, and Related Materials.

Policies, Guidance and Frameworks: Cumulative Risk Assessment, Probabilistic Analysis, Risk Characterization.

Guidelines: Cancer Risk Assessment Guidelines, Cancer Risk Assessment Guidelines-Implementation, Chemical Mixtures Risk Assessment Guidelines and Supplementary Guidance, Developmental Risk Assessment Guidelines, Ecological Risk Assessment Guidelines, Neurotoxicity Risk Assessment Guidelines, Reproductive Toxicity Risk Assessment Guidelines.

Methods: Methods for Derivation of RfCs and Application of Inhalation Dosimetry (U.S. EPA, 1994).

Condition Assessments

The condition assessment asks if there are still effects occurring at current standards and if there are exceedances of the existing standard. If direct information is not available, then effects are predicted based on stressor response associations from the literature. (See predictive assessment below.) For example, current ozone levels could be used to predict expected crop loss and foliage injury to trees. This diverse information is interpolated geographically as a national assessment.

Causal Assessments

The cause is predetermined (the six chemicals previously noted); however, confounding effects such as those of climate change may be evaluated and influence the standard so that it is set "with an adequate margin of safety."

Predictive Assessment–Conventional Risk Assessment

Risk and exposure assessments (REAs) are used to evaluate effects when and where they are not measured.

Predictive Assessment–Benchmark Determination

Given the evidence and the REA, a standard is recommended based on 8-hour exposure on average (3-year period) using the 98th percentile for effects. A proposed rule making is published in the Federal Register, often indicating a range. Recommended standards may apply to certain regions (e.g., Adirondack lakes), scenic vistas, and Class 1 areas (e.g., Grand Canyon).

Predictive Assessment—Management Assessment

The purpose of the Economics and Cost Analysis Support site is to make the documents developed by the Air Benefit and Cost Group (ABCG) available in one place. Tools include the databases and models that have been developed by ABCG for cost, benefit, and economic impact analyses. Documents include analytical guidance and reports on conducting analysis of costs, benefits, and economic impacts of air quality management strategies, programs, and regulations (http://www.epa.gov/ttn/ecas/).

Outcome Assessment
As soon as one cycle ends, another begins to evaluate effectiveness of the program.

Other processes to attain EPA's mission
For the primary standard for human welfare, 8 years after the standard is implemented, there are fines or other repercussions, such as loss of highway funds. There is no penalty for failure to meet the secondary standard. Rather, the responsible entities are to achieve the standard as "expeditiously as practicable." This requirement has never been tested in court. It would seem that the statute is weak and has no stimulus for compliance.

Strongest aspect of existing processes
A new innovation is the combined assessment of NO_x and SO_x because the combined deposition is responsible for the effects of acid rain (U.S. EPA, 2008d). Critical loads are back calculated to air levels

Aspects of the process that could be strengthened
Weaknesses lie in the lack of tools and the standards to assess and define the term "adverse." For example, how much loss to biomass in tree roots is a significant threat to trees, which need energy in subsequent years? Also, data and information are dependent on other groups, as in this case, the Forest Service.

The importance of ecological endpoints is undervalued, and standards are set primarily based on public health.

Suggestions for assuring that scientific information informs and improves decision-making
The 1998 ERA guidelines are good for site-specific assessments but less satisfactory for national assessments that have so many assessment endpoints, sources, and geographic variability.

How do we make uncertainties less influential? How do we explain that directionally correct tightening of a standard may still result in a loss of the resource if the protection is not enough?

The Risk Assessment Forum could address how to apply NAAQS (40 CFR part 50).

<u>Other Divisions in OAR involved with assessments</u>

OAR Condition Assessments and Greenhouse Gases
On April 2, 2007, in **Massachusetts v. EPA**, 549 U.S. 497 (2007), the Supreme Court found that greenhouse gases are air pollutants covered by the CAA. The Court held that the Administrator must determine whether or not emissions of greenhouse gases from new motor vehicles cause or contribute to air pollution, which may reasonably be anticipated to endanger public health or welfare, or whether the science is too uncertain to make a reasoned decision. In making these decisions, the Administrator is required to follow the language of Section 202(a) of the CAA. The Supreme Court decision resulted from a petition for rulemaking under Section 202(a) filed by more than a dozen environmental, renewable energy, and other organizations.

The Administrator signed a proposal with two distinct findings regarding greenhouse gases under Section 202(a) of the CAA:

- The Administrator is proposing to find that the current and projected concentrations of the mix of six key greenhouse gases—carbon dioxide (CO_2), methane (CH_4), nitrous oxide (N_2O), hydrofluorocarbons (HFCs), perfluorocarbons, and sulfur hexafluoride—in the atmosphere threaten the public health and welfare of current and future generations. This is referred to as the endangerment finding.

- The Administrator is further proposing to find that the combined emissions of CO_2, CH_4, N_2O, and HFCs from new motor vehicles and motor vehicle engines contribute to the atmospheric concentrations of these key greenhouse gases and, hence, to the threat of climate change. This is referred to as the cause or contribute finding. (See http://www.epa.gov/climatechange/endangerment.html.)

Residual Risk—Risk and Management Assessments
Residual Risk Program for Air Toxics evaluates the residual risk that remains after using best available technology. These assessments are done by sector-based assessment groups. The Risk and Technology Review is a combined effort to evaluate both risk and technology as required by the CAA after the application of maximum achievable control technology (MACT) standards. Section 112(f) of the CAA requires EPA to complete a Report to Congress that includes a discussion of methods the EPA would use to evaluate the risks remaining after the application of MACT standards. These are known as residual risks. EPA published the Residual Risk Report to Congress in March 1999. Section 112(f)(2) directs EPA to conduct risk assessments on each source category subject to MACT standards, and to determine if additional standards are needed to reduce residual risks.

National Air Toxics Assessments—Relative Risk Assessments
The National-Scale Air Toxics Assessment (NATA) is EPA's ongoing comprehensive evaluation of air toxics in the EPA developed the NATA as a state-of-the-science screening tool for state/local/tribal agencies to prioritize pollutants, emission sources, and locations of interest for further study in order to gain a better understanding of risks. The goal is to identify those air toxics which are of greatest potential concern in terms of contribution to population risk. NATA assessments do not incorporate refined information about emission sources, but rather, use general information about sources to develop estimates of risks, which are more likely to overestimate impacts than underestimate them. NATA provides estimates of the risk of cancer and other serious health effects from breathing (inhaling) air toxics in order to inform both national and more localized efforts to identify and prioritize air toxics, emission source types, and locations that are of greatest potential concern in terms of contributing to population risk. This, in turn, helps air pollution experts focus limited analytical resources on areas and or populations where the potential for health risks are highest. Assessments include estimates of cancer and noncancer health effects based on chronic exposure from outdoor sources, including assessments of noncancer health effects for Diesel PM. Assessments provide a snapshot of the outdoor air quality and the risks to human health that would result if air toxic emissions levels remained unchanged (see http://www.epa.gov/ttn/atw/natamain/).

B.3. TOXIC SUBSTANCES CONTROL ACT (TSCA) AND FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT (FIFRA)

Tala Henry, PhD
Office of Chemical Safety and Pollution Prevention, Office of Pollution Prevention and Toxics

Professional experience or organizational affiliations relevant to environmental assessment
Dr. Tala Henry has been with the U.S. Environmental Protection Agency for over 15 years. She is currently located in the Office of Pollution Prevention and Toxics (OPPT) in Washington, DC working on cross-cutting issues related to assessment and management of industrial chemicals. Dr. Henry also represents the United States in international chemical assessment and management activities, such as the Organization for Economic Cooperation and Development's Existing Chemicals Task Force and Quantitative Structure Activity Relationship (QSAR) Management Group and the United Nations Persistent Organic Pollutants Review Committee. Previously, Dr. Henry worked in EPA's Region 8 office where she conducted risk assessments for RCRA and Superfund hazardous waste sites, in the Office of Water where she led the team that develops Ambient Water Quality Criteria, and in the Office of Research and Development where she conducted research on chemical toxicity and endocrine disruption in aquatic organisms.

Regulations or programs that are informed by assessments
Under the TSCA, OPPT regulates new and existing industrial chemicals. TSCA has differing mandates for "existing" chemicals (those already in commerce) and for "new" chemicals (reviewed by EPA before they are produced or imported).

Guidance
New Chemicals
The process for assessing new chemicals under TSCA is described in general terms at http://www.epa.gov/oppt/newchems/ and http://www.epa.gov/oppt/pubs/oppt101-032008.pdf. More specific risk assessment procedures are not collated into a single publicly available guidance document; however, components of the assessments are described in training materials OPPTS provides to chemical manufacturers (i.e., those who submit premanufacture notices [PMNs]) and other interested parties through Sustainable Futures (http://www.epa.gov/oppt/sf/meetings/train.htm#included).

OPPT has developed many different tools and models both to support its own staff analyses in implementing OPPT programs and regulations, as well as to help external users assess and manage chemical risks. Some of these focus on hazard information, estimating the physical or chemical properties of a substance, its environmental fate, or its toxicity. Others focus on estimating the potential for human exposure or assessing risk by examining both hazard and exposure. OPPT's tools and models have extensive guidance and training materials associated with them (see below for more info on models).

Existing Chemicals
Existing chemicals are the approximately 61,000 chemicals "grandfathered in" when TSCA was passed in 1976. For priority-setting purposes, OPPT has focused its data-development and

data-collection efforts on a subset of approximately 15,000 nonpolymeric chemicals reported in the two most recent IUR cycles as being produced in quantities greater than 10,000 pounds per year. Currently, OPPT is focusing on a subset of approximately 3,000 high production volume (HPV) chemicals, which are produced and/or imported in annual volumes of 1 million pounds or more across all U.S. companies.

A number of technical experts (scientists and engineers) review incoming information on chemicals to assess hazard, exposure, and risk. Although each program is different, there are common elements to the review process. For example, for the HPV chemicals, OPPT developed specific guidance (http://www.epa.gov/chemrtk/pubs/general/guidocs.htm) and was instrumental in developing similar guidance for the Organization for Economic Cooperation and Development (OECD) HPV chemical Programme. OPPT currently follows the OECD guidance for assessing hazards of existing chemicals (http://www.oecd.org/document/7/0,3343,en_2649_34379_1947463_1_1_1_1,00.html). In general, OPPT follows established Agency risk assessment guidance, such as that developed by the Risk Assessment Forum, in conducting risk assessments of existing chemicals.

Condition Assessments
Condition assessments are not part of OPPT new chemical assessments. For existing chemicals, TSCA §8 (http://www.epa.gov/oppt/chemtest/pubs/pdflist8.htm) has a variety of data-gathering authorities. For example, under TSCA §8(e), EPA must be notified immediately of new unpublished information on chemicals that reasonably supports a conclusion of substantial risk to human health or the environment. In addition, TSCA §8(c) provides a mechanism to identify previously unknown chemical hazards in that it may reveal patterns of adverse effects that may not be otherwise noticed or detected. Examples of significant adverse reactions include gradual or sudden changes to animal or plant life in a given geographic area; abnormal numbers of deaths/changes in behavior or distribution of organisms; and long lasting or irreversible contamination of the physical environment.

Causal Assessments
See descriptions under Condition Assessments; in some instances, these might include causal assessments.

Predictive Assessment—Conventional Risk Assessment
This is the predominant type of assessment conducted by OPPT.

<u>*New Chemicals*</u>
For new chemicals, manufacturers are required to notify EPA of their intent to bring new chemicals into the U.S. market but are not required to submit data other than that already available, with their initial notification. A risk-based finding is needed to take regulatory action; hence, EPA must make decisions often with limited information. OPPT has an established process and procedures for performing risk assessments for new chemicals. The process is generally described at http://www.epa.gov/oppt/newchems/ and http://www.epa.gov/oppt/pubs/oppt101-032008.pdf. More specific risk assessment procedures are not collated into a single publicly available guidance document; however, components of the assessments are described in training materials OPPTS provides to chemical manufacturers

(i.e., those who submit PMNs) and other interested parties through Sustainable Futures (http://www.epa.gov/oppt/sf/meetings/train.htm#included). The goal of the Sustainable Futures Initiative is to make new chemicals safer and available faster and at lower cost. It works by giving chemical developers the same risk-screening models that EPA uses to evaluate new chemicals before they enter the market. For new chemical risk assessments, OPPT relies on data from the manufacturer regarding the manufacturing process and potential uses, exposure modeling, and variety of approaches, including structure-activity relationships, nearest analog analysis, chemical class analogy, chemical categories, mechanisms of toxicity, and professional judgment, to conduct screening-level risk assessment for industrial chemicals. For the most part, because these are new chemicals with proprietary and confidential business information restrictions, only EPA and the manufacturer have access to the results of these assessments. The results are best viewed as screening level assessments. OPPT conducts screening-level risk assessments for approximately 1,500−2,000 new chemical, premanufacture notices each year.

Brief descriptions of each of the screening-level models and methods developed by OPPT for chemical assessment are provided here. Additional information on these models can be found at http://www.epa.gov/oppt/sf/index.htm. Presentations on these models and methods from EPA Sustainable Futures training sessions can be found at http://www.epa.gov/oppt/sf/meetings/train.htm#included.

EPI Suite™ estimates physical/chemical properties (melting point, water solubility, etc.) and environmental fate properties (breakdown in water or air, etc.), which can indicate where a chemical will go in the environment and how long it will stay there.

ECOSAR predicts toxicity of chemicals released into water to aquatic life (fish, algae, and invertebrates).

PBT Profiler screens chemicals for potential to persist, bioaccumulate, and be toxic.

OncoLogic™ is a computer software program designed to predict the potential cancer-causing effects of a chemical by applying the rules of structure activity relationship (SAR) analysis and incorporating knowledge of how chemicals cause cancer in animals and humans.

NonCancer Screening Protocol is a stepwise process (not a computerized method) useful for screening untested chemicals for noncancer health effects and is described in the P2 Framework Manual.

E-FAST estimates chemical releases and dose rates to humans from these releases.

ChemSTEER estimates environmental releases and worker exposures resulting from chemical manufacture, processing, and/or use in industrial and commercial workplaces.

Analog Identification Methodology (AIM) is currently being developed to address needs identified by participants in the Sustainable Futures Initiative. AIM is expected to be released to the public by the end of 2009. For chemicals lacking data, identifying a close analog with measured data is the most challenging step in using screening models and QSAR methods that predict the toxicity of chemicals based on their structural similarity to chemicals for which toxicity data are available. AIM is being developed to identify close analogs that have measured data, and it points to sources where those data can be found.

Existing Chemicals

A number of technical experts (scientists and engineers) review incoming information on chemicals to assess hazard, exposure, and risk. Although each program is different, there are common elements to the review process. In general, OPPT follows established Agency risk assessment guidance, such as that developed by the Risk Assessment Forum, in conducting risk assessments of existing chemicals.

Predictive Assessment—Benchmark Determination

OPPT applies a number of policies, many based on specific benchmarks (e.g., levels of exposure, PBT properties, etc.) to require testing and/or limit production or use of chemicals (http://www.epa.gov/oppt/newchems/pubs/policies.htm). For example, the PBT policy sets forth specific criteria for persistence, bioaccumulation, and toxicity, which if met, will result in specific orders or banning of the chemical pending further testing.

Predictive Assessment—Management Assessment

TSCA Section 6 (for existing chemicals) requires cost-benefit analysis as part of the assessment for proposed regulatory action.

Outcome Assessment

Provisions of TSCA Section 8 (described above and available at http://www.epa.gov/oppt/chemtest/pubs/pdflist8.htm) can serve as 'early warning' system as well as indicate adverse effects/outcomes resulting from chemical use.

Strongest aspect of existing processes

The limited availability of data is both a strength and a weakness. Because the data are limited, OPPT has been innovative in developing predictive analytical approaches including SARs, nearest analog analysis, chemical class analogy, chemical categories, mechanisms of toxicity, and professional judgment, and has built these approaches into computer-based models and expert systems. The data limitations have encouraged the development and implementation of intelligent testing. This has also been necessary because the Office must deal with many chemicals.

Aspects of the process that could be strengthened

Having few data increases the uncertainty of the assessment. OPPT models do not cover all relevant toxicological endpoints; in particular, increased availability of predictive tools for assessing health effects is needed. OPPT models also do not cover all types of chemicals. Additional development of predictive models for additional chemical classes is needed.

Suggestions for assuring that scientific information informs and improves decision-making
New chemicals assessment procedures could be published as an integrated document.

Problem formulation could be more explicit.

Greater accessibility or authority to require data would help inform decisions.

William Eckel
Office of Chemical Safety and Pollution Prevention

Professional experience or organizational affiliations relevant to environmental assessment
Dr. Eckel is Senior Science Advisor in Environmental Risk Branch 6, Environmental Fate and Effects Division, Office of Pesticide Programs, where he is involved in ecological risk assessment for threatened and endangered species. Previously, he was in ERB 2 for 10 years, culminating in a 5-month tenure as acting Branch Chief. His PhD in Environmental Science/Public Policy is from George Mason University. His dissertation focused on the 20th century secondary lead smelting industry in the United States. Eckel published one of the earliest (1993) papers on pharmaceuticals in groundwater. Currently, he is working on developing a process for consultation under Section 7 of the Endangered Species Act within the Pesticide Registration Review program.

Regulations or programs that are informed by assessments
Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Endangered Species Act (ESA)—The assessments must predict effects on specific species such as the California red legged frog. So, the question is, does the pesticide pose a risk to these organisms?

Guidance
Guidance is available, and some is publically available. The overall approach is in an overview document, published in 2004. The Office of Pesticide Programs (OPP) uses the same language as the ERA framework. Internal guidance is available for problem formulation and formats are available for different types of risk assessment such as species-specific assessments.

Condition Assessments
Registration review (15-year cycle) each active ingredient and registered use. An example is carbofuran, which went to a series of scientific panel meetings. The registration was cancelled, and the company did not agree. The assessment went from an observed effect to the cause.

Cause
Some observed effects have unknown causes that may include pesticides: colony collapse disorder, intersex, and malformations.

Predictive
These are typical risk assessments that start with the information industry submits. Toxicity test information is supplied for invertebrates, birds, mammals, fish, and vascular and nonvascular plants. Exposure is estimated for different media. They are combined to get a risk quotient,

which is compared to predefined levels of concern, which are different for endangered and nonlisted species. Risk characterization synthesizes it all. A biological and economic analysis division considers benefits when asked. This is not routine.

Outcome assessment

The reregistration program looks at all registered active ingredients on a 15-year basis. Make sure registrations are in keeping with current science and policy.

Sometimes OPP asks for monitoring. Mitigation measures should keep the adverse effects down to reasonable levels.

Improvements

There is a recognized need for improved incident reporting. For example, there were lots of incidents of bird kills associated with carbofuran, but reporting requirements changed. Was it the reporting change or a real change? Outcome assessment would be important for risk mitigation.

What is the strongest aspect of the assessment processes your organization already has in place to inform decision-making?

We are able to require submission of data, so we do not need to estimate toxicity. We have a well laid out procedure and continue improvement of the ERA process. We do all of the work ourselves, not contractors, except for review. Therefore, expertise and knowledge are retained in the government.

What is the weakest link in these processes?

We need to continue improving our ability to make the risk assessment more realistic. There is not enough time to do this and meet requirements to do the risk assessment.

Kristen Keteles, PhD

Region 8

Professional experience or organizational affiliations relevant to environmental assessment

Dr. Kristen Keteles was coordinator of the Coastal Watershed Condition Assessment program for the National Park Service and prior to working for NPS, a professor with the University of Central Arkansas where she maintained a research program investigating environmental factors that influence trace metal availability. She joined EPA Region 8 in 2008.

Keteles has a PhD from Louisiana State University, and her doctoral research examined the fate and effect of metals and polycyclic aromatic hydrocarbons in a Louisiana Salt Marsh. She did a postdoctoral fellowship as a visiting scientist at the Federal Bureau of Investigation (FBI) academy in Quantico Virginia in the Counter Terrorism and Forensic Science Research Unit. Prior to earning a doctorate, she was a research associate at Dartmouth College in the Superfund Basic Research Program investigating the fate of metals in aquatic food webs.

At EPA, Keteles primarily provides technical support regarding TSCA and FIFRA, particularly effects of pesticides and toxics, and manages the R8 Pesticides Water Quality Program. She is also presently involved in studies regarding PCBs, mercury, and pharmaceuticals and personal care products (PPCPs). She is sponsoring a graduate student at Colorado State University to study the effects of endocrine-active chemicals on fish reproduction and to develop a whole effluent toxicity-based approach to assess estrogenicity and androgenicity of effluents. Recently, Keteles has provided technical assistance as a subject matter expert during the Deepwater Horizon Oil Spill to the NRDA trustees and has been deployed to the Gulf on oceanographic cruises to collect data on the oil spill.

Regulations or programs that are informed by assessments
TSCA, FIFRA.

Guidance
There are many pesticides for which there are no criteria or benchmarks. The FIFRA process does not take into account the latest science policy, scientific knowledge, or regulatory implications across programs. Emergent contaminants of concern lag even further behind. When criteria are developed, the EPA's Ecological Risk Assessment framework is used.

Condition Assessments
Some states have hired consultants to evaluate PCB contamination using sediment concentrations, fish tissue levels, and toxic equivalents. These feed into predictive assessments that set remediation targets for cleanup, and they also continue monitoring to determine effectiveness.

Sometimes there are discrepancies on how to handle a problem. For example, the authorities of TSCA and RCRA sometimes overlap, which creates a need for better cooperation.

The National Park Service initiated an Ecological Condition Assessment program in 2003. The assessment involved 280 parks with different ecoregions as diverse as Alaska and the Virgin Islands. They developed an indicator-based framework that focused on shared issues such as physical disturbance, invasive species, and contaminants.

Causal Assessments
The *Stressor Identification Guidance* is used as the framework for assessing causes of biological impairment. There are also some regional guidelines for some effects, sources, wastewater treatment plant (WWTP), and confined animal feeding operations (CAFOs). For example, the week of July 27, fish will be caged above and below CAFOs and WWTPs in a joint study with National Exposure Research Laboratory-Cincinnati, and fish will be assayed for vitellogenin. The hope is that this will lead to strategies for minimizing exposure to and effects of estrogenic compounds.

In another study, intersex in fish has been reported in Rocky Mountain high country lakes. The source of the estrogens is unknown. Pregnant elk, atmospheric deposition, natural effects, and phytoestrogens are considered candidate causes. This proposed work will be submitted to the Regional Applied Research Effort program to develop a conceptual model of this effect and candidate causes.

Causal assessments are routinely undertaken (e.g., presently using stressor identification (ID) process to evaluate cause of intersex fish in a pristine environment). They use the stressor ID document and are working to develop regulatory guidelines for evaluating sources.

Predictive Assessment—Conventional Risk Assessment
Dr. Keteles provided an example of an oil spill in San Francisco Bay in which the concentration in the sediment and water were used to evaluate cumulative risk to biota calculated from toxic equivalents rather than benchmarks. She noted that the EPA and Coast Guard cooperated in developing an oil spill response plan so that differential risks to different resources would be estimated for the mixture. For example, how would a spill differentially affect coral reefs and mangroves?

Guidance for cumulative risks for ecological assessment endpoints would be a valuable tool.

Predictive Assessment—Benchmark Determination
Most of the work that the Region does involves comparing concentrations to existing benchmarks rather than developing them.

Predictive Assessment—Management Assessment
Management assessments would be very useful for evaluating risks and economic costs because reverse osmosis and activated charcoal filtration is expensive for removing PPCP from a waste stream. For example, tire crumbs (ground-up tires) are used for children's play grounds and are being marketed as cover for sides of highways. They contain high amounts of zinc, which is toxic to aquatic life. PAH toxicity is not well known.

Outcome Assessment
Pesticides of interest to states have been monitored and detected in surface and ground water. States have proposed management plans to meet environmental objectives.

Other processes to attain EPA's mission
The jurisdictions of TSCA and RCRA need to be clarified.

Our processes should be compared with Canada's and the Park Service's to get ideas and increase consistency.

Improve communication by providing a list of who is doing what in congruent offices in Regions because now they all have different nomenclature and structure, and it is hard to find other experts.

Suggestions for assuring that scientific information informs and improves decision-making
Guidance for cumulative effects in ecological situations that stress mode of action and appropriate frameworks would be helpful.

EPA Web sites need to be improved so that it will be easier to access and search for information.

Benchmarks are needed for pesticides and PPCP.

Decision tools need to bridge the perceived disconnect between human health and ecosystem health.

We need to take national surveys to the next level including conceptual models that show relationships among groups and among sources, stressors, and effects.

Patti TenBrook, PhD
Region 9, CED-5

Professional experience or organizational affiliations relevant to environmental assessment
Dr. TenBrook has been a life scientist with EPA Region 9 since 2007. She also has 12 years of experience with water and wastewater treatment and environmental laboratory work. She has published several papers on fate, effects, and biotransformation of pesticides in aquatic systems. Prior to joining EPA, she worked on a project for the State of California to develop a method for derivation of water quality criteria with limited data sets. Dr. TenBrook does not perform risk assessments, but she does review OPP assessments with an eye to their adequacy in addressing potential risks to surface and groundwater quality and whether registered pesticide uses might lead to noncompliance with the CWA.

Regulations or programs that are informed by assessments
FIFRA and the CWA both require protection of water resources. Currently, effects characterizations done by the OPP and the Office of Water (OW) are not integrated to provide a common basis for achieving the water quality protection goals established under the CWA and FIFRA statutes. The Agency has begun a process to harmonize effects assessments to meet the goals of both statutes. In addition, OPP exposure assessments often do not adequately consider direct or indirect pathways to surface water, particularly from indoor and outdoor urban uses. This has led to CWA compliance challenges for stormwater and municipal wastewater treatment agencies. CWA agencies cannot regulate pesticides but are responsible for water quality impairments or National Pollutant Discharge Elimination System compliance due to pesticides. One approach to address this disconnect would be for CWA compliance to be an assessment endpoint for FIFRA risk assessments.

Guidance
Most evaluations of the assessments are performed using best professional judgment rather than guidance.

Condition Assessments
Although not in her purview, she noted that condition assessments are used in Region 9 as part of the CWA, Superfund, and National Environmental Policy Act reviews.

Causal Assessments
Once a waterbody is identified as impaired due to a pesticide, state, and federal (i.e., EPA Region 9 Water Division) CWA agencies must develop a TMDL for the specific pesticide for that waterbody. The TMDL requires a source evaluation, which can only be accomplished with a thorough understanding of environmental fate pathways. Many FIFRA risk assessments do not

adequately consider pathways by which pesticides may reach surface water. This is particularly true for urban pesticide use, which can lead to pesticides reaching municipal stormwater, wastewater collection, and treatment systems, and, ultimately, surface waters.

Example: Risk assessments for pyrethroid pesticides typically disregard the importance of potential water column contamination. This is based on the hydrophobicity of pyrethroids and on their high solid/water partition coefficients. The assumption is made that pyrethroids will partition into solids in the environment (or in a wastewater treatment plant) and will not be found at levels of concern in the water column. Pyrethroids are highly toxic to fish and extremely toxic to aquatic invertebrates. Thus, very low concentrations in water can cause toxicity. In a recent study of sources of pyrethroids to the Sacramento River Delta, a University of California, Berkeley researcher found widespread water column toxicity due to pyrethroids downstream of urban areas, with the largest source of pyrethroids being a municipal wastewater treatment plant (WWTP). The study was based entirely on water column sampling. The sources, pathways, and effects found in this study would never have been predicted by the FIFRA risk assessment.

Predictive Assessment—Conventional Risk Assessment
Risk assessment is a key part of OPP's mission in which the consequences of pesticide use are estimated. The process described on the OPP Web site directly uses the EPA Guidelines for Ecological Risk Assessment (see Table B-1). The ecotoxicological methods used by OPP (see Table B-2) differ from the CWA methods for developing safe levels. CWA criteria use more points (8) to develop their water quality criteria. OPP uses benchmarks based on the most sensitive species data available; OPP assesses potential hazards to aquatic life based on as few as three pieces of data. However, inherent in the RA done in conjunction with the registration process, OPP describes mitigation such as rate of use, application methods, and buffers. The result of the process is to reject or register the pesticide with prescriptive label requirements. With new chemicals, there is no public participation because of proprietary or confidential business information. Although not all information falls into this category, there is no practice for releasing information that is not confidential. Because only the manufacturer has information on the proposed pesticide, all information used in the assessment comes from the registrant and not from the literature. Some exposure pathways, particularly in urban scenarios, are often not adequately addressed, or are overlooked entirely.

Table B-1. An outline of the ERA process as implemented by OPP (http://www.epa.gov/oppefed1/ecorisk_ders/)

Problem Formulation
Analysis—Ecological Effects Characterization Studies Needed Ecotoxicity Data Use/DER Templates Ecotoxicity Categories
Analysis—Exposure Characterization Pesticide Degradation/Dissipation Fate and Transport Studies Needed Fate and Transport Data Use/DER Templates Approaches for Evaluating Exposure
Risk Characterization Deterministic Approach Probabilistic Approach

Table B-2. Criteria for ecotoxicological risk used by OPP [a, b] (http://www.epa.gov/oppefed1/ecorisk_ders/)

	Presumption of minimal risk	Presumption of unacceptable risk	
		Nonendangered species	Endangered species
Acute toxicity			
Mammals	EEC < 1/5 of LC_{50}	EEC ≥ 1/2 of LC_{50}	EEC > 1/10 of LC_{50}
	EEC < 1/5 of LD_{50}	EEC > 1/2 of LD_{50}	EEC > 1/10 of LD_{50}
Birds	EEC <1/5 of LC_{50}	EEC ≥ 1/2 of LC_{50}	EEC > 1/10 of LC_{50}
Aquatic organisms	EEC < 1/10 of LC_{50}	EEC ≥ 1/2 of LC_{50}	EEC > 1/20 of LC_{50}
Chronic Toxicity			
	EEC < lowest effect level	EEC ≥ lowest effect level	EEC ≥ lowest effect level

[a] Another criterion for birds and mammals specific to granular products is whether the amount of exposed granules per square foot of soil surface exceeds 1/2 of the LD_{50} for nonendangered species or is greater than 1/10 of the LD_{50} for endangered species.

[b] EEC= Expected Environmental Concentration
LC_{50} = Median Lethal Concentration

Predictive Assessment—Benchmark Determination
OPP uses aquatic life benchmarks to determine whether estimated exposures will pose a risk to aquatic life. See the OPP Web site (http://www.epa.gov/oppefed1/ecorisk_ders/aquatic_life_benchmark.htm).

Predictive Assessment—Management Assessment
FIFRA is a risk/benefit statute. That is, if there is significant benefit in the use of a pesticide, that benefit has to be weighed against identified risks. The risk/benefit assessment typically considers crop or other property losses that might occur if the pesticide were not available. Costs of CWA compliance are not considered. Agencies that are responsible for CWA compliance have no control over pesticide use.

The cost of compliance (with statutes other than FIFRA) is never included with the cost-benefit analysis during registration. Cost analysis is only in terms of crop or property damage. The cost of noncompliance should be factored into the cost-benefit analysis.

Outcome Assessment
No outcome assessment is required for as long as 15 years after registration. Earlier outcome assessment can be requested. Adverse outcomes are often detected by parties that had no opportunity to participate in the registration process (e.g., drinking water/stormwater/wastewater agencies, health agencies, and farmworker advocates). Once a pesticide is registered, it is very difficult to eliminate uses that are subsequently found to be causing or contributing to water quality or other problems. Adding a feedback step (e.g., registrant-required monitoring) within the first 5 years of registration would improve the pesticide RA process.

Aspects of the process that could be strengthened
OPP can ask for a lot of data, but the process for new chemicals is not open. An open process would allow for refinement of the amount and kinds of data that would give the best predictive assessment. Information on new chemicals is not in the open literature and not widely available. There does not seem to be movement toward testing the boundaries of what can and cannot be shared during registration of new chemicals. Currently, OPP cannot share registration data for new chemicals with Regions, which means OPP has to make decisions without Regional perspectives.

There is no public or 3rd party review of the registration process for new chemicals. Even with pesticide re-evaluation, the public processes are not equally accessible to all stakeholders. Proactive outreach is needed to ensure equal participation for those who cannot afford to maintain a presence in Washington, DC.

Cost analysis considers only crop and property damage. It does not consider socioeconomic costs or environmental justice issues or costs incurred to comply with statutes other than FIFRA.

Historically, there has been poor coordination between OPP and OW. OPP can approve a pesticide, which may lead to water quality impairments. OW winds up addressing problems caused by an activity another office has approved. Recent effort to harmonize risk assessments between OPP and OW is a huge step in the right direction.

Suggestions for assuring that scientific information informs and improves decision-making
More transparency—especially for registration of new chemicals—is needed for there to be more accountability.

OPP and OW need to be harmonized with respect to assessment endpoints and analysis for determining, with reasonable assurance, pesticide levels that will not cause harm. There needs to be a way to evaluate if implementation of one statute may cause problems under another statute.

The SOP on submittal of water quality data is likely not achieving what it should. OPP and OW need to explore the extent to which they can share data, and then OPP needs to actively seek data pertaining to pesticides that come up for registration review. For example, state water agencies that have already submitted reports to OW cannot justify expending resources to send that same data to OPP. If they have "sent it to EPA," that ought to be enough.

Allow the guidance to change on a shorter time frame than 10 years.

B.4. CLEAN WATER ACT

Matt Nicholson, PhD
Region 3

Professional experience or organizational affiliations relevant to environmental assessment
Dr. Nicholson's background and training are in natural resource management, and much of his research has been in the field of wildlife conservation. He has research experience with the conservation of avian and mammalian species nationally and internationally. The breadth of conservation challenges he has been involved with ranges from modeling human risk to Lyme disease through quantifying the effects of landscape heterogeneity on the spatial distribution of environmental risks at large scales. A common element of Dr. Nicholson's work over the past 25 years has involved applying the tools of landscape ecology and spatial analysis to questions of environmental health and risk. He has organized several symposia on landscape ecology and risk, has served as guest editor for two journals, and was a panelist for special projects involving the CDC and the Heinz Center.

Regulations or programs that are informed by assessments
Work at Region 3 on CERCLA is linked to the CWA through work on impervious surface, and overall sustainability associated with state conservation plans called "Green Infrastructure" (see Box B-4). The primary objective of his research has been to develop statistical models for predicting the condition of aquatic

Box B-4. Green infrastructure and green communities: linking landscapes and communities.
Green infrastructure can be defined in many ways. In its broadest application, green infrastructure encompasses an "interconnected network of natural areas and other open spaces that conserves natural ecosystem values and functions, sustains clean air and water, and provides a wide array of benefits to people and wildlife."
Green infrastructure is a strategic conservation tool that can be integrated into a comprehensive, Green Communities planning process. In fact, Green Infrastructure planning is compatible with a five-step planning approach as described below. Key to the success of a Green Infrastructure Strategy is broad stakeholder involvement. As with any sustainable planning effort, getting knowledgeable and interested parties involved at the beginning will ensure a successful process. See http://www.epa.gov/greenkit/green_infrastructure.htm [accessed 07/25/2009]).

resources by merging probabilistic survey data with broadly available geographic data to estimate regional stressor patterns.

Dr. Nicholson has also used watershed characteristics as indicators and predictors of aquatic condition in relation to the coordination of state conservation plans and Superfund activities. Although there are statewide conservation plans that attempt to manage resources from a landscape perspective, sometimes other programs are unaware of the plans. For example, key landscape features or parcels of land may be critical habitat required by wildlife and birds. Superfund site managers may be unaware of the conflicting objectives for site cleanup as they relate to habitat preservation. Now, state level plans are readily available to the RCRA or CERCLA site manager, and there are guidance and educational materials to show how to relate a waste site to the larger environment.

Guidance
Dr. Nicholson uses Quality Assurance Project Plan guidance. However, there is no guidance specifically for landscape-level assessment.

Predictive Assessment—Management Assessment
Multicriteria, Integrated Resource Assessment (MIRA) is similar to multicriteria decision analysis and is being used to allocate resources and prioritize efforts such as in abandoned mine lands. Region 3 is working with Doug Norton (also Cynthia Stahl, Christine Mazzarella). Accessed 20090725. (See http://www.epa.gov/reg3esd1/data/pdf/transdisciplinary.pdf.)

Strongest aspect of existing processes
One strength is that the regional scientists are out with the affected parties and involving them in decision-making, including RPMs, the public, and state personnel.

Aspects of the process that could be strengthened
It is difficult to know how to deal with uncertainty without impeding progress.

Suggestions for assuring that scientific information informs and improves decision-making
There is a need for guidance on ecological systems risk rather than risks to species. This might include functions, species dependence, and movement of stressor through ecosystems. This could begin with development of conceptual models and then improving basic scientific understanding through testing resulting in guidance to inform decision-making using that information.

Charles Delos
Office of Water, Office of Science and Technology,
Health and Ecological Criteria Division

Professional experience or organizational affiliations relevant to environmental assessment
Charles Delos has many years of experience developing water quality criteria. Most recently he was instrumental in the reassessment of the ammonia criteria and selenium criteria.

Regulations or programs that are informed by assessments
Criteria development is aimed mainly at NPDES permit development

Guidance
There is little guidance for obtaining data but lots of guidance for developing criteria and for developing permit limits based on criteria.

Condition Assessments
The Clean Water Act requires reporting of chemical, physical, and biological impairments to Congress in the form of 305b and 303d reports. Condition assessments are necessary and usually performed by states. The actual report to Congress is assembled and submitted by EPA. Water quality condition is often used as a surrogate for biological condition.

Causal Assessments
The Total Maximum Daily Load Rule requires that the cause be identified and the amount of loading be allocated among sources. This regulation is administered by Office of Wetlands, Oceans and Watersheds and the Regional Offices with the actual assessments performed by the states.

Predictive Assessment—Conventional Risk Assessment
There are not many types of general guidance left that are needed. This activity does not fit readily into a regulatory framework.

There is little general guidance that pulls things together, that is, links environmental concentration to ecological effect. The main problem is not lack of guidance but lack of basic understanding.

Predictive Assessment—Benchmark Determination
Developing criteria is the primary job of the interviewee. The guidance on setting benchmark concentrations (e.g., water quality criteria) is rather dated (mid-1980s) but still viewed as serviceable. Technical staff has long had an interest in developing a more rigorous and complex approach, while management might prefer a simpler, less data-intensive approach. Although efforts toward a complete revision of the general methodology have been suspended, new methods are developed and applied as the need arises.

Predictive Assessment—Management Assessment
His office is precluded from doing this sort of assessment. The Use Attainability Analyses (UAA) process is the closest thing to this because it considers and economic factors and social preferences.

Outcome Assessment
This is only done with respect to concentration. In a permit context, there is very close monitoring of concentration but no assessment regarding ecological effects—except in Ohio. Generally, once the decision is made, move to the next problem.

Other processes to attain EPA's mission
Outcome assessments would be very desirable because there is so much uncertainty regarding cause and effect with respect to criterion concentrations and biological response.

Strongest aspect of existing processes
The process has clear objectives (chemical criteria) and attainment of concentration goals. However, we must balance simplification against the risk of being incorrect and not protective.

Aspects of the process that could be strengthened
Biocriteria are poorly integrated because of uncertainty regarding cause and effect.

Suggestions for assuring that scientific information informs and improves decision-making
We need basic knowledge about ecology and the causal relationships between stressors and biological effects.

Dana Thomas, PhD
Office of Water, Ecological and Health Protection Branch,

Professional experience or organizational affiliations relevant to environmental assessment
Dr. Thomas has worked primarily on endangered species, biosolids, nutrient criteria, and biocriteria. He is now Branch Chief for Ecological and Health Protection Branch, but had more experience with Endangered Species Act Section 7(a)(2) consultations in the Office of Water. She approached the interview from a OW ESA perspective.

Regulations or programs that are informed by assessments
Section 304(a)(1) of the CWA requires the Environmental Protection Agency (EPA) to develop, publish, and, from time to time, revise criteria for water that accurately reflect the latest scientific knowledge.

The Endangered Species Act, Section 7, requires that all federal agencies that authorize, fund, or carry out any action that could affect a federally listed threatened or endangered species (T&E species) must consult with U.S. Fish and Wildlife or NOAA (the Services) to ensure that the action is not likely to jeopardize the continued existence of any such species or destroy or adversely modify its habitat.

Aquatic Life Criteria must be protective of T&E species, and criteria may need to be customized based on modeling of ecological risk and toxicity to those species.

Guidance
Endangered Species Act

Condition Assessments
Listing a species is a condition assessment. Removing a species from the T&E list is also the result of a condition assessment.

Causal Assessments
Causal assessments may be done when the cause is unknown, such as the case with *Acroporid* corals. However, this assessment is done by NOAA.

Predictive Assessment—Conventional Risk Assessment
These types of assessments are part of the organization's mission. They evaluate water quality criteria (WQC) with respect to endangered species. There is no assessment to compare with standards; rather they perform a theoretical assessment to evaluate whether existing criteria protect endangered species [per Section 304(a)]. Results of this "Biological Evaluation" are given to the Services as a finding of "likely to adversely affect" or "not likely to adversely affect." The Services review EPA's finding and issues a "jeopardy" or "no jeopardy" opinion, which may result in a change or no change in a national or state criterion.

Predictive Assessment—Benchmark Determination
If the Services determine that a WQC is not protective, then the criterion can be reevaluated. For example, endangered unionid mussels were found to be more sensitive to ammonia than the species used to develop the current criteria. A revised criterion for ammonia was developed by EPA and sent to the Services for comment in 2009.

Predictive Assessment—Management Assessment
Inclusion of costs is precluded by law.

Outcome Assessment
There is a clause in the statute that consultations can be revisited if new data suggest that the current criteria may not be protective or if a new species is added to the T&E list.

Other processes to attain EPA's mission
In an attempt to develop a framework that was more transparent, the EPA met with the Services to improve the process. Now the consultation between the EPA and Services is national in scope rather conducted state by state. Although, the process is in place, it has not yet been exercised. EPA also tried to establish what information was necessary to make a biological evaluation, but the Services do not have a process and probably use a different method each time. EPA hopes to take results from experience and back-engineer what information the Services need to perform the risk assessment.

Strongest aspect of existing processes
Available data are very extensive. There is an awareness of what the 1985 guidelines for WQC say regarding what can be screened out, and applicable and not.

Pathways of exposure are fairly well developed and include diet, water, and sediment that are considered with respect to life stages.

Aspects of the process that could be strengthened
There are many data gaps for many T&E species.

The process is too slow; the statute says 90 days, but the last submission was March of 2007 and no biological opinion from the Services yet.

Suggestions for assuring that scientific information informs and improves decision-making
Rather than developing criteria chemical by chemical for every T&E species, it may be more realistic to group by family (for the biological endpoint) or by a mode of action (for chemicals).

B.5. REPORT ON THE ENVIRONMENT

Denice Shaw, PhD
ORD, National Center for Environmental Assessment

Professional experience or organizational affiliations relevant to environmental assessment
Dr. Shaw is a scientist with the National Center for Environmental Assessment responsible for the Report on the Environment (ROE).

Regulations or programs that are informed by assessments
Since the ROE is developed at the discretion of the Administrator, the intent is that the questions and the information should inform a vision for the Agency and the direction for action. However, it is unclear if the ROE has influenced or resulted in changes in regulations, execution of regulations, or programs. However, this is a real need, and refinements to the process for developing the questions and the form of the ROE could make the ROE more influential and useful. For example, the efforts of the ROE could be directed to major issues, such as a national energy policy with directed questions that would lead to the development of assessments within the Agency and later toward the evaluation of the outcomes of effectiveness of those strategies.

The target audience of the ROE is diffuse and diverse. (Note that Australia has a State of the Environment Report that is more assessment in nature.) The ROE is more fact and less assessment-oriented to ensure that the information is scientifically rigorous and that it will not be delayed due to interpretive uncertainties).

Guidance
There is no guidance for the selection and development of the questions that are addressed by the ROE. There is no guidance for the processes for selecting indicators or evaluating those indicators. The ROE has continued to be improved by consultations with the Science Advisory Board (SAB) and from reviewer comments.

Condition Assessments
When there are established benchmarks or standards, the ROE does indicate if those benchmarks are being met. However, often there are no consistent benchmarks, or the set of questions that the ROE addresses has little or no direct influence on decision-making. For example, the Threatened and Endangered Species Act, involves all agencies, but the determination is by the Services, NOAA, and FWS. It is not the mission of the EPA to document the condition of T&E species, but sometimes, these types of questions are inserted into the list to be included in the ROE. However, it could be relevant if the question was more directed such as, “how well are granivorous birds, including T&E species, protected by OPPT regulations”?

Causal Assessments
Levels of stressors and trends are reported but not whether they are causing harm or the causes of harm.

Predictive Assessment—Conventional Risk Assessment
SAB has called for assessment rather than a characterization of the environment, but the ROE authors believe that this would dilute the effort and that the ROE would serve better as a potential starting point for assessments. For example, the ROE includes human health area data on asthma and data on particulate matter. However, the two data streams are not interpreted or synthesized in an assessment.

Outcome Assessment
The ROE was initiated by Administrator Whitman. She wanted the report to help evaluate how her tenure had influenced environmental outcomes.

Other processes to attain EPA's mission
Within the next 3 months, the questions that will be addressed by the ROE will be selected. The ROE is framed by a set of questions that are of critical importance to EPA. As work begins on the development of the 2012 report, the ROE developers are seeking input review and suggestions for revising the framework questions for relevance and significance.

Aspects of the process that could be strengthened
The scientific content and application is spotless.

Peer review was extensive.

There was extensive involvement of many components of the Agency. NCEA facilitated, but the leads were usually from the program offices and regions.

The team also repeatedly attempted to connect policy by working with Office of the Chief Financial Officer (OCFO) and Office of Policy, Economics, and Innovation, but this was not as successful as was hoped for.

Suggestions for assuring that scientific information informs and improves decision-making
It would be helpful to have a single document describing the roles of different agencies.

It would be helpful if there were a framework or guidance for developing environmental policy and environmental vision for the Agency.

It would also be helpful to have guidance for determining emerging issues and for identifying questions that need to be answered as a concerted effort of an Agency rather than separate activities.

It would be helpful if the Agency had a vision that informs policy development for the longer term. That seems to be lacking and restricted to a 3-year window. Need a longer-term policy vision.

Canada has issued their yearly report that focuses on particular laws and how well the government is addressing the intent of those legislative pieces. See pdf at http://www.oag-bvg.gc.ca/internet/docs/parl_cesd_200905_00_e.pdf (accessed July 22, 2009).

As the ROE has changed since its inception, the original question format was based on the Hines report. Later it was based on recommendations from the EPEC to include ecological attributes rather than entities, such as forests. The authors of the ROE believe the next evolutionary step would be to develop issues that are depicted in a conceptual model that focuses efforts not only for the Report but for the direction of the Agency to answer or address the identified problems.

We need to open up the OCFO process for problem identification and, ultimately, program and project direction.

The Agency's position needs to be known as a corporate position so that its credibility remains polished, and other agencies can better coordinate with us.

B.6. REFERENCES

U.S. EPA (Environmental Protection Agency). (1994) Methods for derivation of inhalation reference concentrations and application of inhalation dosimetry. Office of Research and Development, Office of Health and Environmental Assessment, Environmental Criteria and Assessment Office, Washington, DC; EPA/600/8-90/066F. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=71993.

U.S. EPA (Environmental Protection Agency). (1997) Ecological risk assessment guidance for superfund: process for designing and conducting ecological risk assessments - interim final, Office of Solid Waste and Emergency Response, Washington, DC; EPA/540/R-97/006 http://www.epa.gov/oswer/riskassessment/ecorisk/ecorisk.htm.

U.S. EPA (Environmental Protection Agency). (2005) Contaminated sediment remediation guidance for hazardous waste sites. Office of Solid Waste and Emergency Response. Washington, DC; EPA/540/R-05/012. Available online at http://www.epa.gov/superfund/health/conmedia/sediment/pdfs/guidance.pdf.

U.S. EPA (Environmental Protection Agency). (2006) EPA Superfund record of decision: Hiteman Leather EPA ID: NYD981560915 OU 01 West Winfield, NY, 09/28/2006. EPA/ROD/R2006020001430. Available online at http://www.epa.gov/superfund/sites/rods/fulltext/r2006020001430.pdf.

APPENDIX C
TABLE OF GUIDANCE

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Agency-Wide Guidance for Human and Ecological Assessment																																							
Guidance on Cumulative Risk Assessment Part 1 – Planning and Scoping	x	x			x	x	x	x	x	x	x		-	-				x	x									x	x						x	-	-	-	
Framework for Cumulative Risk Assessment	x	x			x	x	x	x	x	x	x		-	-				x	x									x	x						x	-	-	-	
A Summary of General Assessment Factors for Evaluating the Quality of Scientific and Technical Information	x	x										x							x																				

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Risk Characterization Handbook	x	x									x				-		-		x								-	x	x						x	-	-	-	-
Guidance for Risk Characterization	x																																						
Probabilistic Analysis in Risk Assessment	x	x			-	-	-	x	x	x	x			-	-		x						x					x	x						x	-	-	x	-
Guidelines for Ecological Risk Assessment	x	x		x	x	x	x	x	x	x	x		-	-	-		-		x									x	x						x	-	-	-	-
Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment	x	x			x	x	-							-	-				x								x	x		x	x				x	-	-	-	-
Stressor Identification Guidance Document	x	x			x	x	x	x					x				x	x	x								x	x	x	x	x				x	x			

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Framework for Application of the Toxicity Equivalence Factors (TEF) Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment	x	x	-			-	-	x	x	-	-	x					x	-	x									x	x			x				-	-	-	-
Framework for Metals Risk Assessment	x	x					-	x	x	-			-		-				x									x	x			x				-	-	-	
Guiding Principles for Monte Carlo Analysis	x	x			-	-	-	x	x	x	x			-	-		x						x					x	x						x	-	-	x	-

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Program-Specific Guidance																																							
Guidelines for Deriving Numerical National Water Quality Criteria for the Protection of Aquatic Organisms and their Uses		x					x	x		x											x							x	x				x					x	
Framework for Developing Suspended and Bedded Sediment (SABS) Water Quality Criteria		x			x	x	x	x	x	x	x				x		x		x								x	x	x				x					x	
Modeling Framework Applied to Establishing the Aquatic Life Criteria Attainment Frequency, June 2008 Draft			x		x		x			x											x						x		x				x					x	

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

Document title	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
AQUATOX (Release 3), Modeling Environmental Fate and Ecological Effects in Aquatic Ecosystems. Volume 2: Technical Documentation			x		x	-	-	x	x	x					x		x	-	x									x	x				x			x		x	
Best Practices for Identifying Reference Condition in Mid-Atlantic Streams.			x			x	x			x											x						x	x			x		x				x		
Proof of Concept for Integrating Bioassessment Results from Three State Probabilistic Monitoring Programs			x			x	x			x											x						x	x			x		x				x		

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Developing Biological Indicators: Lessons Learned from Mid-Atlantic Streams			x			x	x			x		-									x						x	x			x		x				x		
Biological Indicator Variability and Stream Monitoring Program Integration: A Maryland Case Study			x			x	x			x							x				x						x	x			x		x				x		
Estuarine and Coastal Marine Waters: Bioassessment and Biocriteria Technical Guidance.																																							
Nutrient Criteria Technical Guidance Manual Wetlands																																							

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

Document title	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Lake and Reservoir Bioassessment and Biocriteria, Technical Guidance Document																																							
Use of Biological Information to Better Define Designated Aquatic Life Uses in State and Tribal Water Quality Standards: Tiered Aquatic Life Uses. Draft																																							
Consolidated Assessment and Listing Methodology, Toward a Compendium of Best Practices, First Edition																																							

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Biocriteria and Biological Assessment Guidance																																							
Nutrient Criteria Guidance Documents																																							
Interim-Final Guidance for RCRA Corrective Action Environmental Indicators																																							
Screening Level Ecological Risk Assessment Protocol for Hazardous Waste Combustion Facilities, Peer Review Draft		x			x	x	x	x	x	x	x				x		x							x				x	x						x			-	

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments, Interim Final		x		x	x	x	x	x	x	x	x		x		x		-	-					x					x			x				x	-	-	-	-
Guidance for Developing Ecological Soil Screening Levels		x						x															x					x	x				x					-	
Guidance for Data Useability in Risk Assessment (Part A) April 1992		x	x	x					x			x											x												x				
Guidance for Data Usability in Risk Assessment (Part B)		x	x	x					x			x											x												x				

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components: Problem formulation				ERA process components: Analysis		ERA process components	Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale: Org. level		Level/scale: Spatial			Scope of guidance				Type of assessment			
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Issuance of Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund OSWER Directive 9285.728P																																							
Ecological Risk Assessment and Risk Management Principles for Superfund Sites (Issuance of Final Guidance)	x	x		-							-		x	-	-								x												x				
Eco Update The Role of the BTAGs in Ecological Assessments		x		x	-	-	-	-	-	-	-		-										x												x				

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Eco Update Ecological Assessment of Superfund Sites: An Overview		x		x																			x												x				
Eco Update the Role of Natural Resources Trustees in the Superfund		x		x									x										x												x				
Eco Update Developing a Work Scope for Ecological Assessments		x	x	x																			x												x				
ECO Update Briefing the BTAG: Initial Description, Setting, History and Ecology of the Site		x		x									x										x																

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
ECO Update Using Toxicity Tests in Ecological Risk Assessments		x	x				x			x													x					x	x						x	-	-	-	-
ECO Update Catalogue of Standard Toxicity Tests for Ecological Risk Assessments		x	x				x			x													x					x	x						x	-	-	-	-
ECO Update Field Studies for Ecological Risk Assessment		x	x	x	-	-	x		x	x	-	-											x					x	x						x		x		
ECO Update Selecting and Using Reference Information in Superfund Ecological Risk Assessments		x	x	x			-			-	-		-		-								x					x	x						x	-	'-		

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components: Problem formulation				ERA process components: Analysis		ERA process components	Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale: Org. level		Level/scale: Spatial			Scope of guidance				Type of assessment			
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Eco Update Ecotox Thresholds		x	x					x			x												x					x	x						x		x		
ECO Update Ecological Significance and Selection of Candidate Assessment Endpoints		x		x		x	-				-												x												x	-	-	-	-
ECO Update the Role of Screening - Level Risk Assessments and Refining Contaminants of Concern in Baseline Risk Assessments		x		x				x		x	x												x					x	x						x	-	-	-	

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
Document title	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Eco Update/ Groundwater Forum Issue Paper Evaluating Ground-Water/Surface-Water Transition Zones in Ecological Risk Assessments		x		x	x				x																			x	x						x	-	-		
Role of the Ecological Risk Assessment in the Baseline Risk Assessment																																							

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

Document title	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Revised Interim Soil Lead Guidance for Comprehensive Environmental Response, Compensation, and Liability Act Sites and Resource Conservation and Recovery Act Corrective Action Facilities																																							
Risk Assessment Guidance for Superfund (RAGS): Volume III – Part A, Process for Conducting Probabilistic Risk Assessment		x			-	-	-	x	x	x	x			-	-		x						x					x	x						x	-	-	x	-

Table C-1. A preliminary table of available guidance for ecological assessments in the EPA (continued)

Document title	Document scope				ERA process components							Rel. comp.	Corollary issues						Regulatory framework/program								Level/scale					Scope of guidance				Type of assessment			
					Problem formulation				Analysis																		Org. level		Spatial										
	Science policy	Guidance and other supporting documents	Tool	Planning and scoping	Conceptual Model	Assessment endpoints	Measures	Hazard/toxicity assessment	Exposure assessment/analysis	Effects analysis	Risk characterization	DQOs, QA/QC	Stakeholder involvement	Risk communication	Risk management	Benefit services	Uncertainty	Risk integration	Agency	TSCA	Water	Pesticides	CERCLA	RCRA	Air	Brownfields	Population	General	General	Landscape	Site	Chemical	Media	Receptor	General	Causal	Condition	Predictive	Outcome
Memorandum. EPA Risk Characterization Program.	x										-		-	-					x																x				
Overview of the Ecological Risk Assessment Process in the Office of Pesticide Programs		x			x	x	x	x	x	x	x				-		x	-				x						x	x						x		-	-	-
Population Risk Assessment Workshop Summary																																							

"x" indicates that the topic is directly addressed in the document, "-" indicates that it touched upon, and a blank indicates that it is not addressed.

CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act; DQO = data quality objectives; EPA = U.S. Environmental Protection Agency; Org. = Organizational; OSWER = Office of Solid Waste and Emergency Response; RCRA = Resource Conservation and Recovery Act; Rel. comp. = Related components; TSCA = Toxic Substances Control Act.

APPENDIX D
SUPPORTING MATERIAL FOR
SECTION 6. RESPONSE TO SAB AND NRC COMMENTS

D.1. ENHANCE COMMUNICATION OF ECOLOGICAL RISK ASSESSMENT RESULTS

Methods to improve the communication of the results of an Ecological Risk Assessment (ERA) to managers and stakeholders have been needed since the Chicago Bears won the Superbowl. The lack of a bright line in ERA that defines this is good and this is bad to risk managers is one issue. The variable decision structure for different U.S. Environmental Protection Agency (EPA) Program Offices and Regions is another issue. Also communication of risk assessments that include uncertainty and variability discussions can be difficult and can result in a confusing message to managers and stakeholder.

The Risk Assessment Forum (RAF) needs to take a new look at communication issues by studying within the various offices of the EPA how ERA results are communicated and to identify what processes or structures are in place that may inhibit an informed discussion of the ERA results. Another task could gather case studies on successful communication strategies and incorporate the thoughts of external experts and managers.

D.2. THE FOLLOWING FOURTEEN ROE QUESTIONS INCLUDE AN ECOLOGICAL COMPONENT

1. What are the trends in outdoor air quality and their effects on human health and the environment?

2. What are the trends in extent and condition of fresh surface waters and their effects on human health and the environment?

3. What are the trends in extent and condition of wetlands and their effects on human health and the environment?

4. What are the trends in extent and condition of coastal waters and their effects on human health and the environment?

5. What are the trends in the condition of consumable fish and shellfish their effects on human health?

6. What are the trends in land cover and their effects on human health and the environment?

7. What are the trends in wastes and their effects on human health and the environment?

8. What are the trends in chemicals used in land and their effects on human health and the environment?

9. What are the trends in contaminated land andtheir effect on human health and the environment?

10. What are the trends in the extent and distribution of the Nation's ecological systems?

11. What are the trends in the diversity and biological balance of the Nation's ecological systems?

12. What are the trends in the ecological processes that sustain the Nation's ecological systems?

13. What are the trends in the critical physical and chemical attributes and processes of the Nation's ecological systems?

14. What are the trends in the biomarkers of exposure to common environmental pollutants in plants and animals?

D.3. A SUMMARY OF ECOLOGICAL ENTITIES SPECIFICALLY TARGETED FOR PROTECTION BY ENVIRONMENTAL LAWS

Ecological entities	Federal laws											
	CAA	CWA	CZMA	CERCLA	ESA	FIFRA	MMPA	MPRSA	MBTA	NEPA	RCRA	TSCA
Environment	✓	✓		✓		✓		✓		✓	✓	✓
Natural resources	✓		✓	✓				✓		✓		
Ecosystems	✓	✓		✓	✓							
Marine ecosystems							✓	✓				
Biota/living things				✓								✓
Aquatic or marine life	✓	✓										
Endangered species	✓				✓			✓				
Wildlife	✓	✓	✓	✓		✓		✓				
Fish		✓	✓	✓		✓		✓				
Birds									✓			
Marine mammals							✓					
Shellfish		✓										

Ecological entities	Federal laws											
	CAA	CWA	CZMA	CERCLA	ESA	FIFRA	MMPA	MPRSA	MBTA	NEPA	RCRA	TSCA
Plankton		✓						✓				
Plants	✓	✓				✓						
Land				✓		✓					✓	✓
Soil	✓					✓						
Water	✓	✓		✓		✓					✓	✓
Coastal waters	✓	✓	✓									
Wetlands		✓	✓									
Shorelines, beaches		✓	✓					✓				
Estuaries, flood plains, dunes, barrier islands, coral reefs			✓					✓				
National parks, wilderness areas, and other special areas	✓											
Great Lakes, Chesapeake Bay, Lake Champlain	✓	✓						✓				

CAA = Clean Air Act; CWA = Clean Water Act; CZMA = Coastal Zone Management Act; CERCLA = Comprehensive Environmental Response and Liability Act; ESA = Endangered Species Act; FIFRA = Federal Insecticide, Fungicide and Rodenticide Act; MPRSA = Marine Protection, Research and Sanctuaries Act; MBTA = Migratory Bird Treaty Act; MMPA = Marine Mammal Protection Act; NEPA = National Environmental Policy Act; RCRA = Resource Conservation and Recovery Act; TSCA = Toxic Substances Control Act

D.4. THE USE OF SERVICES OF NATURE IN AN ASSESSMENT OF AIR POLLUTANTS

Ecosystems differ in biota, climate, geochemistry, and hydrology, and concomitantly responses to pollutant exposures can also vary greatly between ecosystems. The Final Risk and Exposure Assessment in the Integrated Science Assessment (ISA) for Oxides of Nitrogen and Sulfur–Ecological Criteria addresses four main ecosystem effects (U.S. EPA, 2008).

- Aquatic acidification due to nitrogen and sulfur
- Terrestrial acidification due to nitrogen and sulfur
- Aquatic nitrogen enrichment, including eutrophication
- Terrestrial nitrogen enrichment

Since these ecosystem effects are not evenly distributed across the United States, case studies were developed for these analyses based on ecosystems identified as sensitive to nitrogen and/or sulfur deposition effects. This assessment builds upon the scientific information presented in the ISA, and ecological indicator(s) and case study locations were selected based on this information. Eight case study areas were identified in recognized sensitive ecosystems nationwide focusing on each of the targeted effect areas.

For assessing this set of secondary National Ambient Air Quality Standards (NAAQS), in addition to assessing the degree of scientific impairment of ecological systems relating to inputs of nitrogen oxides (NO_x) and sulfur oxides (SO_x), the *Final Risk and Exposure Assessment* (U.S. EPA, 2009b) presents an overview of the concept of ecosystem services. The analysis of the effects on ecosystem services helps to link what is biologically adverse effects with known or anticipated adverse effects on public welfare. In the assessment, ecosystem services are used to show the impacts of ecological effects on public welfare and to help explain how these effects are viewed by the public (U.S. EPA, 2006). The ability to inform decisions on the level of a secondary NAAQS required the development of clear linkages between biologically adverse effects and effects that are known or anticipated to be adverse to public welfare. The concept of adversity to public welfare does not require the use of ecosystem services, yet they were envisioned as a beneficial tool that may provide more information on the linkages between changes in ecological effects and known or anticipated adverse public welfare effects.

As described in the EPA's Ecological Benefits Assessment Strategic Plan, it is necessary to recognize that in the analysis of the environmental responses associated with any particular policy or environmental management action, some of the ecosystem services likely to be affected are readily identified, while others will not be quantified (U.S. EPA, 2006). Of those ecosystem services that are identified, some changes can be quantified, whereas others will remain unidentified. Within services whose changes are quantified, only a few will likely be monetized, and many will remain un-monetized. Similar to health effects, only a portion of the ecosystem services affected by a policy can be monetized. A conceptual model integrating the role of ecosystem services in characterizing known or anticipated adverse effects to public welfare is shown in Figure D-1.

Knowledge of the relationships linking ambient concentrations and ecosystem services can be used to inform a policy judgment on a known or anticipated adverse public welfare effect. The conceptual model outlined for aquatic acidification in Figure D-1 can be modified for any targeted effect area where sufficient data and models are available. This information can then be used to characterize known or anticipated adverse effects to public welfare and to inform a policy based on welfare effects.

While there will always be inherent variability in ecological data and uncertainties associated with modeling approaches, there is a high level of confidence from a scientific perspective that known or anticipated adverse ecological effects are occurring under current ambient loadings of nitrogen and sulfur in sensitive ecosystems across the United States.

For aquatic and terrestrial acidification effects, a similar conceptual approach was used (critical loads) to evaluate the impacts of multiple pollutants on an ecological endpoint, whereas the approaches used for aquatic and terrestrial nutrient enrichment were fundamentally distinct. Although the ecological indicators for aquatic and terrestrial acidification (i.e., acid neutralizing capacity [ANC] and base cations: aluminum ratio Bc/Al) are very different, both ecological indicators are well-correlated with effects such as reduced biodiversity and growth. While aquatic acidification is clearly the targeted effect area with the highest level of confidence, the relationship between atmospheric deposition and an ecological indicator is also quite strong for terrestrial acidification. The main drawback with the understanding of terrestrial acidification is that the data are based on laboratory responses rather than field measurements. Other stressors that are present in the field but that are not present in the laboratory may confound this relationship.

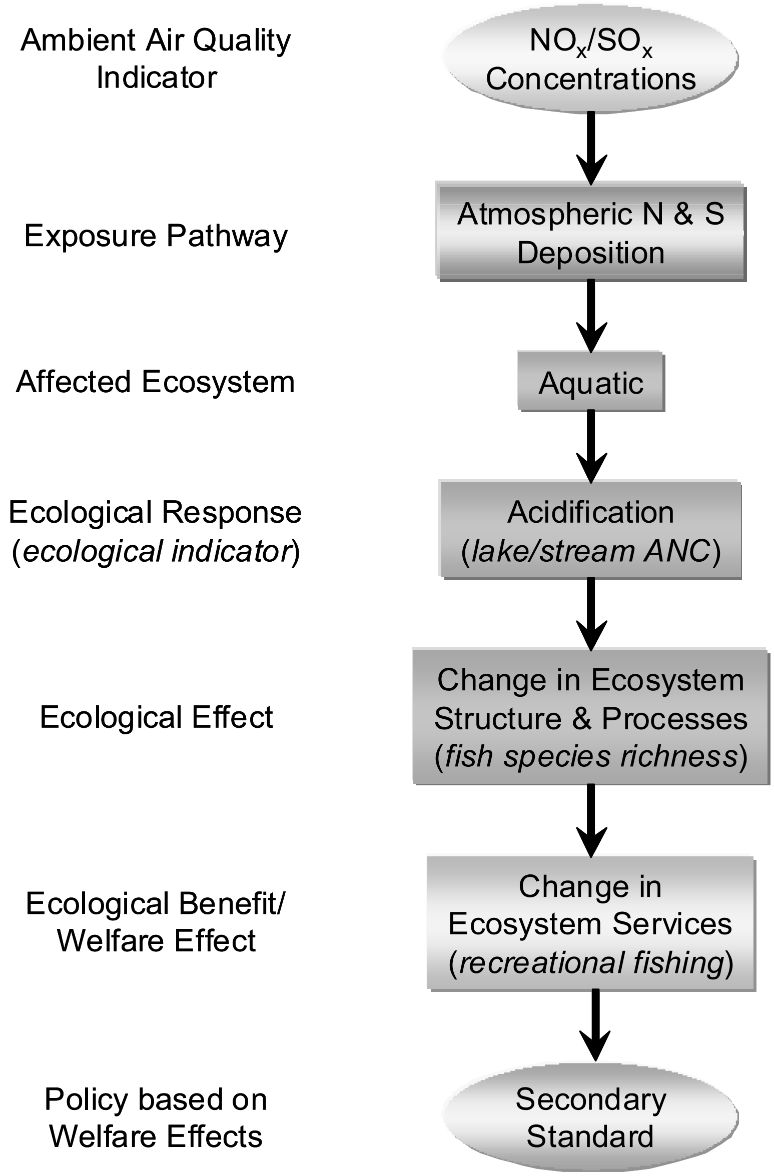

Figure D-1. Conceptual model showing the relationships among ambient air quality indicators and exposure pathways and the resulting impacts on ecosystems, ecological responses, ecological effects, and finally, on the quality of a particular activity (e.g., recreational fishing) known to influence public welfare.

The ecological indicator chosen for aquatic nutrient enrichment, the ASSETS eutrophication index (EI), seems to be inadequate to relate atmospheric deposition to the targeted ecological effect, likely due to confounding factors. Further, there is far less confidence associated with the understanding of aquatic nutrient enrichment because of the large contributions from nonatmospheric sources of nitrogen and the influence of both oxidized and reduced forms of nitrogen, particularly in large watersheds and coastal areas. However, a strong relationship exists between atmospheric deposition of nitrogen and ecological effects in high alpine lakes in the Rocky Mountains, because atmospheric deposition is the only source of nitrogen to these systems. There is also a strong weight-of-evidence regarding the relationships between ecological effects attributable to terrestrial nitrogen nutrient enrichment, but ozone and climate change may be confounding factors. In addition, the response for other species or species in other regions of the United States has not been quantified.

A summary of the information presented by this Risk and Exposure Assessment that may be useful for characterizing known or anticipated adverse effects to public welfare is shown in Table D-1. This information will be used to aid the Administrator's decision about what levels of protection might be appropriate to protect public welfare from known or anticipated adverse ecological effects such as acidification in sensitive ecosystems.

The Final NO_x/SO_x Secondary NAAQS Risk and Exposure Assessment, as well as related documents developed as part of the planning and science assessment phases of this review (e.g., Integrated Review Plan, the ISA), are available at http://www.epa.gov/ttn/naaqs/standards/no2so2sec/index.html.

Table D-1. Summary of information assessed in the risk and exposure assessment to aid in informing policy based on welfare effects (EPA, 2009b).

Exposure pathway (current deposition levels)	Affected ecosystem (case study areas)	Ecological response (targeted effect)	Ecological indicator	Ecological effect	Ecosystem service affected
Adirondack Case Study Area: 10 kg N/ha/yr 9 kg S/ha/yr Shenandoah Case Study Area: 11 kg N/ha/yr 11 kg S/ha/yr	Adirondack Mountains, NY Blue Ridge Mountains and Shenandoah National Park, VA	Acidification in lakes and streams	Fish species richness, abundance, composition, ANC	Species losses of fish, phytoplankton, zooplankton; changed community composition, ecosystem structure, and function	Annual recreational freshwater fishing in New York State = more than 13 million days Approximately $66.4 million in implied value to New York anglers from a zero-out of nitrogen and sulfur deposition
Kane Experimental Forest Case Study Area: 14 kg N/ha/yr 210 kg S/ha/yr Hubbard Brook Experimental Forest Case Study Area: 8 kg N/ha/yr 7 kg S/ha/yr	Kane Experimental Forest (Allegheny Plateau, PA) Hubbard Brook Experimental Forest (White Mountains, NH)	Acidification of forest soils	Tree health Red spruce, sugar maple Bc/Al ratio	Decreased tree growth Increased susceptibility to stress, episodic dieback; changed community composition, ecosystem structure, and function	Provision of wood products (sugar maple) 900 million board feet timber production
Potomac River/Potomac Estuary Case Study Area: 13 kg N/ha/yr Neuse River/Neuse River Estuary Case Study Area: 14 Kg N/ha/yr	Potomac River Basin, Chesapeake Bay Neuse River Basin, Pamlico Sound	Nutrient enrichment in main stem river of an estuary	ASSETS EI	Habitat degradation, algal blooms, toxicity, hypoxia, anoxia, fish kills, decreases in biodiversity	Current saltwater recreational fishing 26.1 million activity days (North Carolina-Massachusetts)
Coastal Sage Scrub from 3 to 10 kg N/ha/yr Mixed Conifer Forest (San Bernardino Mountains and Sierra Nevada Range): from 3 to 10 kg N/ha/yr	Southern California Coastal Sage Scrub Mixed Conifer Forest (San Bernardino Mountains and Sierra Nevada Mountains, CA)	Nutrient enrichment in terrestrial ecosystems	Species composition	Species changes, nutrient enrichment of soil, changes in fire regime, changes in nutrient cycling	Annual benefits to California residents hunting, fishing, and wildlife viewing = approximately $4.6 billion; state expenditures for fire suppression = $300 million (2008)

Note: ANC = acid neutralizing capacity, Bc/Al = Base cation: Aluminum, QA/QC = quality assurance/quality control.

D.5. RELATEDNESS OF CUMULATIVE AND ECOLOGICAL RISK ASSESSMENT

Various parts of the EPA have been developing cumulative risk assessment (CRA) approaches and tools for several years. One of the formal EPA efforts to develop CRA began in 1999 when the RAF began its process to develop Agency-wide CRA guidelines. The RAF chose to follow the same sequential progression that it used to develop its Agency-wide *Guidelines for Ecological Risk Assessment*. This multiyear, 3-phase developmental process consists of sequentially developing (1) a framework; (2) issue papers and case studies; and (3) guidelines.

Phase I was completed in 2003 with release of the *Framework for Cumulative Risk Assessment* (EPA/630/P-02/001F). Several objectives were achieved with the CRA Framework. It is an informational document which is focused on identifying and describing various aspects, key issues, and basic elements of cumulative risk. The CRA Framework defines cumulative risk assessment as "an analysis, characterization, and possible quantification of the combined risks to human health or the environment from multiple agents or stressors." Additionally, common cumulative risk terms are defined and a flexible structure is provided. As Agency-wide guidelines, no attempt was made to lay out protocols or set procedures.

Phase II is nearing completion as the corresponding report, *Issues and Case Studies in Cumulative Risk Assessment,* is currently undergoing internal peer review. In the Phase II report, key issues are explored, which were identified in the Framework, and numerous case studies are described to illustrate the basic CRA elements, as well as various aspects of CRAs. Phase III will commence during 2010 and will culminate with publication of the Agency-wide CRA guidelines.

In addition to the common developmental process, CRA and ERA share other commonalities. Both types of risk assessment tend toward integration of assessment elements (e.g., considering aggregate exposures to multiple agents or stressors), exploring interconnections and interrelationships between and among environmental components, rather than segregating components with a deconstructive approach. Thus, they both can be viewed as tending toward being holistic approaches.

From this perspective, it is not surprising that the CRA paradigm illustrated in the CRA Framework is nearly identical to the ERA paradigm as presented in the ERA Framework and Guidelines. Especially prominent is the emphasis on problem formulation as being a key component to the success of both risk assessment types. Clear definition and statement of

(1) questions being asked; (2) objectives being desired; (3) assessment endpoints being evaluated; (4) measures and indicators being used; (5) conceptual model being envisioned; and (6) analysis plan being undertaken become increasingly important as the risk assessment complexity increases due to increasing consideration of interrelationships and interconnectedness of the risk assessment elements.

D.6. WEB SITES ILLUSTRATING THE EPA'S INTERNATIONAL, FEDERAL, STATE, AND TRIBAL PARTNERSHIPS ON SCIENCE AND MANAGEMENT

- Information about EPA cooperation with Europe
  http://www.epa.gov/international/regions/Europe

- EPA projects to assist in the environmental recovery of the former Soviet Union and other Central and Eastern European countries
  http://www.epa.gov/international/regions/Europe/darkpast.htm (HTML)

- An overview of the international activities related to pesticides
  http://www.epa.gov/oppfead1/international

- Home page for EPA's international air and climate pages
  http://www.epa.gov/international/air

- Information about partners in managing marine pollution issues
  http://www.epa.gov/international/water/marine/partners.html

- international agreement on **global** control of **mercury** pollution
  http://www.epa.gov/international/toxics/mercury.html (HTML)

- Information on Agency-wide efforts to strengthen public health and environmental protection with Native Americans http://www.epa.gov/tribal

- Information on the Mississippi River/Gulf of Mexico Watershed Nutrient Task
  http://www.epa.gov/msbasin/members.htm

- Information on the Columbia River Basin landscape, including parts of seven states and British Columbia ... http://yosemite.epa.gov/R10/ECOCOMM.NSF/Columbia/Columbia

- Information about water quality standards and the Endangered Species Act
  http://www.epa.gov/waterscience/standards/esa.html

D.7. INCLUDE ECOSYSTEM SERVICES AS ASSESSMENT ENDPOINTS WHERE APPROPRIATE

Ecological relevance, susceptibility to the stressor and relevance to management goals are the key considerations when selecting assessment endpoints responsive to the needs of the decision-maker (U.S. EPA, 1998). Attention to the first two of these helps to ensure the scientific credibility of the ERA; attention to the third enhances the significance of assessment results to decision-makers and the public. As stated in EPA (1998)…

> Ultimately, the effectiveness of a risk assessment depends on whether it is used and improves the quality of management decisions. Risk managers are more willing to use a risk assessment for making decisions when it is based on ecological values that people care about. Thus, candidates for assessment endpoints include endangered species or ecosystems, commercially or recreationally important species, functional attributes that support food sources or flood control (e.g., wetland water sequestration), aesthetic values such as clean air in national parks, or the existence of charismatic species such as eagles or whales. However, selection of assessment endpoints based on public perceptions alone could lead to management decisions that do not consider important ecological information. While responsiveness to the public is important, it does not obviate the requirement for scientific validity.

Elsewhere in this document we discussed the tendency in the Agency to default to human health risks as the key drivers in environmental decisions (although instances in which ecological risks influenced decisions more strongly were described above). The issues surrounding this fact are both simple and complex—simple in that humans are making the decisions and our perceptions typically are ones of protecting human health being paramount; complex in that program policies and the political will of decision-makers interplay in ways that influence how various types of scientific information are used in the decision-making process. But a substantial part of EPA's mission is to protect the environment. One means by which ecological risk can be put on a par with that of human health risk is to couch ecological effects in terms of ecosystem services, ecological benefits, and social welfare.

We encourage selection of assessment endpoints that can be tied closely to ecosystem goods and services—the outputs of ecological functions or processes that directly or indirectly contribute to social welfare or have the potential to do so in the future (U.S. EPA, 2006a). In this regard, EPA (2004) describes the relationships between the individual generic ecological assessment endpoints and several of the environmental values that the public ascribes to ecological entities and functions. Having this relationship well described is particularly relevant to the translation questions of concern here, because linking assessment endpoints to public values can help to identify economic methods appropriate for monetization. Although monetization is not always required nor desired, quantification of the risks to ecosystem services in biophysical terms still provides information most easily communicated to and understood by decision-makers and the public.

Problem formulation of the Agency's risk assessments should included ecosystem services to the extent that they can help to inform decision-making. Rationale for selecting such endpoints should include explicit explanation of the linkages existing among the endpoints used and social welfare. When assessment endpoints are included whose relationships to welfare are less obvious (e.g., benthic community structure), care should be taken to describe how adverse effects to those endpoints can manifest to loss of ecosystem services. Identifying appropriately valued assessment endpoints likely will require involvement of social scientists is some significant way—either during planning and problem formulation themselves, or in precursor planning activities that might identify a suite of ecosystem service assessment endpoints as proposed by Munns et al. (2009). The rationale underlying selection of such endpoints can become critical components of strategies communicating the assessment approach and results.

D.8. THE TREATMENT OF SCALE IN EPA PROGRAM OFFICES

D.8.1. Office of Pesticide Programs

The Office of Pesticide Programs conducts ecological risk assessments over a range of spatial scales depending upon uses, fate, transport, and effects of pesticides. National scale assessments are based on conservative regional scenarios to evaluate the potential risks from pesticides in the specific locales where they are most likely to be applied to meet regional pest pressures. Specific regional scenarios are developed for specific crops (e.g., Maine potatoes). The scenarios incorporate regional climate data (e.g., rainfall, temperature) base don historical weather data. The exposure estimates for the scenarios are based on modeled exposure data, and monitoring data where available. Temporal scale of OPP risk assessments is defined by the use pattern of the active ingredient. For residential and consumer use patterns, use may be at any time of the year. For agricultural use patterns, the temporal scale is defined by agronomic practices such as application timing in relation to plant growth stage. Timing and duration of exposure may also be assessed through the use of time-series monitoring data. The biological scale of OPP risk assessments is based on mortality, growth, and reproduction as assessment endpoints. For endangered species, additional sublethal effects are considered. Effects on higher levels of biological organization are assessed through probit-slope relationships for acute effects (percent effect on populations), and by consideration of indirect effects (food supply and predator-prey relationships). Endangered species assessments require an analysis of effects on listed critical habitat which may be addressed at the ecosystem-level analysis, depending on the size of the habitat.

D.8.2. Office of Water

The Office of Water develops national ambient water quality criteria as science based recommendations that EPA considers protective of the aquatic life use. Criteria are not regulations, nor are they enforceable. When criteria are linked to a designated use and adopted into a water quality standard by a state, the standard becomes enforceable. Accordingly, the Office of Water and states are coregulators that work together to consider and prioritize pollutants for criteria development. The Office of Water works with EPA Regions and states to identity and select criteria candidates. Because ambient water quality criteria are developed on a national scale, pollutants of broad national or multiregional interest are given priority over those limited to a single region. National criteria are developed according to EPA (1985) and do not explicitly address exposure spatially. Rather, it is conservatively assumed that aquatic life is exposed to the pollutant. Temporal scale is typically considered in terms of two categories, short-term (acute) and long-term (chronic) exposures. If a pollutant is more prevalent during particular seasons, or if toxicity is affected by seasonal temperature variation, a criteria recommendation may be proposed with a seasonal temperature component. Additionally, frequency and duration of exceedences may also be included in a criterion recommendation. Seasonal DO regimes based on living resources physiologic requirements and seasonal and hydrologic/bathymetric constraints were considered during the scoping and problem formulation step for development of dissolved oxygen criteria for the Chesapeake Bay.

D.8.3. Office of Solid Waste and Emergency Response

The Office of Solid Waste and Emergency Response considers scope, boundaries, and scale to be important elements during the development of conceptual site models for ecological risk assessments. Scope, target populations, and boundaries are established using EPA's Guidance on Systematic Planning Using the Data Quality Objectives Process (U.S. EPA, 2006). The scope and boundaries of the conceptual site model are developed during problem formulation and reflect the scope and boundaries of the risk management decision. The conceptual site models present geographic scales of risk management decisions. EPA's *Guidance for Conducting Remedial Investigations and Feasibility Studies (RI/FS) Under CERCLA* (U.S. EPA, 1988) encourages EPA risk managers to identify options to address contamination at a site early in the process. EPA risk managers come to EPA risk assessors with their initial plans for conducting a RI/FS. The schedule and project boundaries and other requirements are often specified in a consent decree or signed by the potentially responsible parties. When EPA contractors are preparing the risk assessment documents, the schedule and requirements are communicated in the Scope of Work. Usually there is also a meeting between EPA's risk managers, contractors, risk assessors, and contract officers to begin a project.

Superfund legislation defines the site as the extent of contamination. When the extent of contamination is determined by the remedial investigation, adaptive site management can provide flexibility in the site boundaries as the extent of contamination is characterized. The spatial extent of the affected ecological population is not usually considered in the ecological risk assessment problem formulation. Rather, a locally affected population (or part of the population) is assumed to be an appropriate assessment spatial scale. The conceptual site model may also identify where separate decisions for the smallest subpopulation or time period may be of interest to risk managers. Cleanup decisions requiring a predictive risk assessment are targeted to potential remedies identified by risk managers in early stages of the RI/FS. Therefore, the geographic scoping can relate to source areas and specific migration pathways. A larger site may be subdivided into operable units, solid waste management units, or exposure units to support decisions targeted to specific sources or pathways. These decisions are made during planning, before initiation of the risk assessment. Decisions are revisited as new information becomes available or as management objectives change. The boundaries and scale of the risk evaluation is designed to reflect the scale of the risk management decision. The risk assessment evaluates current and potential future risks. Remedies should achieve protectiveness within a reasonable time frame. The definition of "reasonable" will depend on the severity of impacts and magnitude of effect within an ecosystem. Outcome assessments are evaluated in five year review cycles which may also include trend analyses. The exposure profile considers temporal aspects of exposures and ecosystem responses, such as seasonal use or pulsed exposures. The exposure profile is used to guide development of biological studies, the selection of toxicity reference values, and monitoring. The technical support document for the development of the ecological soil screening values (U.S. EPA, 2005) specifies survival, growth, and reproduction of organisms as the biological scale. Office of Solid Waste and Emergency Response risk assessments also consider protection of populations and communities. The biological scale can depend on the spatial scale of the site or of the spatial scale of the decision unit in the case of a larger site.

D.8.4. A Case of Assessment Scaling

The case example includes three sequential assessments that moved through Broad Regional, watershed, and site-specific concerns involving the Grand Calumet River and a Northern Indiana Public Service Company (NIPSCO) facility. EPA Regions have developed is a geographic information system based ecological assessment tool called the Critical Ecosystem Assessment Model or CrEAM (White et al., 2008). CrEAM has been used to evaluate the undeveloped areas of the six EPA Region 5 states (Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin). The CrEAM assessment was requested by the Region 5 managers who were interested in identifying and protecting ecologically important regional landscapes. The planning and problem formulation for CrEAM included: (1) interactions with senior managers to define management goals; (2) establishing a multidisciplinary, cross-program team; (3) obtaining stakeholder input from tribal, federal, state, and local governments; (4) developing a conceptual model; and (5) developing an analysis plan that incorporated ecological assessment endpoints and measures of exposures and effects. This effort identified that Grand Calumet River was subject to pollution from multiple sources.

The Grand Calumet River was also identified as one of 27 American, 12 Canadian, and 3 bi-national areas of concern in the Great Lakes region. The areas of concern were established by the Great Lakes Water Quality Agreement (GLWQA) between Canada and the United States to mutually address gross water pollution. The GLWQA emphasizes an ecosystem approach to the management of the Great Lakes, and identifies 14 potential Beneficial Use Impairments

(BUIs). The Grand Calumet River is located in the northwestern corner of Indiana, originating in the east end of Gary. It winds for 13 miles through the heavily industrialized cities of Gary, East Chicago, and Hammond, discharging about 1 billion gallons per day into Lake Michigan. Approximately 50 Superfund (CERCLA) and 420 hazardous waste (Resource Conservation and Recovery Act or RCRA) sites are in close proximity to the river. Additionally, the river contains 5 to 10 million cubic yards of contaminated sediment (PAHs, PCBs, heavy metals, oil, and grease) that is 20 feet deep in some places. Natural areas that contain globally rare or state significant community types, plants, and birds are intermingled with contaminated sites. Numerous assessments of environmental conditions, contamination, and environmental impacts have been conducted by federal and state agencies and nongovernmental organizations within this large, complex area. Collectively, these studies were tied together into an ecosystem area of concern tied together by the area of concern problems defined by the BUIs. Delisting targets associated with measurable indicators that can be applied to the entire area of concern are being developed. The delisting targets are management objectives for the Grand Calumet River area of concern (AOC). One aspect of delisting target development is determining the appropriate spatial scale in which to evaluate metrics. The NIPSCO facility is a northwest Indiana RCRA Corrective Action site located adjacent to the Indiana Dunes National Lake Shore of Lake Michigan. Having the smallest assessment area, it completes the 3-part spatial sequence illustration. The NIPSCO is a coal-fired power generating plant which potentially has associated hazardous waste releases to the National Lake Shore and Lake Michigan. The scope and objectives of the ecological risk assessment are stipulated in the corresponding Administrative Order of Consent. For this site-specific spatial context, the problem formulation is much more discrete and defined than for those of the CrEAM or the Grand Calumet River AOC assessments.

D.8.5. Office of Air

In EPA's Office of Air, ecological risk assessments are often national in scale to support National Ambient Air Quality Standards (NAAQS). Spatial resolution is described by distribution of sources, distribution of receptors, and enabling legislative authorities. The distribution of ambient air sources affects the distribution of sensitive receptors which ultimately defines the spatial scale of the assessment. In addition, atmospheric mixing processes and residence times will also impact the spatial scale of the ecological effect being addressed. For example, sulfur dioxide emitted from power plants and motor vehicles is mixed and transported within an airshed (up to hundreds of miles) resulting in a cumulative impact from many sources on a given ecological receptor. Enabling legislative authorities define the spatial scale of an ecological risk assessment as in the 1990 Clean Air Act (CAA) Amendments. For example, air toxics are regulated under the Hazardous Air Pollutant (HAP) program (Section 112 of the CAA) which focuses on major releases (more than 10 tons per year from a single HAP or 25 tons per year from multiple HAPs) from source categories of air pollutants (i.e., industrial boilers, halogenated solvent cleaners, or hazardous waste incineration). Title IV of the CAA regulates sulfur emissions from the power sector nationally, although the trading sector only encompasses the east coast. The National Ambient Air Quality Standards (NAAQS) for welfare effects addressed in Section 108 of the CAA must be national in scope. Under these authorities, ecological risk assessments can be focused on one site (sole source of an air toxic), multiple sources within a region (power generation), or national scale from all ambient sources (criteria pollutants).

D.8.6. Interagency Assessment Scales

The spatial scale examples discussed above emphasize program office activities; the Agency is also working with other federal agencies on the Global Earth Observation System of Systems (GEOSS). As a part of that activity, the Agency has established the EPA Group on Earth Observations (EPA GEO) to facilitate and coordinate responses and contributions to the development of GEOSS. The goal of GEOSS is to provide decision-makers with scientific information that can address societal benefit areas including human health, ecosystems, climate change, and air and water quality. EPA GEO is currently in the investigatory phase. One of its principal activities is guiding Office of Research and Development (ORD)'s Advanced Monitoring Initiative (AMI) pilot projects for improving environmental health decision-making. In 2010 EPA GEO is offering Decision-Making Engagement Workshops in several EPA programs and regions to demonstrate AMI tools to decision-makers so that they may be incorporated into decision-making by EPA, EPA's partners and the public. EPA representatives also coordinate EPA's GEOSS role with United States Group on Earth Observations—a standing subcommittee reporting to the White House's National Science and Technology Council's Committee on Environment and Natural Resources (CENR). This CENR subcommittee coordinates all U.S. Government agencies within the international GEOSS mechanism known as GEO (Group on Earth Observations). The scope of U.S. EPA's role in GEOSS is indicated by the current version of the ***Strategic Plan for the U.S. Integrated Earth Observation System*** (see www.epa.gov/geoss/ or http://usgeo.gov). GEO is a voluntary partnership of governments and international organizations that provides a framework for collaboration for exploiting the growing potential of Earth observations to support decision-making in an increasingly complex and environmentally-stressed world.

D.9. THE TREATMENT OF LEVELS OF BIOLOGICAL ORGANIZATION IN THE EPA

Generally, ecological risk assessments can be conducted at any level of biological organization. The level or levels to be addressed may be affected by enabling legislation and regulations, risk management questions, and assessment objectives. It is not uncommon for multiple levels of the biological hierarchy to be included in a single assessment. Endocrine disruption and a commensurate feminization of fish is a case in which multiple levels of biological organization may be needed for an assessment. If observed fish feminization is suspected to be caused by pharmaceutical products being released into a stream, the planning and problem formulation for the corresponding ecological risk assessment could specify analysis of in situ fish metabolic pathways, hormone levels, and tissues. Additionally, fish population surveys could be specified to evaluate sex and age distributions of the various fish species inhabiting the river reach under investigation. Assessments involving potential harm to individuals of a particular species are required when a threatened or endangered species is involved. EPA (2003) identifies a range of organisms, populations, communities, and ecosystems for which policy or precedents exist for ecological assessment endpoints.

Numerous scientific arguments have been made about the need to focus on population and higher-level ecological attributes. A central question is whether population-level assessment endpoints would improve the quality of the risk assessment for the specific decisions they are intended to inform. Wentsel et al. (2004) noted that population-level assessment endpoints may be inappropriate for certain decision contexts.

1. Certain environmental laws and regulations may preclude a population endpoint in some ecological risk assessments.

2. The species evaluated might be endangered or otherwise highly valued and the individual organisms might be considered the appropriate assessment entity.

3. For some assessments, population-level endpoints may not be relevant. Examples include situations where tumors or other abnormalities in fish and amphibians are primary concerns of the public.

4. A resource such as air quality, as it relates to visibility in a park, may bear no relation to populations.

5. Population endpoints may be impractical as measurement endpoints using an empirical approach. The guidance for conducting risk assessments at Superfund sites (U.S. EPA, 1997) points out that even in the absence of the stressors examined in an assessment, populations of at least some kinds of organisms fluctuate so greatly that it is impractical to quantify the effect of a stressor. The authors mention populations of small mammals and fish as especially variable. Given the variability inherent in some populations, it might take several years of data from reference sites to establish reliable bounds of reference populations. So although maintenance of population size may be a relevant assessment endpoint, it may be necessary to use individual-level measures of performance (e.g., survival, reproductive output) as measurement endpoints.

6. The quality of the habitat may be considered by the assessor as the resource to protect. For example, when setting sediment quality criteria, the purpose may be to protect aquatic life in general, and there is no local population to assess.

7. Cost is also a consideration, and a population assessment might be considered too expensive in particular circumstances.

Similar considerations are relevant when considering community and ecosystem level assessments.

The choice of biological scale to be evaluated in regulatory ERAs can be challenging. The enabling legislation of many of EPA's programs either explicitly or implicitly identifies protection of ecological populations as management goals. Most ERAs conducted for chemicals by EPA, and indeed by most organizations worldwide, focus on organism-level attributes (e.g., survival, growth or reproduction) but population-level entities (e.g., a rainbow trout population) (Suter et al., 2005). These endpoints are practical because they often can be estimated through toxicological testing and other means, and are expedient because they are commonly presumed to provide protection of population-level attributes (e.g., abundance and persistence). Further, methods and practice are well established for assessing risk to organism-level attributes, but documentation of consensus methods for estimating risks to population-level attributes is lacking. Consequently, risk to populations has only occasionally been evaluated directly by EPA (e.g., extirpation of trout populations in Adirondack lakes in the

National Acid Precipitation Assessment). This situation results from several factors affecting assessment planning, including the perceived relationships between assessment endpoints and environmental management goals, historical precedence, the assumption that protection of the organism-level attributes of a population will result in protection of its population-level attributes, and importantly, the lack of recognized consensus and guidance about methods. In addition, assessment of population-level attributes may be inappropriate in some contexts (see Section D.9).

Many of the Agency's assessments evaluate the condition of communities (collections of interacting populations), and some metrics intended to reflect the condition of those communities (e.g., indices of biotic integrity) are being used to inform certain environmental protection decisions. Yet, methods for assessing risks to communities, and even less so for risk to ecosystem functions, are poorly developed at present (although some ecosystem models are available to evaluate higher order effects). We recommend that additional guidance be developed concerning the issues and considerations cogent to selecting assessment endpoints at the community and ecosystem levels of organization.

The EPA Risk Assessment Forum has started to develop best practice guidelines for population-level assessment endpoints (U.S. EPA, 2009a). Initial efforts have focused on the state of the science and practice for population assessment techniques, and identifying key activities that might lead to the development of best practices. These efforts will likely continue over the next few years, with supplemental guidelines for population-level ecological risk assessment, including for planning, scoping, and problem formulation, being one outcome. Many Agency assessments evaluate the condition of communities, and metrics intended to reflect the community condition (e.g., indices of biotic integrity) have been used to inform certain environmental protection decisions. However, methods for evaluating communities are primarily descriptive rather than causative or predictive. Risks method for ecosystem functions are poorly developed at present, although some ecosystem models are available to evaluate higher order effects.

D.10. TRIBAL ISSUES

Current risk assessment methodology does not explicitly address tribal culture, values, and/or lifeways. The impact to tribes when tribal resources are contaminated extends beyond impacts to human health and the overall ecosystem to these larger issues. The processes fail to adequately account for or include a holistic approach for assessing the social, cultural, and spiritual values, beliefs, and practices that link tribal people to their environment.

Tribal traditional lifeways encompass the unique cultural, spiritual, economic, and language practices pursued by tribal communities. Tribal Science Council (TSC) representatives have identified traditional tribal lifeways as the overarching issue under which all of the tribal science priorities fall. The importance of each science priority is directly related to the way in which the issue impacts not only tribal health and the environment, but also the way in which it directly impacts the ability of tribal communities to pursue their traditional tribal ways of life—with direct implications for cultural, spiritual, economic, and language practices of tribal communities.

The TSC recognizes that EPA currently utilizes the risk assessment paradigm as the basis for environmental decision-making and seeks to improve the policies and practices to incorporate tribal traditional lifeways. In addition, the TSC recognizes that the fundamental assumptions and approach of EPA's risk assessment paradigm cannot fully address tribal issues and perspectives and seeks a longer-term goal of developing a new environmental decision-making paradigm for EPA consideration—one focusing on human and ecological health well-being (http://www.epa.gov/osp/tribes/key/html).

There is a need for a broadened perspective regarding temporal and spatial aspects of ecological risk assessment, and this is particularly evident in the context of assessments involving Native American tribes, Alaska Native communities, and similar indigenous peoples. Tribal perspectives on risk assessment emphasize the need to include traditional ecological knowledge in assessments, such as observational data on ecosystems and other natural resources collected over multiple human generations. In addition, while the Agency is largely media focused, tribes are most focused on context-specific issues that stress the interdependence of various risk factors, many of which require analysis at lengthy temporal and/or expansive spatial scales to discern effects. Finally, tribes possess a culture-based knowledge of ecosystems, often linked to their original creation stories, which may be an integral part of their tribal decision-making processes regarding protection of the natural environment.

At the Tribal Science Council Risk Assessment/Health and Well-being Workshop, February 19 and 20, 2003, the TSC identified as the top science priority the need for the integration of tribal concerns into EPA's risk assessment and management process. TSC representatives stressed that they are seeking policy-level changes as well as methodological improvements. An EPA representative noted that one of the big hurdles to getting such policy moved through the Agency lies in being able to quantify the benefits of policy decisions to the Office of Management and Budget (OMB), noting that OMB holds great sway over policy implementation at the Agency. She added that only if it can be proven to the managers that the proposed policy change is workable and viable will it move forward within the Agency (http://www.epa.gov/osp/tribes/pdf/rah&w.pdf).

Executive Order 12898: *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations*. "Developing and conducting EPA's programs, policies, and activities that substantially affect human health and the environment to ensure the fair treatment of all people including minority and/or low-income populations." This Executive Order is particularly relevant not only to ecological risk assessments involving Tribes and their deep interconnectedness with ecosystems, but also to ecological risk assessments conducted in areas with limited opportunities for human interactions with the natural environment, due to the scarcity of unimpacted ecosystems. The adequate assessment, remediation, and protection of these areas results in benefits to not only the ecological receptors within the systems, but also to the human inhabitants utilizing those environments for consumptive and nonconsumptive uses (http://www.epa.gov/compliance/resources/policies/ej/index.html).

D.11. REFERENCES

Munns, WR, Jr; Helm, RC; Adams, WJ; et al. (2009) Translating ecological risk to ecosystem service loss. Integr Environ Assess Manag 5(4):500−514.

Suter, GW, II; Norton, SB; Fairbrother, A. (2005) Individuals versus organisms versus populations in the definition of ecological assessment endpoints. Integr Environ Assess Manag. 1(4):397−400.

U.S. EPA (Environmental Protection Agency). (1985) Guidelines for deriving numerical National Water Quality Criteria for the protection of aquatic organisms and their uses. PB85-227049. Office of Research and Development, Environmental Research Laboratories, Duluth, MN, Narragansett, RI, Corvallis, OR. Available online at http://www.epa.gov/waterscience/criteria/library/85guidelines.pdf.

U.S. EPA (Environmental Protection Agency). (1988) Guidance for conducting remedial investigations and feasibility studies under CERCLA (Interim Final). PE89-184626. EPA/540/G-89/004. OSWER Directive 9355.3-01. Office of Emergency and Remedial Response, Washington, DC.

U.S. EPA (U.S. Environmental Protection Agency). (1997) Ecological risk assessment guidance for superfund: process for designing and conducting ecological risk assessments, Interim final. Office of Solid Waste and Emergency Response, Washington, DC; June 1997, EPA/540/R-97/006. Available online at http://www.epa.gov/oswer/riskassessment/ecorisk/pdf/intro.pdf.

U.S. EPA (Environmental Protection Agency). (1998) Guidelines for ecological risk assessment. Risk Assessment Forum, Washington DC; EPA/630/R-95/002F. Available online at http://www.epa.gov/raf/publications/pdfs/ECOTXTBX.PDF.

U.S. EPA (Environmental Protection Agency). (2003) Generic ecological assessment endpoints (GEAE) for ecological risk assessment. Risk Assessment Forum, Washington, DC; EPA/630/P-02/004F. Available online at http://www.epa.gov/raf/publications/pdfs/GENERIC_ENDPOINTS_2004.PDF.

U.S. EPA (Environmental Protection Agency). (2005) Guidance for developing ecological soil screening levels. November 2003, revised February 2005. Office of Solid Waste and Emergency Response. Washington, DC. OSWER Directive 9285.7-55. Available online at http://www.epa.gov/ecotox/ecossl/pdf/ecossl_guidance_chapters.pdf.

U.S. EPA (Environmental Protection Agency). (2006) Guidance on Systematic Planning Using the Data Quality Objectives Process. Office of Environmental Information, Washington, DC; EPA QA/G-4. Available online at http://www.epa.gov/quality/qs-docs/g4-final.pdf

U.S. EPA (Environmental Protection Agency). (2006) Ecological benefits assessment strategic plan. Office of Policy, Economics and Innovation, National Center for Environment Economics, Washington, DC; EPA/240/R-06/001.

U.S. EPA (Environmental Protection Agency). (2008) Integrated science assessment (ISA) for oxides of nitrogen and sulfur-ecological criteria. Office of Research and Development, Research Triangle Park, NC; EPA/600/R-08/082F. Available online at http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=201485.

U.S. EPA (Environmental Protection Agency). (2009a) Summary report: risk assessment forum technical workshop on population-level ecological risk assessment. Risk Assessment Forum, Washington, DC, EPA/100/R-09/006. Available online at http://www.epa.gov/raf/files/population_level_era_report_supp_materials.pdf.

US EPA (United States Environmental Protection Agency). (2009b). *Risk and Exposure Assessment for Review of the Secondary National Ambient Air Quality Standards for Oxides of Nitrogen and Sulfur.* Final. U.S. Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment, Research Triangle Park, NC.

Wentsel, R., N. Beyer, V. Forbes, S. Maud, and R. Pastorok. (2007) A framework to apply population-level methods to ecological risk assessment. Chapter 10. In: Population-Level Ecological Risk Assessment. Eds. Barnthouse, Munns, and Sorensen. Taylor & Francis, New York, NY.

White, ML; Maurice, CG; Mysz, A; et al. (2008) The critical ecosystem assessment model (CrEAM) - identifying healthy ecosystems for environmental protection planning. In: Campbell, JC; Jones, KB; Smith, H; et al; eds. North America Land Cover Summit, Chapter 12. Washington, DC: Association of American Geographers; pp. 181−213. Available online at http://www.aag.org/galleries/nalcs/CH12.pdf.

APPENDIX E
WORKGROUP RECOMMENDATIONS

Each of the four work groups developed position statements and recommendations for their topics. Most of this material, including all of Workgroup 1's products, was integrated into the main text or appear in Appendix E as responses to specific Science Advisory Board (SAB) and NRC recommendations. Other recommendations are presented here.

WORKGROUP 2

Review of the existing Ecological Risk Assessment (ERA) guidance leads to the following conclusions:

While general in nature, there is a sufficient body of guidance on the process for conducting ERAs; while there can be improvement on specific aspects of the process.

A notable area of insufficient guidance is ecological risk communication. This topic area is viewed to overlap with stakeholder involvement in the there is a need to effectively communicate with stakeholders (including the public) on issues related to the risk assessment itself (process and methodologies) but also the risk characterization and ultimately the risk management decisions.

A second area which guidance is lacking is data quality objectives (DQOs) and quality assurance/quality control (QA/QC). There is Agency guidance on DQO process and requirements for the development of investigation objectives and design. While the DQO guidance which exists, if followed, should result in improved problem formulation; guidance translating DQO guidance into a format specific to the ERA process would facilitate conducting ERAs. With respect to QA/QC issues there is limited guidance on handling data (typically only chemical data) within a risk assessment; and given data quality limitations, how the data may be used within a risk assessment. However, guidance on QA/QC directly related to biological/ecological data, in ERAs, was not evident in the documents reviewed.

There is a continuing need for development and improvement of hazard assessment/toxicological data bases and guidance. Of notable absence is the lack of toxicity data on reptiles and amphibians. The chemical risk data base for other organisms is also lacking in many areas and/or the quality of the data is questionable. Data bases/guidance on other stressors may also be insufficient.

Risk integration was noted as being having limited guidance and the guidance developed largely focuses on human health risk assessment. Guidance needs in this are could include how and when hazard quotients may be defensibly combined in the risk characterization, or how to combine risks from multiple stressors.

There will be a need for additional stressor specific risk guidance; nanotechnology was called out as an example.

Receptor specific risk guidance was also noted as limited. As presented above, reptile and amphibian toxicity guidance is notably lacking however there are significant limitations on available toxicological data for all organism groups for many stressors (toxicants).

The review of the Agency guidance on ERA and ERA related documents does demonstrate that there is an uneven distribution of program-specific guidance. While this may be an artifact of the utilization of the Agency-wide guidance; the observation may warrant further evaluation.

WORKGROUP 3

Identify potential linkages between assessments in different programs and create a mechanism for creating them. Although contaminants move among media and receptors, a lack of integration across media and contaminant specific assessments can result in unintended consequences. Means to address this problem potentially include:

- Representation of other programs during Problem Formulations
- A standing interprogram liaison group
- Standard links
- Make a "regulatory LCA" part of the problem formulation
- Create an Agency ERA committee to determine how to make links
    - Create a linkage diagram

Create interest groups for ecological assessors
The Nanometers and ERAF are models

Create avenues for interagency data sharing
Office of Science and Technology Policy should lead?

Create means to routinely share methods and tools across regions and programs
Simple tools e.g., check lists, boiler plate
Common problems such as endangered species consultations

We want new laws!

Develop RAF guidelines for fully integrated framework to facilitate communication and clarify tasks

WORKGROUP 4

Initial Investigative Priorities

- Biomarker and mechanistic data in exposures assessment
- Consideration of ongoing global change processes and indirect effects at different scales as part of risk
- Interface between risk assessment and monitoring programs
- Tools for cumulative risk from multiple stressors
- Methods for Ecosystem services

Initial Implementation Priorities

- Explore adaptive management with iterative triggers for risk assessment and risk management to deal with uncertainties
- Beneficial ecological consequences from risk management decisions
- Life cycle analysis for product safety evaluations
- Promote dialogue between RA/RM through post decision auditing and monitoring to develop standards of practice
- Characterize and communicate uncertainty in all key computational steps of RA

RECOMMENDATIONS FROM PRECOLLOQUIUM INTERVIEWS

Aspects of the Process that Could be Strengthened

Largest dilemma is how to define "protective." E.g., protect population or community? Industry often wants community-level protection because it takes longer and the results are ambiguous.

Problem formulation is weak because there are poorly defined assessment endpoints and often no decision criteria. Also, there is a sense that there is just too much paper and information to manage. In some cases, problem formulation becomes an assessment in itself, but without the rigor or protocols to guide the process.

Cost analysis considers only crop and property damage, not socioeconomic costs or environmental justice issues or costs incurred to comply with statutes other than the Federal Insecticide, Fungicide and Rodenticide Act.

Coordination and harmonize assessment practices so that all laws are met.

Suggestions for Assuring that Scientific Information Informs and Improves Decision-Making

Need a forum for RA's with negative results. This serves several purposes. The cases help to illustrate that these results do occur and that helps to build confidence when others determine similar results. For archival purposes, the RA should be recorded if at a later date new science suggests otherwise. Also, sharing these decisions increases the sharing of knowledge. Compare our processes with Canada and the Park Service to get ideas.

Need Eco-Risk training course for Superfund and hazardous waste sites. New generation does not have the hard learned experience. Current training emphasizes human health and eco-risk is glossed over.

Web sites need to be improved so that it will be easier to access and search for information.

Benchmarks are needed for pesticides and pharmaceuticals and personal care products.

Decision tools need to bridge the perceived disconnect between human health and ecosystem health.

Guidance

The 1998 *Guidelines for Ecological Risk Assessment* are good for site specific assessments, but less satisfactory for national assessments that have so many assessment endpoints, sources, and geographic variability.

- Additional development of predictive models for additional chemical classes is needed.
- Not adequate for nano materials.
- New chemicals assessment procedures could be published as an integrated document.

There is a need for guidance on Ecological Systems Risk rather than species. This might include functions, species dependence, and movement of stressor through ecosystems. This could begin with development of conceptual models and then improving basic scientific understanding through testing resulting in guidance to inform decision-making using that information.

- Guidance before developing criteria to establish causal relationship
- It would be helpful to have a single document describing the roles of different agencies.
- It would be helpful if there were a framework or guidance for developing environmental policy and environmental vision for the Agency.
- It would also be helpful to have guidance for determining emerging issues and for identifying questions that need to be answered as a concerted effort of an Agency rather than separate activities.

Communication Tools

How do we make uncertainties less influential? How do we explain that directionally correct tightening of a standard may still result in a loss of the resource if the protection?

Improve communication by providing a list of who is doing what, congruent offices in Regions because now they all have different nomenclature and structure and it is hard to find other experts.

Decision Tools

Greater accessibility or authority to require data would help inform decisions s not enough?

Other

Compare our processes with Canada and the Park Service to get ideas.

APPENDIX F
NOTES FROM THE CLOSING SESSION

The following notes represent highlights from the plenary discussion in the last few hours of the Colloquium. They are not prioritized or otherwise ordered or sequenced. Names of speakers have been deleted.

Eco-risk communication needs to be developed. A workshop or research of methods for effective eco-risk communication may be a mechanism to do this. Outside experts in communication could be brought in to train or help us craft the products. Different groups need different communication tactics.

RAF could focus on "state of the science" papers. It was felt that a workshop would be a productive way to collect the information for the paper as NGO's, industry, and academia could all be involved.

State-of-science papers that integrate eco and human health should be preferred. Some topics may be of interest to both groups and these would be good ones to focus on initially and would help us build rapport with the human health folks.

EPA relies on contractor support to the detriment of training internal people to be experts in fields. We need to think about our current skill mix and where we need to be in 5 years.

Important to mentor new employees so that they can learn the Agency, history, and useful skill sets.

Workshops and forums for new EPA employees could be a good mechanism for them to learn what is going on at the Agency. These are much more informative than reading guidance.

Interagency coordination and communication on eco issues are necessary.

It is hard to figure out who is doing what at the EPA. We need better communication across EPA program offices.

We need to simplify the terms we use when we are communicating with each other and the public. "Ecosystem Services" does not make much sense to most people. Saying things like "we have found that if we protect ecosystems, human health will improve" is comprehensible to almost everyone. Essentially, we could use phrases like these to raise the importance of eco in people's minds.

At the beginning of the risk assessment process, we should set criteria so you can know how you are going to make your decision (RAF could aid in this effort).

RAF is here to help documents through the onerous Agency review process. Half-finished self-started efforts can be identified and brought to the RAF to help them along the rest of the way.

A lot of guidance in programs never gets finalized and published because is hard to get through peer review and clearance. The Forum exists for getting documents out, reviewed, and cleared. The Forum can do that for you if you have Agency-wide or multiprogram significance.

So far, the idea of throwing more science at ecological problems hasn't worked as well as hoped. Someone has to say, take ecological effects more seriously. Office and Division directors would be especially good targets for the message because they are the career professionals who have a major influence over EPA's path.

The water program is taking ecological issues seriously. Your water bill is 2/3 is sewer charges to treat conventional pollutants, and that is all eco. So, society is actually spending money on eco protection. The attention to ecology depends on the program. Don't be wining.

We need an ecological liaison in the Administrator's office so that we can convey that ecological endpoints that are meaningful. This is critical.

We need to emphasize risk communication and think outside the box. We don't do research in sociology and environmental economics.

The STPC has no official eco risk group. We need some kind of unifying body at top of agency. There needs to be a cross-agency body that has people with right expertise on it to make decisions on eco issues.

RAF can focus on state of science rather than guidance. Extremely useful to have papers on where we are on these things to allow program offices to trigger only see where going, small things that can be implemented. Guidance is 5 years away. Program office and regions love to see state of science on all those issues. May not be able to deal with all uncertainty, challenge, see state of science and move that piece along.

We need to change the business model. Managers should be asking question, how are we dealing with eco risk in this project? Many managers believe that if they take care of human health issues, eco issues are being addressed at the same time. Needs to be a mind change within managers to consistently ask—are we dealing with ecological risk? Training for managers could be useful but better to make them accountable. Make it a critical job element.

Our field is so complex that need to be familiar with—someone working in regional office, work under someone? Spend some time in OW or work in ORD so understand resources tools, apprenticeship type program. Maybe pick from several categories. Would love to know more about X, Y, Z. would be helpful.

When things became concrete, then people get it. Make useful guidance by pulling together documents that exist. Then you need good examples.

In the late 60s and 70s bathing beaches on Lake Erie were closed by alewife die offs. There was not a communication problem. The impetus wasn't from within the Agency. It was external to bring resources to bear. Did the Agency ever tell the stories of where we were and get credit for those good things that have occurred. It would be worth the effort to try a history of where our environment stood in 1960s and where we are now.

I have been starving for a forum like this since I started 5 years ago. I have learned more last 3 days than last 5 years. There is no motivation to read guidelines. This is where the pieces are put together. I wished we had more venues like this, encourage new scientists to learn about the Agency, where it has been, where it is going and issues are on the table. We need to have more things like this annual/semiannual to get new employees, middle management and older folks who think they know everything to get together.

Guidelines are open-ended by necessity because they are applied so many different ways. Case studies are ultimately way more helpful. Getting together to hear someone else's good ideas is super helpful.

Other agencies are doing ERA. We should do better job coordinating with other federal agencies.

We need to clearly defining critical terms at the beginning when meeting with stakeholders, and risk managers. What is adverse or protective? Define criteria for how the decision will be made and know what information to provide.

If you want to have any legacy, develop professional networks to really look at what need to do and not just look at as a crush of work.

The STPC and RAF hear from senior and more experienced staff. They need to hear from the younger staff as well.