Recommended Actions to Improve U.S. EPA Ecological Risk Assessment Practices

March 2019

Risk Assessment Forum

U.S. Environmental Protection Agency
Washington, DC

Table of Contents

List of Abbreviations
Authors

1. SUMMARY OF RECOMENDATIONS

2. INTRODUCTION
2.1 Risk Assessment Forum and Ecological Oversight Committee
2.2 Purpose and Organization of this Report

3. TECHNICAL PANEL
3.1 Purpose of the Technical Panel
3.2 Selection and Composition of the Technical Panel
3.3 Panel Activities

4. SURVEY OF EPA ECOLOGICAL ASSESSORS AND MANAGERS
4.1 Purpose of the Survey
4.2 Scope of Survey
4.3 Summary of Process
4.4 Summary of Results

5. COLLOQUIUM ON ECOLOGICAL RISK ASSESSMENT PRIORITIES
5.1 Overview and Purpose
5.2 Pre-Colloquium Discussion Paper
5.3 Colloquium Organization and Participation
5.4 Recommendations from the Colloquium

6. PROCESS FOR DETERMINING PRIORITIES FOR IMPROVING ERA PRACTICE
6.1 Information Considered
6.2 Developing Consensus Priorities

7. RECOMMENDED ACTIONS FOR IMPROVING ERA PRACTICE
7.1 Ranking of ERA Panel Priorities by the Panel
7.2 Topical Area Priorities

8. NEXT STEPS

9. REFEREENCES

APPENDIX A Timeline of Ecological Risk Assessment Milestones in the Risk Assessment Forum

APPENDIX B Pre-Colloquium Discussion Paper Summary of Recommendations

ED_002682_00245683-00002

List of Abbreviations

ERA – ecological risk assessment
RAF – Risk Assessment Forum
EOC – RAF Ecological Oversight Committee
CERCLA – Comprehensive Environmental Response, Compensation, & Liability Act (Superfund)
RCRA – Resource Conservation and Recovery Act
CWA – Clean Water Act

EPA Technical Panel Members and Authors

Catherine Aubee	Risk Characterization	Office of Pesticide Programs
Mace Barron	Panel Co-Chair	Office of Research and Development
Christine Davis	Problem Formulation	Office of Air and Radiation
Bruce Duncan, Ret.	Panel Co-Chair	Region 10
Karen Eisenreich	Toxic Effects Assessment	Office of Pollution Prevention and Toxics
Kristina Garber	Exposure Assessment	Office of Pesticide Programs
Kathryn Gallagher	Toxic Effects Assessment	Office of Water
Tara Greaver	Risk Characterization	Office of Research and Development
Wade Lehmann	Exposure Assessment	Region 4
Lawrence Martin	RAF Science Coordinator	Office of the Science Advisor
Wayne Munns	Problem Formulation	Office of Research and Development
Mary Reiley	Risk Communication	Office of Water
Kristin Riha	Risk Communication	Office of Air and Radiation
Glenn Suter II, Ret.	Integration and Synthesis	Office of Research and Development

ED_002682_00245683-00003

1. SUMMARY OF RECOMMENDATIONS

These recommendations are an interim product of the Risk Assessment Forum (RAF) Technical Panel on Developing a 5-year Action Plan for Ecological Risk Assessment (Panel). The Panel's charge was to develop a 5-year action plan for improving ecological risk assessment (ERA) practice within the EPA. These recommendations are provided for internal EPA and external review. Comments received on these recommendations will be used to finalize the 5-year Plan. The preparation of these recommendations followed from a cross-EPA survey of eco-assessors, and a colloquium of ERA practitioners and risk managers within the EPA. The Panel's recommended actions include:

- Create and host an EcoRisk Portal (*highest priority*). The portal would be a single website organizing all Agency ERA guidance, tools, and case studies to facilitate access and ease of use. Expected outcomes include increased efficiency and consistency in ERA practice by providing single source access to models, methods and other tools such as on-line training.

Commented [Anon1]: OCSPP supports the concept of the EcoRisk Portal;

- Develop tools to support ERA at the EPA (*medium priority*). Illustrative is the demand for ecotoxicity benchmarks. An outcome of this tool would be reduced redundancy and inconsistency in benchmark development by providing IRIS-equivalent toxicity values for ERA.

- Develop training modules on ERA practice (*medium priority*). Training would target a range of EPA ecological risk assessors, from those new to EPA to those seeking more specialized training in advanced ERA practices. Expected outcomes would include greater proficiency and consistency in applying ERA guidance and informing risk management decisions.

- Develop essential Agency guidance (*lower priority*). Development of RAF guidance documents and white papers would focus on only the highest priority needs for cross-Agency guidance and address the most significant cross-Agency needs.

The Panel recommends these activities for inclusion in a 5-year ERA action plan for the RAF. The topical areas identified as the highest priority for action by the Panel include uncertainty and confidence, communication of results, and systematic review.

2. INTRODUCTION

2.1 Risk Assessment Forum and Ecological Oversight Committee

The RAF, created in 1988, is a standing committee of senior EPA scientists supported by the EPA Office of the Science Advisor. The RAF was established to promote Agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate EPA risk assessment guidance. The RAF facilitates the sharing of risk assessment knowledge and approaches while harmonizing EPA risk assessment practices.

ED_002682_00245683-00004

The RAF brings together experts from across EPA to study and report on risk assessment issues from an Agency-wide scientific perspective, thus continually enhancing the Agency's approach to risk assessment. The RAF provides the means for the EPA to consistently address key aspects of risk assessments and to achieve clarity and transparency in the risk assessment findings that inform Agency decisions (RAF 2016).

The Ecological Oversight Committee (EOC) within the RAF is responsible for direction and scientific quality of ERA focused products. The EOC organizes and leads the RAF's oversight of ERA technical workgroups, including review and approval of project charges, workplans, and products. The EOC has been instrumental in convening colloquia and workshops, and in developing work products such as frameworks, issue papers, guidelines, reviews of progress in ERA, and action plans (Attachment A).

2.2 Purpose and Organization of this Report

The purpose of this report is to provide recommendations to improve ERA practices within EPA for internal EPA and external review by states and tribes. These recommendations and consideration of comments will form the basis for a 5-year action plan for the EOC. The recommendations are based on input from a technical panel of topic experts, a survey of Agency ecological risk assessors, a 2018 colloquium, and a prioritization process following the colloquium (Section 6).

The report is organized to describe the steps followed in developing the Panel's consensus priorities for ecological risk assessment practice:

- Section 3 describes the formation, purpose, selection, composition, and activities of the technical panel established by the EOC to develop recommended actions for improving ERA practice within EPA.
- Section 4 summarizes the 2017 survey of EPA ecological assessors and managers used to determine cross-Agency priorities for improving ERA practice.
- Section 5 describes the 2018 colloquium that was convened to bring together eco-assessors and managers from across EPA to discuss and develop recommendations for improving ERA practice.
- Section 6 summarizes the consensus priority recommendations of the technical panel.
- Section 7 presents next steps for review and approval of the panel's recommendations.

3. TECHNICAL PANEL

3.1 Purpose of the Technical Panel

The Science Technology Policy Council (STPC) charged the RAF Technical Panel to develop a 5-yr Action Plan for Ecological Risk Assessment on June 30, 2017. The charge included four components (RAF 2017):

ED_002682_00245683-00005

- Develop an ERA priorities discussion paper that summarizes responses to a survey of EPA risk assessors as to what they perceive to be the needs and opportunities in the context of current Ecological Risk Assessment methods and risk management requirements, as well as recommendations from recent RAF reports and guidance.
- Convene a colloquium of Agency ecological risk assessors and risk managers to discuss personal and programmatic experiences and current science, leading to proceedings with summary list of high, medium & low priority focus areas to advance ecological risk assessment.
- Engage EPA stakeholders, including states and tribes, to inform priorities.
- Propose a five-year ERA action plan reflecting knowledge and perspectives gained from the colloquium and EPA stakeholders.

3.2 Selection and Composition of the Technical Panel
The members of the technical panel were nominated to ensure that the necessary technical expertise and cross Agency program and regional perspectives were represented. The selection was made by the EOC and approved by the RAF Steering Committee.

3.3 Panel activities
The RAF Technical Panel on Developing a 5-yr Action Plan for Ecological Risk Assessment conducted a survey of EPA ecological risk assessors and managers, discussed in section 4. The findings from the survey were used in the development of a pre-colloquium discussion paper described in section 5.2. The Panel formed a Colloquium Agenda Committee that used the discussion paper as a framework for the Colloquium Agenda (see section 5). The Colloquium was held September 25 and 26, 2018. The Panel provided comments on the Colloquium Report (sec. 5.4) and contributed to the preparation of this draft ERA Priorities Recommendations Report.

4. SURVEY OF EPA ECOLOGICAL ASSESSORS AND MANAGERS

4.1 Purpose of the Survey
In 2017, the Panel was tasked to develop a survey to obtain input from ecological risk assessors. The survey was sent to a broad cross-section of EPA staff and managers who had experience with ecological risk assessment. The survey sought information on their practice areas, program needs and/or priorities, and potential participation in a colloquium to identify priority areas to advance risk assessment.

4.2 Scope of Survey
A sub-group of the Panel (workgroup) identified contacts in EPA program offices and regions with ecological risk assessment responsibilities, as well as other offices with substantive ecological science responsibilities. These contacts identified additional staff and managers who were likely to have a perspective on ecological risk assessment. A list of 400 eco-assessors and

ED_002682_00245683-00006

managers was ultimately identified based on previous colloquium contact lists, Ecological Risk Assessment Forum members, and input from RAF members for initial outreach.

The Panel workgroup developed a series of questions that were reviewed, revised and approved by the Panel. A survey was then created through Survey Monkey (surveymonkey.com) to reach out to prospective respondents. The survey had two categories of questions:

- Questions with "check boxes" (i.e., no detailed comments to be provided by the respondent) relating to general inquiries regarding when and where to hold the colloquium, respondents' respective expertise levels, and interest in attending the colloquium in person or remotely, and
- Questions with optional "response boxes" (i.e., an opportunity to submit detailed comments) inquiring about priority needs.

4.3 Summary of Process

The survey was sent out in December 2017. The survey introduction described its purpose and requested that anyone who thought they had received it erroneously to request to be removed from the list. A subsequent scrub of the list to remove those who indicated that preference, along with those who had moved or retired, provided a final number of 368. A second invitation to take the survey was sent to the final list.

4.4 Summary of Results

Responses were received anonymously from a total of 123 EPA employees, for an overall response rate of 33% (RAF 2018a). Most survey respondents identified themselves as risk assessors who work with the CERCLA, RCRA or the CWA statutes and use risk assessments for site/remedial and water quality/chemical criteria investigations. Stakeholders in ecological risk assessments were identified by respondents as staff from state/local governments, other Federal agencies, industry, the public, communities, tribes, and EPA product managers. The major challenges identified by respondents were resources (both in terms of funding and FTE) and tight deadlines (RAF 2018a).

Additional challenges were identified in all phases of risk assessment, as follows:

Integrated Problem Formulation/Scoping/Planning

- Understanding stakeholders' needs and expectations
- Conceptual models are not sufficiently useful or relevant
- Terrestrial risks are difficult to address in ecological risk assessment

Exposure Characterization

- Distinguishing exposure processes in different ecosystems and at different spatial and temporal scales; extrapolating local data to national-scale assessments and relating national scale results to local concerns
- Addressing bioavailability
- Updated tools and guidance are needed for exposure modeling

ED_002682_00245683-00007

Effects Characterization

- Biota sampling needs encouragement to use, and guidance on how to use the results in ERA
- Extrapolation of test data to other species and levels of organization
- Exposure-response modeling versus benchmark values
- Develop standard toxicological benchmark values
- Use of suborganismal and mechanistic data and application of Adverse Outcome Pathways

Risk Characterization

- Using field effects data including causality and confounding factors
- Cumulative risk characterization
- Quantification in risk characterization beyond risk quotients

Risk Communication

- Appropriate simplification of ERA for communication with non-technical audiences
- Explaining the nature and importance of ecological effects including ecosystem services
- Data visualization methods and tools

When presented with technical topics from the previous colloquium and asked which topics the RAF should develop, many respondents identified the following topics as highest priority: mixtures and multiple stressors; cumulative risk; new data types or methods; and adaptive management. Respondents indicated that these challenges could be met in a variety of ways such as documenting best practices, training, decision support tools, case studies, new or revised guidance, and/or white papers.

The results of the survey were used to design the Colloquium Agenda (Section 5.1) and as the primary input to the pre-colloquium Discussion Paper (Section 5.2).

5. COLLOQUIUM ON ECOLOGICAL RISK ASSESSMENT PRIORITIES

5.1 Overview and Purpose

The Intra-Agency Colloquium was convened by the Panel on September 25 and 26, 2018, at EPA's Potomac Yards facility in Alexandria, Virginia. The RAF has previously used colloquia successfully to identify priority project needs in ecological risk assessment in 1999 and 2007. The second colloquium in 2007 addressed EPA Science Advisory Board (SAB 2008) and National Research Council (NRC 2009) recommendations for advancing risk assessment (USEPA 2010). Each of these colloquia led to the development of high priority products, including white papers and EPA guidance on ERA practice across the EPA (Attachment A).

The purpose of this third Colloquium on Ecological Risk Assessment Priorities was to bring together ecological assessors and risk managers from across EPA to review the state of

ED_002682_00245683-00008

ecological risk assessment, and to recommend actions to improve ecological risk assessment practices within the EPA.

5.2 Pre-Colloquium Discussion Paper

A pre-colloquium Discussion Paper (RAF 2018) was developed by a Panel Workgroup as orientation material for participants in advance of the colloquium. The Discussion Paper used the results of the Survey (Section 4) and Panel members' expertise to provide information for deliberation prior to and during discussion at the colloquium. The Discussion Paper was organized by the four components of risk assessment as intended discussion topics: planning and problem formulation, analysis of exposure, analysis of effects, and risk characterization. An additional section addressed ecological risk communication as a cross-cutting issue for assessors, including engagement with decision makers and stakeholders. This pre-colloquium paper served as a roadmap for discussion of ERA priorities at the Colloquium and included a preliminary list of potential priorities for consideration by the participants (for summary, see appendix B).

5.3 Colloquium Organization and Participation

The Colloquium was organized around the components of the ecological risk assessment paradigm and the pre-colloquium Discussion Paper, with five sequential sessions of Planning and Problem Formulation, Exposure Characterization, Effects Characterization, Risk Characterization, and Risk Communication (RAF 2019b). Each session was facilitated by technical panel topic leads and other identified EPA experts (RAF 2019b).

Invitations to the Colloquium were sent to all members of the survey list, as well as additional risk managers and senior leaders within EPA. Participants in the Colloquium included 30 in person attendees, and 26 remote access, and included eco-assessors from eight EPA Regions, and seven EPA program offices.

5.4 Recommendations from the Colloquium

A short list of potential priority actions to improve ecological risk assessment within EPA were determined from each of the five colloquium sessions. The list of potential priority actions was then refined through a multi-voting and consensus building exercise (RAF 2019b). A final report of the Colloquium on Ecological Risk Assessment Priorities was developed to capture participants' recommendations for improving ERA practice across EPA. Rank order priorities included methods for uncertainty analysis, guidance and best practices for extrapolation, best practices for quality review of field studies, incorporation of ecosystem services into ERA tools, a tools compendium website, systematic review of studies, and supplementation of the Registry of EPA Applications, Models, and Data Warehouses[1] (READ) (RAF 2019b).

[1] [HYPERLINK "https://ofmpub.epa.gov/sor_internet/registry/systmreg/searchandretrieve/basic/search.do"]

ED_002682_00245683-00009

6. PROCESS FOR DETERMINING PRIORITIES FOR IMPROVING ERA PRACTICE

6.1 Information Considered

The information considered by the Panel in determining priorities for improving ERA practice included:

- deliberations among the Panel members and the initial shortlist of potential priorities documented in the pre-colloquium Discussion Paper (RAF 2018; see Section 5.2)
- results of the survey of the Agency's ecological assessors (see Section 4.4)
- recommendations of needs and actions from the participants of the Colloquium on Ecological Risk Assessment Priorities (RAF 2019; see Section 5.4).

6.2 Developing Consensus Priorities

Consensus priorities were determined through a synthesis of information and Panel balloting. The first step was to develop an overall synopsis of priorities from a review and synthesis of the survey results, pre-colloquium Discussion paper, and colloquium recommendations. Based on a synthesis of this information, four priority areas were posed to the Panel for balloting: (a) Compile tools and resources in a useful manner, (b) Develop and provide training modules, (c) Develop tools for ecological risk assessment, and (d) Develop RAF guidelines and white papers.

Each Panel member was asked to rank the four priority areas, and also rate specific topics within the guidance and white paper development category as low, medium, or high. Following the panel balloting, the results were rank ordered by the number votes cast for each of the four priority areas. Summary results were then shared within the Panel to confirm that a consensus on priorities had been reached. Finally, a list of priority recommendations was determined from the consensus priorities (Section 7.2).

7. RECOMMENED ACTIONS FOR IMPROVING ERA PRACTICE

7.1 Ranking of ERA Priority Activities by the Panel

The rank order priorities for improving ERA practice recommended by the Panel followed upon discussion of the recommendations from supporting prioritization exercises undertaken in support of the Colloquium, as well as the Colloquium itself, and include the assessors' survey, the colloquium discussions and a Panel exercise to narrow and focus priorities. This subsection focuses on programmatic or "activity" priorities, and subsection 7.2 identifies topical priorities.

The four programmatic strategies ranked in order of priority by the Panel were:

1. Compilation Portal. Many comments and responses pointed to a need for assistance in finding existing guidance, tools and information to perform ecological assessments. Addressing

ED_002682_00245683-00010

this need by assessors would be a new direction for RAF. This initiative requires on-going maintenance and updating to provide a reliable service. The RAF has the capacity to curate the content and to determine how to best organize the material so that it would be useful. (A similar effort is EcoBox[2] which has a lot of potentially useful tools but has not been optimized.) Participants referred to the "portal" as a decision support system or a dashboard. A generic strategy for this that is widely practiced is the expert system. A complementary option identified is a community of practice. An example of such a community of practice at EPA is the Ecological Risk Assessment Forum, one function of which is to connect Superfund site assessors to share technical information.

2. Tool Development. Tools used by EPA risk assessors include models, analytical methods for exposure and toxicity, data tables and other information sources. Risk assessors identified various needs for which tools could be developed to help them be more effective and efficient. The RAF's capacity for tool development is limited by its members' expertise and time availability, and the availability of extramural resources. Additionally, the RAF is not a research organization, and so its role would need be to consistent with its mission. The most prominent need identified for tool development was Agency-determined ecotoxicity benchmarks. Rather than just a compilation of existing screening values and criteria, the ecotoxicity benchmarks would be analogous to EPA's Integrated Risk Information System of human health benchmarks. The ecotoxicity benchmarks could be made site-specific through ERA-specific modification of the toxicity values. An update to exposure models was also noted as a need.

3. Training. Ecological Risk Assessment is a core duty at EPA for which we do not have a formal training program or continuing education requirement. Training would target a range of EPA ecological risk assessors, from those new to EPA to those needing more specialized training in advanced ERA practices. The RAF previously maintained a basic introductory level "Eco-risk Training," for which source materials are retained but which are no longer made available. Other recent RAF guidance on the use of ecosystems services and weight of evidence approaches would lend themselves to trainings and would be relevant to risk assessors of various experience levels.

4. RAF guidelines and white papers. This activity has been the standard product from the RAF since its inception. The implication for this activity now being identified as a lower priority is that ecological risk assessment has become largely standardized and that new guidance is less necessary. A query to the Panel related to this activity was the identification of specific topical areas of greatest interest. These are addressed in Sec. 7.2.

Table 7.1 summarizes recommended actions, rationale and expected outcomes to improve ERA practice within EPA. These recommendations are to be considered for inclusion in a 5-year action plan for the RAF.

---

[2] [HYPERLINK "https://www.epa.gov/ecological-risk-assessments-era"]

ED_002682_00245683-00011

Table 7.1 Summary of Recommended Programmatic Strategies and Actions for Improving ERA Practice		
Recommended Action	**Rationale**	**Expected Outcome**
EcoRisk Portal	Highest overall priority. Facilitate eco-risk assessments by maintaining a single website for accessing all ERA guidance and tools.	Increased efficiency and consistency in Agency ERA practice by providing single source access to ERA guidance and tools.
Tool Development	Medium priority. Improve eco-risk assessments with targeted tool development. A popular suggestion was to establish Agency ecotoxicity benchmarks.	Targeted tool development will assist risk assessors by improving technique. Ecotoxicity benchmarks will reduce redundancy and inconsistency in benchmark development.
Training	Medium priority. Develop training modules for eco-risk assessors to improve capacity for assessments.	Greater proficiency and consistency in applying Agency ERA guidance, and risk management decisions.
Guidelines/ White Papers	Lower priority. Focus only on highest priority needs for cross-Agency guidance	Addresses only the most significant cross-Agency needs for guidance.

7.2 Topical Area Priorities

The Panel identified 15 different topical areas of interest from the various prioritization exercises identified above. They were listed, and Panel members were asked to identify the highest five priorities based upon their understanding of results from the prioritization exercises (see below). The priorities identify topics that risk assessors may need improved ability or capacity. They are not an indication of the Panel's perception of the topical area's importance.

- Stakeholder engagement
- Decision maker engagement
- Conceptual models suited for purpose
- Systematic review, to enable reviews with Agency-wide acceptability
- Uncertainty and confidence
- Temporal and spatial scales
- Trophic transfer and accumulation from various media
- Estimation of ecotoxicity without whole organism testing
- Extrapolation of toxicity test results
- Use of field data to estimate effects
- Cumulative risk

ED_002682_00245683-00012

- Emergent and novel contaminants (e.g., gene drives, microplastics)
- Communication of results to different audiences
- Executive summaries for different audiences
- More information on use of ecosystem services

The results of the Panel's topical area prioritization exercise were binned into three categories of high, medium and low (Table 2). While these topics were associated with the guidelines and white papers activity area, they may also transfer to other activity areas (e.g., training and tools).

Table 2. Priority topical areas for risk assessors

Highest	Medium	Lowest
Uncertainty and confidence	Ecosystem services	Stakeholder engagement
Communication of results	Estimation of ecotoxicity	Decision maker engagement
Systematic review	Temporal and spatial scales	Use of field data to estimate effects

8. NEXT STEPS

The recommended actions will be used to collect comments and serve as the foundation for the RAF Ecological Oversight Committee's 5-year Action Plan. The following steps will guide the process for finalizing the 5-year Action Plan.

- Finalization of *Recommended Actions* by Technical Panel and Ecological Oversight Committee (March 2019)
- Approval of *Recommended Actions* by the RAF for STPC concurrence (March 2019)
- Concurrence by STPC for State and Tribal review, and public comment (March-April 2019)
- Comments from States & Tribes (April-May 2019)
- Revision of *Recommended Actions* into draft 5-Year Action Plan (June-July 2019)
- Concurrence of RAF for STPC concurrence (July-August 2019)
- Concurrence by STPC on the RAF ERA 5-year Action Plan (August-September 2019)

9. REFERENCES

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.

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.

ED_002682_00245683-00013

USEPA (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. U.S. Environmental Protection Agency. Risk Assessment Forum. Washington, DC. EPA/100/R-10/004

RAF (2019) Risk Assessment Forum Colloquium on Ecological Risk Assessment Priorities. *Internal Deliberative Draft*

RAF (2018a) Summary of Results from a Survey of Ecological Assessors in the U.S. EPA, Concerning Project Priorities for the Ecological Oversight Committee, Risk Assessment Forum. March 2018. *Internal Deliberative*

RAF (2018b) Risk Assessment Forum Ecological Risk Assessment Priorities: Colloquium Issue Priorities Discussion Paper. Risk Assessment Forum, U.S. Environmental Protection Agency. September 2018. *Internal Deliberative Draft*

RAF (2017) Charge to the RAF Colloquium on Ecological Risk Assessment Priorities Technical Panel Risk Assessment Forum – Ecological Oversight Committee. Month, 2017. *Internal Deliberative*

RAF (2016). United States Environmental Protection Agency Risk Assessment Forum Charter. November 9, 2016. See: [HYPERLINK "https://www.epa.gov/sites/production/files/2016-11/documents/raf_charter_11_9_16.pdf"]

ED_002682_00245683-00014

APPENDIX A

Time Line of Ecological Risk Assessment Milestones in the Risk Assessment Forum

1988 The RAF's efforts in ERA began with Agency staff studying prior efforts, identifying issues and developing principles.

1990 A series of seven workshops were held with Agency and outside experts and representatives of states and federal agencies. The results were published that year in *Summary Report on Issues in Ecological Risk Assessment.*

1991 A 3-day strategic planning workshop of EPA and outside experts was held to provide guidance to the Agency on the development of ERA guidelines. The *Report on the Ecological Risk Assessment Guidelines Strategic Planning Workshop* was published in 1992.

1992 *Framework for Ecological Risk Assessment.* This is the first product in the development of risk assessment guidelines for ecological effects. It provides a simple, flexible structure for conducting and evaluating ecological risk assessment within EPA.

1994 *Ecological Risk Assessment Issue Papers.* Nine issues were identified as needing review before completing the ERA guidelines. Each issue was addressed by an EPA work group, two outside authors, and three external reviewers. The external reviews were published as a separate volume: *Peer Review Workshop Report on Ecological Risk Assessment.*

1998 *Guidelines for Ecological Risk Assessment*. The Guidelines expand on and replace the *Framework* by explaining how to perform each step in the assessment process. This has been a highly influential document, serving as a model for other institutions and for the 2014 framework for human health risk assessment.

1999 First ERA colloquium. It developed priorities for RAF ecological projects to follow the guidelines. The broad priorities were: effects at higher levels of biological organization, assessment endpoints, and risk characterization methods. Proceedings were not published.

2001 *Workshop Report on the Application of 2,3,7,8-TCDD Toxicity Equivalence Factors to Fish and Wildlife.* Proceedings of an EPA/RAF workshop with participation by Department of Interior scientists.

2004 *Generic Ecological Assessment Endpoints (GEAE) for Ecological Risk Assessment.* Answers the question, what ecological assessment endpoints are supported by Agency policy and precedent?

2006 The Science, Advisory Board's Ecological Oversight Committee (EOC) held a workshop to review progress in ERA since the 1998 guidelines. They submitted a report to the Administrator in 2007.

2007 *Framework for Metals Risk Assessment.* A joint eco and human health document that dealt with metal assessment issues such as naturally occurring levels, mixtures, and speciation. Both chairmen were ecologists.

2009 *Framework for Application of the Toxicity Equivalence Methodology for Polychlorinated Dioxins, Furans, and Biphenyls in Ecological Risk Assessment.* Guidance on how to use TEFs to estimate ecological risks from dioxin-like compounds, organized in terms of the ERA framework.

ED_002682_00245683-00015

2008 *Summary Report: Risk Assessment Forum Technical Workshop on Population-level Ecological Risk Assessment.*

2009 Second ERA colloquium. Held in Potomac Yards, to respond to the EOC's report to the Administrator on ERA in the Agency and the National Research Council's Report *Science and Decisions, Advancing Risk Assessment* and to develop new priorities for the EOC.

2010 *Integrating Ecological Assessment and Decision Making at EPA: A Path Forward.* A report from the 2009 colloquium that responded to SAB and NRC comments, made recommendations for advancing ERA and identified priorities for the EOC.

2013 *RAF Ecological Assessment Action Plan*. A condensed version of the priorities of EOC activities with 5 high priorities.

2014 *Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies*. This document is a product of a RAF-wide project that had an ecologist as co-lead. It is an example of a review of best practices and case studies rather than guidance.

2016 *Ecosystem Services as Assessment Endpoints in Ecological Risk Assessment, Technical Background Paper.* Not official guidance, but in in practice it guides assessors through the application of ecosystem services to ERA.

2016 *Generic Ecological Assessment Endpoints (GEAEs) For Ecological Risk Assessment: Second Edition with Generic Ecosystem Services Endpoints Added.* An update of the 2004 document with ecosystem services endpoints added to the conventional ecological endpoints.

2016 *Expanding the Use of Ecological Risk Assessment in Agency Decision Making: Guidance, Training, Outreach.* Report of a technical panel based on and EOC comment, comments from the 2009 colloquium participants about the difficulty of engaging with decision-makers about ecological risks and a subsequent survey on assessor-manager communication.

2016 *Weight of Evidence in Ecological Assessment.* A guidelines document for assembling, weighting and weighing multiple pieces and types of evidence in ecological assessments.

ED_002682_00245683-00016

APPENDIX B

Pre-Colloquium Discussion Paper Summary of Recommendations

Planning & Problem Formulation

Planning involves consultation with decision makers and potentially with stakeholders to ensure that the assessment will meet the decision maker's needs. Problem formulation generates hypotheses about the agents being assessed, the effects of concern, and the processes by which exposure and effects may occur. Based on pre-colloquium survey results, the Panel recommends four activities for consideration as future EOC priority projects associated with planning and problem formulation:

- A compendium of best practice descriptions and case study illustrations of approaches for interactions with non-assessors during assessment planning.
- Enhanced guidance on conceptual model development focusing on model content, level of detail, geographic scope, and level of effort.
- Enhanced guidance for linking ecological endpoints to human health and well-being.
- Guidance for identifying and resolving information needs identified during problem formulation.

Exposure Assessment

More than fifty percent of the respondents to the ecological assessor survey identified exposure characterization as a key area to be addressed by the RAF. Exposure assessment analyzes the processes from release of an agent to exposure of endpoint entities. As the cornerstone of ecological assessments, defining exposure can direct the ongoing focus of assessments. Identifying lack of exposure is a critical stopping point in the process. Other priorities included:

- Training was a high priority in survey results for exposure analysis.
- Updating tools and guidance for exposure modeling.
- Distinguishing exposure processes in different ecosystems (aquatic, sediment, riparian, terrestrial and their intersections) and at different spatial and temporal scales.
- Extrapolating local data to large scale assessments and relating large scale results to local concerns.

Toxics Effects Assessment

Effects assessment analyzes the relationship between exposure and effects. The major suggestions from the RAF survey of ecological assessors were:

- Use of field data
- Extrapolation of lab test data
- Exposure-response modeling
- Use of sub-organismal effects data

ED_002682_00245683-00017

- Development of standard benchmark values

Risk Characterization

Risk characterization is the phase in ERA in which exposure and exposure-response information are combined to estimate risks. It may weigh estimates from multiple approaches and combine risk estimates for multiple stressors. Finally, it provides and expression of confidence in the results. Major issues identified from the survey are characterization of:

- uncertainty and confidence
- risks based on effects in the field
- cumulative risks
- risks from novel stressors
- risk quantification techniques beyond quotients

Risk Communication

Communication of ecological risks poses different challenges from human health risk communication. While the audience for HHRA knows what cancer or asthma is and understands their importance, the various measures of biodiversity are likely to be unfamiliar and unappreciated. The respondents to the cross-EPA survey of ecological assessors expressed many concerns about communication with both decision makers and stakeholders.

Major Cross-Cutting Themes

Certain themes, which were important to many of the survey respondents and were mentioned with respect to multiple topics, are important to the entire ERA process. They cut across the entire process, not just a single step as discussed in the preceding topics. This cross-cutting property implies added importance and potentially higher priority. It also implies that a project addressing these issues must include experts in all phases of ERA.

- **Cumulative Risk.** Cumulative risks result from exposure to chemical mixtures or to simultaneous exposure to chemicals and other agents.
- **Confidence and Uncertainty.** Uncertainty in the risk estimates and confidence in the qualitative and quantitative results are reported in the risk characterization, but they must be determined at each step and propagated through the analyses.
- **Engagement and Communication.** Decision makers and stakeholders are engaged with assessors at the beginning and end of the ERA process.
- **Spatial and Temporal Scale.** Scale was particularly emphasized with respect to analysis of exposure, but it is relevant to all steps in the ERA framework. In particular, the appropriate scales must be defined during problem formulation.

ED_002682_00245683-00018

Types of Processes for RAF Projects

Respondents were asked to suggest which of several types of activities the EOC should focus on for the next 3-5 years. Approximately half of the 83 respondents indicated training (53%), best practices (55%), and decision support tools (49%) to be important, whereas fewer thought that the EOC should focus on case studies, new/revised guidance, and white papers. However, in response to the question about "process uncertainties and limitations when conducting eco-assessments" 46% chose guidance and 36% chose training. Several comments expressed a concern that their workload left no time for training or reading guidance.

ED_002682_00245683-00019