

Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) Draft Report (5/9/12) to Assist Meeting Deliberations. Do Not Cite or Quote. This draft report is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered SAB, and does not represent EPA policy.

This draft report contains Committee member edits and comments on the 4/16/12 draft of the SAB EPEC Report on EPA's Ecological Assessment Action Plan.

EPA-SAB-12-xxx

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Review of the EPA's Ecological Assessment Action Plan

Dear Administrator Jackson:

The EPA Office of the Science Advisor (OSA) requested that the Science Advisory Board (SAB) review the EPA Risk Assessment Forum's (RAF) draft Ecological Assessment Action Plan titled *Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan (August 11, 2011)*. The Plan sets forth proposed science policy and technical practice initiatives aimed at improving the quality, scope, and application of the EPA's ecological assessments. The Plan was developed in response to a 2007 EPA Science Advisory Board (SAB) Report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision-Making* and a 2009 National Research Council (NRC) report, *Science and Decisions: Advancing Risk Assessment*. To develop the Plan, the Risk Assessment Forum convened an intra-agency colloquium that included ecologists from across the EPA. The initiatives in the Plan address recommendations in the 2010 EPA colloquium report, *Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward*.

The science policy initiatives in the Plan focus on: (1) developing a systems approach to ecological assessment that integrates multiple media, endpoints, and types of assessments; (2) developing weight of evidence as an option for inference in ecological assessments; (3) improving communication of ecological assessment issues and results; (4) incorporating ecosystem services into ecological risk assessment methods; (5) using adaptive management for testing and revising risk management actions; and (6) strengthening the EPA's ecological protection goals. Other specific technical practice initiatives in the Plan focus on the need for improvements in: training, quality assurance, guidance to address multiple and specific receptors, life cycle evaluations, uncertainty analysis, and access to information.

In response to the OSA's request, the SAB Ecological Processes and Effects Committee, augmented with additional experts, met by teleconference on February 22-23, 2012 to review the Plan. The OSA requested that the SAB comment on the technical merit of the initiatives outlined in the Plan and provide advice on how the Plan could be further developed and implemented. The enclosed report provides the consensus advice and recommendations of the SAB.

1
2 The SAB finds that the initiatives in the Plan are responsive to previous SAB and NRC
3 recommendations. Moreover, the SAB has not identified any significant omissions in the agency's
4 proposed set of initiatives. The Plan is a solid starting point for the EPA's effort to integrate ecological
5 risk assessment and decision-making. However, the Plan should be developed in greater detail. The SAB
6 finds that three of the initiatives in the Plan have the greatest likelihood of advancing the agency's goals
7 in the near term. These three initiatives are: use of weight-of-evidence approaches in ecological risk
8 assessments; improved communication of ecological assessment issues and results to decision-makers;
9 and incorporation of ecosystem services into ecological risk assessment methods. **The three initiatives**
10 **have not been ranked according to priority.** The SAB provides the following key recommendations for
11 developing and refining the Plan.

Comment [JM1]: Meyer - Clarify that these are not listed in order of priority. I recall that we didn't try to prioritize these.

12
13 • The SAB finds that the Plan is "EPA-centric." The EPA should explore relevant activities of
14 other U.S. agencies involved in resource management and collaborate with those agencies on the
15 integration of ecological risk assessment and decision-making. The EPA should also carefully
16 review related activities occurring in other countries including **Canada, Australia, China and the**
17 **European Union.** In addition, the EPA should obtain input from social scientists. Their
18 perspectives on issues such as sustainability, adaptive management, communication, and
19 environmental justice **would be very helpful improve the Plan.**

Comment [PC2]: Chapman – include Canada.

Comment [JM3]: Meyer – Would it be better to say "would improve the Plan."

20
21 • The SAB recommends that the EPA incorporate probabilistic quantitative approaches such as
22 Bayesian methods into its ecological risk assessments. EPA should develop case studies to
23 illustrate the use of such new approaches because it appears that, in many cases, ecological risk
24 assessment guidance documents have not been highly effective or given substantial attention
25 within the agency.

26
27 • The Plan calls for developing a systems approach to ecological assessment that includes multiple
28 media and endpoints as well as integration of different types of assessments. EPA scientists
29 presented a good preliminary framework for integrated environmental assessment to the SAB.
30 The SAB recommends that this preliminary framework be further developed, and that it address
31 the cumulative effects of multiple stressors in the context of climate change. Ecosystem services
32 endpoints should also be explicitly incorporated into the framework.

33
34 • The Plan calls for developing guidance for weighing and integrating multiple lines of evidence in
35 ecological risk assessments. The scientific merit of using a weight-of-evidence approach is clear.
36 Moreover, successful implementation of the integrated assessment framework will hinge on a
37 weight-of-evidence determination. A scientifically rigorous weight-of-evidence approach must
38 rely on statistically-based decision points. Therefore, the SAB recommends that the EPA develop
39 program-specific guidance that provides statistically-based decision-making frameworks for
40 weighing and integrating multiple lines of evidence in ecological risk assessments.

Comment [WL4]: Landis - The high prioritization of weight of evidence (WoE) in the introductory letter and in the text should be examined more closely. I agree that there should be an overall process to improve the use of quantitative methods in risk assessment and WoE is one of many tools. I have used WoE. In the introductory letter WoE is given a high priority. However, there are other tools that can be even more useful. Qualitative and quantitative meta-analysis has a number of advantages.

41
42 • The Plan calls for developing methods for better communication of ecological assessment issues
43 and results. The SAB supports this initiative and recommends that the scope of the EPA's
44 proposed work in this area be broadened to address better communication performance

1 | throughout all stages and by all participants in the risk assessment/risk management process,
2 | including risk assessors, managers, and key stakeholders. The EPA should also develop
3 | performance standards and success criteria for the communication of ecological assessment
4 | issues and results. The EPA should develop guidance, supporting tools and strategies that can be
5 | adapted to the needs of specific regulatory applications and a range of intended audiences. In
6 | addition, the SAB recommends that the EPA consider obtaining external technical input from
7 | social scientists, ethicists, marketing professionals, and media specialists who have a good
8 | understanding of risk communication and broader environmental concerns.

Comment [BGR/5]: Biddinger - The recommendation needs to emphasize communication at all stages of process as well as by all participants. The added phrase should get it done.

Comment [BGR/6]: Biddinger - This additional sentence brings forward two key recommendations that seem to have been left out.

9 |
10 | • The Plan calls for incorporating ecosystem services into ecological risk assessment methods. The
11 | SAB strongly supports this initiative. The use of ecosystem services endpoints affords the
12 | opportunity to move ecological risk assessment from identifying *what* is at risk to *why* that risk
13 | matters to humans. Although more information is needed to evaluate the potential success of the
14 | EPA's proposed work in this area, the SAB encourages the agency to complete the proposed
15 | ecosystem services white paper and to submit a shorter version to a peer-reviewed publication in
16 | order to make it available to a wider audience. The SAB recommends that EPA assess the role
17 | of ecosystem services information throughout all stages of the ecological risk assessment
18 | process. As well, the SAB supports the Agency's intent to update the current guidance on
19 | Generic Ecosystem Assessment Endpoints and recommends that any updates be a thorough
20 | revision rather than an addendum. The SAB also recommends that the EPA incorporate more
21 | current ecosystem services concepts and definitions into its existing ecosystem assessment
22 | endpoints guidance document. Finally, the SAB recommends that the Agency look to other
23 | federal agencies for operating models of the integration of ecosystem services information into
24 | their management decision processes.

Comment [BGR/7]: Biddinger - I realize that I have made this bullet quite long with these additions so if there is a need to break into two bullets then suggest that break could be to move the text on guidance into a separate bullet.

25 |
26 | • The Plan calls for use of adaptive management as a tool to methodically improve risk
27 | management decisions. The SAB supports the goal of incorporating adaptive management
28 | principles into the agency's risk assessment framework, and recognizes that implementation of
29 | this goal may be difficult given the complexity of consistent and continuous ecosystem
30 | monitoring and evaluation over appropriate time scales.

31 |
32 | • Monitoring and evaluation provide an indication of the efficacy of mitigation actions and
33 | therefore should be incorporated into the EPA's risk management activities. The SAB
34 | recommends that principles of rigorous statistical design be applied in order to implement
35 | effective adaptive management approaches.

Comment [LJ8]: Johnson - This is a critically important point and it should be called out as a separate bullet to make sure it is not lost. Monitoring continues to be the first thing removed from budgets, yet is the underpinnings of good predictions as well as detection of past trends.

36 |
37 | • Finally, to strengthen the EPA's ecological protection goals, the SAB recommends that the
38 | agency's ecological risk assessors develop information and perspectives that will enable them to
39 | communicate more effectively with decision-makers and the public. Clearly, ecosystem health
40 | and human health are bound tightly together, and incorporation of ecosystem services into the
41 | ecological assessment process can strengthen the EPA's ecological protection goals.
42 | Environmental justice is also a useful platform to highlight the relationship of ecosystem
43 | condition to the health of vulnerable human populations.

Comment [WL9]: Landis - The term **ecosystem health** is used in several places. The term ecosystem health is Normative (see Lackey (2001, 2004)) and is not definable as a scientific description. If this is going to be an influential technical document then technical language is preferable.

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1 The SAB appreciates the opportunity to provide advice to EPA on the Ecological Assessment Action
2 Plan. We look forward to receiving the agency's response to this report.

3
4
5 Sincerely,

Comment [JM10]: Meyer – This letter is longer than these usually are. I think it should be cut by a third, i.e., be two pages. We could say less about each bulleted point. I also think the bulleted points that relate to the three topics we say should be the first focus should be the first bullet points (WOE, eco services, improve communications), then others that are more general can follow (e.g., that the Plan is EPA centric).

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10 Enclosure
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**U.S. Environmental Protection Agency
Science Advisory Board (SAB)
Ecological Processes and Effects Committee (EPEC) Augmented for Review of the
Ecological Assessment Action Plan**

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NOTICE

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This report has been written as part of the activities of the EPA Science Advisory Board, a public advisory committee providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. This report has not been reviewed for approval by the agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. Reports of the EPA Science Advisory Board are posted on the EPA Web site at: <http://www.epa.gov/sab>

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1. EXECUTIVE SUMMARY

The Risk Assessment Forum (RAF) in the EPA Office of the Science Advisor (OSA) has developed a draft Ecological Assessment Action Plan titled *Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan (August 11, 2011)*. The draft Ecological Assessment Action Plan (hereafter referred to as the “Plan”) sets forth proposed science policy and technical practice initiatives to improve the quality, scope, and application of the EPA’s ecological assessments. The Plan was developed in response to a 2007 EPA Science Advisory Board (SAB) Report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision-Making* and a 2009 National Research Council (NRC) report, *Science and Decisions: Advancing Risk Assessment*. To address the recommendations in these reports, the RAF convened an intra-agency colloquium to review the EPA’s ecological risk assessment practices and guidance in light of the SAB and NRC advice. The initiatives in the EPA’s Plan correspond to key recommendations in the colloquium report, *Integrating Ecological Assessment and Decision-making at EPA: A Path Forward* (hereafter referred to as the Colloquium Report). The science policy initiatives in the Plan focus on: (1) developing a systems approach to ecological assessment that integrates multiple media, endpoints, and types of assessments; (2) developing weight of evidence as an option for inference in ecological assessments; (3) improving communication of ecological assessment issues and results; (4) incorporating ecosystem services into ecological risk assessment methods; (5) using adaptive management for testing and revising risk management actions; and (6) strengthening the EPA’s ecological protection goals. Other specific technical practice initiatives in the Plan focus on the need for improvements in: training, quality assurance, guidance to address multiple and specific receptors, life cycle evaluations, uncertainty analysis, and access to information.

The EPA Office of the Science Advisor requested that the SAB review the EPA’s Plan and provide advice on the technical merit and implementation of the proposed initiatives. This Executive Summary highlights the findings and recommendations of the SAB in response to the charge questions provided in Appendix A.

Overall Technical Merit of the Proposed Science Policy and Technical Practice Initiatives (Charge Question 1)

The EPA asked the SAB to comment on whether the initiatives in the Plan are responsive to the advice previously provided by SAB and NRC and whether they reflect the most important set of activities needed to advance the application of ecological risk assessment in environmental decision-making.

The science policy and technical practice initiatives proposed in the Plan follow logically from the EPA Colloquium Report and are responsive to the previous SAB and NRC recommendations. Moreover, the SAB has not identified any significant omissions in the proposed set of initiatives. The Plan is a solid starting point for the EPA’s effort to integrate ecological risk assessment and decision-making.

However, the Plan should be developed in more detail (it is only four pages long) and the SAB has provided recommendations for refining and developing it. Presentations from EPA staff provided additional information considered by the SAB in its review of the Plan.

Comment [JM11]: Meyer - I think that we need to make a specific statement about the brevity and lack of detail in the plan and that presentations from EPA staff provided additional information for the SAB evaluation.

1
2 | The Plan appears to be very myopic (i.e., EPA-centric) with ~~little~~ recognition or inclusion of ideas
3 from other U.S. agencies or international agencies that have worked on ecological problems of national
4 and international scope. The EPA should explore relevant activities of other U.S. agencies involved in
5 resource management, including the National Oceanic and Atmospheric Administration (NOAA), U.S.
6 | Forest Service (USFS), ~~and U.S. Geological Survey (USGS)~~, and collaborate with these agencies on the
7 integration of ecological risk assessment and decision-making. The EPA should also carefully review
8 | related activities occurring in other countries, including ~~Canada~~, Australia, China and the European
9 Union. The Plan would also benefit from additional input from social scientists. Their perspectives on
10 issues such as sustainability, adaptive management, communication, and environmental justice would be
11 very helpful.

Comment [JM12]: Meyer - The USGS does not do resource management.

12
13 In developing state of the art approaches for ecological risk assessment, the EPA should incorporate
14 probabilistic quantitative approaches such as Bayesian methods, rather than point estimates. In general,
15 the SAB recommends development of case studies to illustrate these new approaches. The emphasis on
16 generating more guidance documents, at least in their current form, for new approaches merits scrutiny.
17 In many cases it appears that these documents are not highly effective and are not given substantial
18 attention within the agency.

Comment [LJ13]: Johnson - This doesn't seem accurate - point estimates are not the only contrast to probabilistic quantitative approaches.

19
20 In its presentation to the SAB, the EPA also requested advice concerning prioritization of the initiatives
21 in the Plan. The SAB recommends that the EPA address the following three initiatives first because they
22 have the greatest likelihood of advancing the agency's goals in the near term: (1) use of weight-of-
23 evidence approaches in ecological risk assessments; (2) communication of ecological assessment issues
24 and results to decision-makers; and (3) incorporation of ecosystem services into ecological risk
25 | assessment methods. ~~These three initiatives have not been ranked by the SAB according to priority.~~

Comment [JM14]: Meyer - Are we sure about that? I recall Greg Biddinger saying that they were widely used in the regulated community. I am not comfortable with the statement. I think we were critical of how they proposed to organize this document (i.e., we wanted more case studies), and had some concerns about doing it as an addendum to existing guidance rather than revising the entire guidance document.

Comment [JM15]: Meyer - We need to clarify that these are not in priority order. We didn't try to order these.

27 Importance of Developing an Integrated Assessment Approach (Charge Question 2)

28
29 The Plan calls for developing a systems approach to ecological assessment. This approach would
30 include multiple media and endpoints as well as integration of different types of assessments. The EPA
31 asked the SAB to comment on how guidance for an integrated approach might contribute to better
32 decision-making.

33
34 In general, the SAB finds that EPA decision-makers would benefit from using an ecological risk
35 assessment approach that combines multiple assessment types and integrates multiple and varied
36 assessment activities across the agency. EPA presented the framework for such an approach to the SAB.
37 This preliminary framework provides a good approach for integrating different components of the risk
38 assessment process across the EPA and it should be further developed.

Comment [LJ16]: Johnson - Cormier and Suter 2008 should be cited here. <<DFO note - we generally do not include citations in the executive summaries of SAB reports. The Cormier and Suter article is cited in the body of the report.>>

39
40 A number of key issues should be addressed in implementing the integrated risk assessment approach.
41 First, successful implementation of the integrated assessment framework will hinge on a weight-of-
42 evidence (WOE) determination, and additional guidance on weighing and integrating multiple lines of
43 evidence is needed by EPA risk assessors and managers. Second, implementation of an integrated
44 framework will hinge on the integrity of the data and models used in each of the individual ecological
45 assessment types, and it is not clear whether sufficient data (both quantity and quality) are available to

1 fully implement the framework. Third, in developing the framework, the EPA should address the issues
2 of appropriate spatial and temporal scales of assessments and the cumulative effects of chemical,
3 physical, and biological stressors. In this regard, the EPA should take advantage of multiple stressor
4 research that is being conducted outside of the agency. Fourth, the SAB recommends that each of the
5 assessment processes in the framework be considered in the context of changing climate, and that
6 ecosystem services endpoints be explicitly incorporated. Finally, the SAB strongly encourages the EPA
7 to develop and apply adverse outcome pathway and adaptive management approaches as part of the
8 framework.

Comment [JM17]: Meyer - We need to provide some reference to what we mean here. Where is the work being conducted? Can we provide citations (maybe not here but in the body of the report and refer to that here)?

9 **Use of a Weight-of-Evidence Approach in Ecological Risk Assessments (Charge Question 3)**

11 The Plan calls for developing guidance for weighing multiple lines of evidence (LOE) in ecological risk
12 assessments. The SAB was asked to comment on the scientific merit and limitations of using a ~~weight-~~
13 ~~of-evidence(WOE)~~ approach in decision-making and to offer advice on weighing lines of evidence.

Comment [JM18]: Meyer – I'm not convinced we need these acronyms, but if we introduce them, we should use them.

15 The SAB strongly supports development of guidance for weighing and integrating multiple ~~lines of~~
16 ~~evidence~~LOE in ecological risk assessments. The scientific merit of using a ~~weight-of-evidence (WOE)~~
17 approach is clear as evidenced in the large number of scientific publications on this subject and in the
18 consistent and continuing use of WOE in ecological risk assessment. A scientifically rigorous WOE
19 approach must rely on statistically-based decision ~~points~~ rather than best professional judgment, but this
20 will not be possible without EPA WOE guidance that is program-specific and ideally provides structured
21 decision-making frameworks.

Comment [PC19]: Chapman – Previously defined.

Comment [JM20]: Meyer – Based on the text in the report, I think we are contrasting a statistically based approach with one based on just best professional judgment. I think making that explicit here makes our statement more understandable.

22
23
24 There are a number of challenges inherent in using WOE in ecological risk assessments for decision-
25 making. The EPA has used a WOE approach in the context of human health risk assessment (e.g.,
26 carcinogens and toxicology). However, it seems unlikely that ecological risk assessments are as
27 amenable to formalization as human cancer risk assessments, which have thresholds for mortality and
28 morbidity. Many ecological risk assessments are inherently unique, and a high degree of flexibility to
29 address the nuances associated with a particular assessment will remain desirable for the foreseeable
30 future. WOE approaches have often been based on best professional judgment and have varied widely in
31 their scientific rigor and statistical credibility. Therefore, a consistent approach to interpreting LOE and
32 WOE in ecological risk assessments should be developed. In particular, the SAB recommends
33 development of guidance, with associated case studies, on the use of statistical methods such as
34 Bayesian analysis and causal argumentation to develop hypotheses or risk questions focused on causal
35 relationships and WOE. The case studies should cross the different EPA regulatory programs in which
36 WOE is used.

37
38 In general, the SAB recommends that a comprehensive set of LOE be utilized in the WOE process. The
39 LOE should adequately characterize physical, chemical and biological conditions. This will ensure a
40 cumulative evaluation that considers commonly occurring stressors such as habitat, water flow and
41 nutrients. The weight given to particular LOE is likely to be very case-specific, and quality of the data
42 underlying a particular LOE should factor into the assigned weights. LOE that are clearly linked to
43 ecological population or community attributes should receive greater weights than those that are not.
44
45

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2
3 **Communication of Ecological Assessment Issues and Results to Decision-Makers and**
4 **Stakeholders (Charge Question 4)**
5

6 The Plan calls for development of methods for better communication of ecological assessment issues
7 and results to decision-makers and stakeholders. The SAB was asked to comment on whether the project
8 developed by an RAF Communication Technical Panel is an appropriate approach to address this issue,
9 and to provide observations on why ecological risk assessment has or has not been well incorporated
10 into decision-making.

11
12 The one-page RAF Communication Technical Panel project description indicates that the EPA intends
13 to: (1) gather data through surveys and interviews of EPA risk assessors and decision-makers to explore
14 how ecological risk assessments are used in agency decision-making, and (2) develop guidance for risk
15 assessors and decision-makers on how to better communicate and enable the use of ecological risk
16 assessment information. The SAB supports developing methods for better communication of ecological
17 assessment issues and results. However, the SAB finds that the RAF Communication Technical Panel's
18 approach to data collection is quite general, and the scope of the proposed investigation is somewhat
19 one-directional and narrow (i.e., it is not designed to provide exchange of information about
20 communication issues important to participants involved in each step of the risk assessment and
21 management process). Therefore, as currently described, the project is not likely to achieve the stated
22 goals of promoting full use of ecological risk assessment across EPA Programs and meeting managers'
23 needs for useable ecological risk assessment information to support decisions.

24
25 The SAB recommends that the scope of the RAF Communication Technical Panel project be broadened
26 to focus on improved communication across the entire risk assessment and management process. The
27 project should address better communication performance by all participants including EPA risk
28 assessors and other scientists, managers, and key stakeholders. Communication should be elevated to ~~a~~
29 an essential core activity of the ERA process element with its own performance standards and success
30 criteria. The EPA should conduct a systematic evaluation of the challenges and opportunities for better
31 communication across a range of different decision types. The EPA should also recognize that
32 communication strategies may vary with decision types and target audiences. The RAF project should
33 focus on developing guidance and support tools that can be customized to the need of specific regulatory
34 applications decisions and a range of intended audiences. The report of a recent SAB study, *Science*
35 *Integration for Decision Making at the U.S. Environmental Protection Agency*, provides additional
36 information about the interface between risk assessors and managers and recommendations to address
37 the challenge of bringing science to bear on agency decisions.

38
39 The SAB recommends that, in developing guidance and tools for improved communication, the EPA
40 consider incorporating external technical input from social scientists, ethicists, marketing professionals,
41 and media specialists who have a good understanding of risk communication and broader environmental
42 concerns. The SAB notes that there are many reasons why ecological risk assessment output has not had
43 an optimal impact on decisions. A robust communication process that leads to a clear understanding of
44 the context for the decisions, and how various data or ecological risk analysis improve or support the
45 decision at hand, will lead to better alignment of assessments and decisions.

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Incorporation of Ecosystem Services into Ecological Risk Assessment Methods (Question 5)

The Plan calls for incorporation of ecosystem services endpoints into ecological risk assessment methods. The SAB was asked to comment on whether the project developed by the RAF Ecosystem Services Endpoints Technical Panel captures the full range of opportunities to incorporate ecosystem services into the EPA’s ecological risk assessment methods.

The Plan does not provide much information to indicate how the proposed ecosystem services project will be implemented. It states that an RAF Ecosystem Services Endpoint Technical Panel has been created and expects to produce case studies and guidance on how to relate ecological endpoints to ecosystem services. The Technical Panel’s one-page project description indicates that the following products will be developed: (1) a white paper interpreting conventional measurement and assessment endpoints in the context of ecosystem services; (2) a case study(s) of applying the ecosystem services concept in ecological risk assessment; and (3) an addendum to the RAF Generic Ecosystem Assessment Endpoints guidance (GEAE).

More information is needed to evaluate potential success of the Ecosystem Services Endpoint Technical Panel project, although the material presented to the SAB by EPA staff indicated that considerable progress has been made. However, ~~t~~The SAB encourages the EPA to complete the ecosystem services white paper and recommends that the authors submit a shorter version to a peer-reviewed publication to make it available to a wider audience. The decision to incorporate case studies into the white paper will increase its value. The SAB also recommends that the white paper include an evaluation of the use of ecosystem services endpoints throughout the entire risk assessment and risk management decision process. Considering the entire range of process steps will help make ecological risk assessment more useful to decision-makers. The ecosystem services white paper should also include a description of how the concept of ecosystem services is being used in other agencies and other countries. Many natural resources agencies (e.g., U.S. Forest Service) routinely include ecosystem services in their management strategies.

Neither the GEAE nor the Colloquium Report captures the full range of concepts embodied by the term ecosystem services. The EPA should incorporate more current ecosystem services concepts and definitions into the GEAE document, replacing older terminology and meaning. The EPA should also consider updating the original GEAE guidance rather than producing an addendum. If both an original and an addendum are in circulation, a practitioner could mistakenly use only one, which could lead to errors. The SAB also recommends that the RAF Ecosystem Services Endpoint Technical Panel consider looking at the other policy focus areas in the Ecological Assessment Action Plan to determine where ecosystem services information should be incorporated into those other topics.

Use of Adaptive Management for Testing and Revising Risk Management Actions (Charge Question 6)

1 The Plan calls for use of adaptive management as a tool to methodically improve risk management
2 decisions. The SAB was asked to comment on how adaptive management approaches can be developed
3 to provide optimal value for EPA programs.
4

5 The six elements of adaptive management identified by the NRC and described in section 6 of the
6 Colloquium Report are consistent with the EPA's existing ecological risk assessment framework. The
7 SAB recommends that the EPA take action to implement the goal of incorporating adaptive management
8 principles into the framework. However, implementing this goal this may be difficult given the
9 complexity of consistent and continuous ecosystem monitoring and evaluation over appropriate time
10 scales and the scope and magnitude of resource limitations currently facing the EPA. Incorporation of
11 the adaptive management approach into the risk assessment framework may be particularly useful for
12 addressing certain technical concerns (e.g., climate change) or programmatic issues (e.g., Office of
13 Pesticide Programs, Superfund, Office of Air) facing the EPA. However, the adaptive management
14 approach may not be appropriate for all risk assessment applications in all EPA programs.
15

16 One key aspect of adaptive management, monitoring and evaluation, is not always fully implemented-
17 and when budgets are tight is often a target for elimination. This aspect of adaptive management is an
18 important means of evaluating uncertainty and measuring the efficacy of mitigation, and should be
19 incorporated into the EPA's risk management activities. Further, these data form the underpinnings of an
20 understanding of past trends and predictions of future conditions and thus are essential for adaptive
21 strategies. The SAB notes that the use of Bayesian approaches, causal argumentation, and probabilistic
22 risk assessment would facilitate the development of hypotheses that could be evaluated as part of the
23 adaptive management process.
24

25 **Strengthening the EPA's Ecological Protection Goals (Charge Question 7)**

26

27 The Plan indicates that there is little consensus in the EPA about goals for the protection of ecological
28 systems. The SAB was asked to comment on aspects of ecological risk assessment science that make
29 ecological risk information difficult to communicate and use in decision-making. The SAB was also
30 asked to provide recommendations to strengthen the EPA's ecological protection goals.
31

32 To strengthen the EPA's ecological protection goals, ecological risk assessors should develop
33 information and perspectives that enable them to communicate more effectively with decision-makers
34 and the public. Clearly, ecosystem health and human health are bound tightly together; certainly, there
35 cannot be good human health without good ecosystem health. Incorporation of ecosystem services into
36 the ecological assessment process will strengthen the EPA's ecological protection goals. Environmental
37 justice is also a useful platform to highlight the relationship between ecosystem condition and the health
38 of vulnerable human populations.
39

40 Many of the risk assessment practices recommended in the 2007 SAB report on advancing the science
41 and application of ecological risk assessment would lead to the development of stronger ecological
42 protection goals at the EPA. In particular, scale (both in time and space) should be explicitly considered
43 in the problem formulation stage of ecological risk assessments. Ecological risk assessments should link
44 biomarkers of exposure to biomarkers of effect, and post-remedial assessments and adaptive
45 management programs should be incorporated into the risk assessment and management process.

Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) Draft Report (5/9/12) to Assist Meeting Deliberations. Do Not Cite or Quote. This draft report is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered SAB, and does not represent EPA policy.

1 Environmental cleanup success stories also should be developed and used to enhance the
2 communication process between risk managers, assessors and environmental scientists. An overarching
3 recommendation of the SAB is that ecological risk assessment teams should use better communication
4 | techniques to educate management, policy makers, and the general public.
5

2. INTRODUCTION

The Risk Assessment Forum (RAF) in the EPA Office of the Science Advisor (OSA) has developed a draft Ecological Assessment Action Plan titled *Integrating Ecological Assessment and Decision-making at EPA: 2011 RAF Ecological Assessment Action Plan (August 11, 2011)*. The draft Ecological Assessment Action Plan (hereafter referred to as the “Plan”) sets forth science policy and technical practice initiatives to improve the quality, scope, and application of the EPA’s ecological assessments. The Plan was developed in response to a 2007 EPA Science Advisory Board (SAB) Report, *Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision-Making* (U.S. EPA SAB 2007) and a 2009 National Research Council (NRC) report, *Science and Decisions: Advancing Risk Assessment* (NRC 2009). These reports put forward recommendations to improve the application of ecological risk assessment in environmental decision-making. To address the recommendations in these reports, the RAF convened an intra-agency colloquium that included ecologists from across the EPA. Colloquium participants reviewed the EPA’s ecological risk assessment practices and guidance in light of the SAB and NRC advice and recommended actions to improve ecological risk assessment in the agency. The initiatives in the EPA’s Plan address recommendations in the colloquium report, *Integrating Ecological Assessment and Decision-making at EPA: A Path Forward* (U.S. EPA 2010^b) (hereafter referred to as the Colloquium Report).

The EPA’s Plan sets forth six science policy initiatives aimed at improving the agency’s ecological assessments and better informing decision-makers. These initiatives focus on: (1) developing a systems approach to ecological assessment that integrates multiple media, endpoints, and types of assessments; (2) developing weight of evidence as an option for inference in ecological assessments; (3) improving communication of ecological assessment issues and results; (4) incorporating ecosystem services into ecological risk assessment methods; (5) using adaptive management for testing and revising risk management actions; and (6) strengthening the EPA’s ecological protection goals. The EPA’s Plan also lists other specific initiatives aimed at incrementally improving ecological risk assessment practice. These technical practice initiatives focus on the need for improvements in: training, quality assurance, guidance to address multiple and specific receptors, life cycle evaluations, uncertainty analysis, and access to information.

The EPA Office of the Science Advisor requested that the SAB review the Plan as well as descriptions of two projects undertaken by RAF technical panels (the Communication Technical Panel and the Ecosystem Services Endpoint Technical Panel) and provide advice on the technical merit and implementation of the proposed initiatives. The background documents provided to the Committee included the 2007 SAB report on ecological risk assessment and the EPA Colloquium Report. In response to the OSA’s request, the SAB Ecological Processes and Effects Committee, augmented with experts who developed the previous SAB ecological risk assessment report, held public teleconferences on February 22-23, 2012 to review the Plan. The EPA’s charge questions (provided in Appendix A) focus on the major science policy initiatives in the Plan. The SAB was specifically asked to comment on: the technical merit of the initiatives in the Plan, how the integrated assessment approach might contribute to better decision-making, the scientific merit and limitations of the weight-of-evidence approach, the merit of proposed RAF communication and ecosystem services projects, how adaptive management approaches can be developed to provide value for the EPA, and how the EPA’s ecological

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1 protection goals could be strengthened. This SAB report provides the consensus advice and
2 recommendations of the Committee.

3. RESPONSES TO THE EPA'S CHARGE QUESTIONS

3.1. Overall Technical Merit of the Proposed Science Policy and Technical Practice Initiatives

Charge Question 1: The RAF Ecological Assessment Action Plan proposes six high priority overarching science policy initiatives and seven specific technical practice initiatives to improve the quality, scope, and application of EPA's ecological assessments. Please comment on whether the initiatives proposed in the Plan are: (a) responsive to SAB and NRC recommendations; and (b) reflect the most important set of activities needed to address the key scientific and technical challenges for advancing the application of ecological risk assessment in environmental decision-making. Please also consider whether there are other key science policy or technical practice initiatives that should be considered for inclusion in the Plan.

The six major science policy initiatives and the other technical practice initiatives recommended in the Plan follow logically from the EPA Colloquium Report (U.S. EPA 2010b), are responsive to previous SAB and NRC recommendations, and are very reasonable. Moreover, the SAB has not identified any significant omissions in the proposed set of initiatives. The proposed initiatives in the Plan address subjects that have the potential to greatly improve environmental assessment and decision-making at the EPA. The SAB commends the RAF for creating a Plan that is a solid starting point for the EPA's effort to integrate ecological risk assessment and decision-making. However, after examining the relevant documents, observing the presentations made by several EPA scientists about the Plan, and deliberating on the response to the charge question, the SAB has raised a number of issues to be addressed. The SAB urges the RAF to consider the following major recommendations for refining and developing the Plan.

Recommendations

- The RAF is encouraged to carefully review related activities occurring in other countries, including [Canada](#), Australia, China and the European Union. The Plan appears to be very myopic, that is, overly "EPA-centric." On some important aspects of ecological risk assessment, it appears that the U.S., and the EPA in particular, has lost its former leadership role, which is unfortunate. In any event, the agency can benefit from attention to advancements in other countries.
- The EPA should explore relevant activities by other U.S. agencies involved in resource management, including the National Oceanic and Atmospheric Administration (NOAA), [and](#) U.S. Forest Service (USFS), ~~and U.S. Geological Survey (USGS)~~, and collaborate with those agencies on the integration of ecological risk assessment and decision-making. In this regard, the USFS makes a number of "threat" assessments regarding fires, invasive species, and climate change. Fishery managers directly manage specific ecosystem services using probabilistic tools.
- In general, the issues identified in the Plan should be developed in more detail. While the recommendations in the Plan are ~~very~~ laudable, overall the Plan is ~~rather~~ only four pages long and is vague in discussing how the recommendations they will be achieved. The EPA has indicated that it anticipates the need for more substantive development of the policy issues identified in the Plan. There appears to be heavy reliance on subsequent workshops to develop implementation strategies. This generates ~~some~~ concern that implementation discussions could lag behind the evolution of

Comment [PC21]: Chapman – Qualitative terms do not belong, removed here and later in the document where they appear.

1 science underlying ecological assessments and constantly emerging new ecological problems.
2 However, the SAB recognizes that the issues being addressed by the EPA and the RAF are
3 enormous in complexity and importance.
4

- 5 • The SAB recommends additional input from social scientists. The Plan would benefit from
6 additional input by social scientists, ~~which-who~~ are admittedly rare in the agency. However, their
7 perspectives on issues such as sustainability, adaptive management, communication, and
8 environmental justice would be ~~very~~ helpful. Failure to sufficiently incorporate social sciences
9 overlooks the reality that ecological risk assessments occur within a given social, economic, political
10 context and will be most useful when skillfully aligned with community values and/or management
11 objectives.
12
- 13 • The EPA should determine whether the Plan would benefit from further consideration of
14 environmental justice. Environmental justice illustrates the interdependence of ecological and human
15 health. Although this may not need to be a separate initiative, the concept of environmental justice
16 seems noticeably absent from the Plan.
17
- 18 • Incorporation of case studies and success stories is recommended as an approach to increasing the
19 utility of guidance documents. ~~The SAB recommends development of case studies.~~ The emphasis on
20 generating more guidance documents, at least in their current form, merits scrutiny. It appears that in
21 many cases, these documents are not highly effective and are not given substantial attention within
22 the agency. Incorporation of case studies and success stories is suggested as an approach to
23 increasing the utility of guidance documents. The SAB also notes that, as recognized in the EPA
24 Colloquium Report, development of new guidance documents should include planning for training.
25
- 26 • In developing state of the art approaches for ecological risk assessments, the agency should
27 incorporate probabilistic quantitative approaches such as Bayesian methods, rather than point
28 estimates. The SAB notes that some EPA researchers have been doing work in this area (e.g.,
29 Carriger and Barron 2011).
30
- 31 • As part of a broad communication strategy, the EPA might consider use of community-based
32 participatory research approaches that engage stakeholders throughout the entire risk assessment
33 process. This could serve as a way to incorporate traditional knowledge from indigenous peoples.
34
- 35 • The Plan should explicitly address the importance of the problem formulation stage of ecological
36 risk assessment in ensuring a systems-level approach. Prior to and during problem formulation, an
37 open dialogue among scientists, risk assessors, risk managers, decision-makers and stakeholders is
38 essential (likewise, broad engagement also sets the stage for effective communication of results).
39 One point highlighted by the 2007 SAB workshop on ecological risk assessment was that ecological
40 risk assessments have been most effective when clear management goals were collaboratively
41 developed and incorporated into problem formulation. Peer review at the problem formulation stage
42 would be an excellent strategy to ensure that systems approaches are used. In particular, peer review
43 by ecologists would make it more likely that the ecological risk assessment sufficiently addressed
44 ecological end points and protected ecosystem health.
45

Comment [LJ22]: Johnson - Perhaps this is also an opportunity to call out the relationship between environmental health and economic prosperity as well. The two topics are really intertwined. We can then reference this concept again in the discussion of ecosystem services

Comment [JM23]: Meyer - I questioned this statement in the Executive Summary.

Comment [LJ24]: Johnson - As noted above, I don't think point estimates are the only contrast to probabilistic quantitative approaches. But one of the statisticians will have to help rephrase this. I like the way this is framed below in the response to Charge question 2 better - use of Bayesian methods, especially where data are sparse.

Comment [LJ25]: Johnson - An example would be helpful here.

Comment [LJ26]: Johnson - can we also incorporate a call for greater use of

Comment [LJ27]: Johnson - Reference the community-based approaches here too?

- 1 • In its presentations to the SAB, the EPA also requested advice concerning prioritization of the
2 RAF's recommendations. The SAB has selected several of the proposed initiatives in the Plan that
3 the agency should address at the outset, not necessarily because they were considered more
4 important in the long run, but because they had the greatest likelihood of advancing the agency's
5 goals, in the near term and with the agency's limited resources. These are (in order provided in the
6 Plan):
7
 - 8 – Use of weight-of-evidence approaches in ecological risk assessments.
 - 9 – Communication of ecological assessment issues and results to decision-makers.
 - 10 – Incorporation of ecosystem services into ecological risk assessment methods.
 - 11
 - 12
 - 13

14 **3.2. Importance of Developing an Integrated Assessment Approach**

15
16 *Charge Question 2. The RAF Action Plan proposes that EPA develop a systems approach to*
17 *ecological assessments that includes multiple media and endpoints as well as integration of*
18 *different types of assessments as described by Cormier and Suter in A Framework for Fully*
19 *Integrating Environmental Assessment, Environmental Management 42:543-556, and in*
20 *chapter 3 of the EPA colloquium report integrating Ecological Assessment and Decision-*
21 *Making at EPA: A Path Forward. The framework focuses on resolving environmental*
22 *problems by integrating different types of assessments: (1) condition assessments to detect*
23 *chemical, physical, and biological impairments; (2) causal pathway assessments to determine*
24 *causes and identify their sources; (3) predictive assessments to estimate environmental,*
25 *economic, and societal risks, and benefits associated with different possible management*
26 *actions; and (4) outcome assessments to evaluate the results of the decisions of an integrative*
27 *assessment. Please comment on how guidance for an approach to assessment that integrates*
28 *different media and endpoints and different types of assessments might contribute to better*
29 *decision-making (e.g., assessment of complex issues, cumulative risk assessment and*
30 *sustainability analysis).*
31

32 In general, the SAB finds that the EPA would clearly benefit from developing an ecological risk
33 assessment approach that combines multiple assessment types and integrates multiple and varied
34 assessment activities across the agency. The framework proposed by Cormier and Suter (2008) provides
35 an approach for integrating different components of the risk assessment process across the EPA. ~~The~~
36 ~~framework is elegant in its simplicity and logic.~~ It is a good preliminary framework that needs to be
37 developed further and populated. The key issues discussed below should be addressed in order to
38 develop a framework that will enable decision-makers to more effectively manage complex
39 environmental problems.
40

41 **3.2.1. Weight-of-evidence Determination and Integrity of Data and Models**

42
43 Successful implementation of the integrated assessment framework will hinge on a weight-of-evidence
44 (WOE) determination, which is addressed in the response to Charge Question 3 in this report. Use of a
45 WOE approach in ecological risk assessment has clear scientific merit but additional guidance on its use

1 and application is required. The “bottom-line” is that integration of different lines of evidence (LOE) is
2 essential given that “today’s environmental challenges are increasingly subtle and complex” (Anastas
3 2012), particularly so given the reality of global climate change (cf. U.S. Fish and Wildlife Service [and](#)
4 [National Oceanic and Atmospheric Administration et al.](#) 2012). Clarification of how WOE is
5 implemented in ecological risk assessment is likely to contribute to better decision-making across the
6 EPA. Bayesian approaches, which are especially useful in situations where data are sparse, are
7 recommended.

8
9 Full implementation of an integrated framework will hinge on the integrity of the data and models used
10 in each of the individual assessment types; it is not altogether clear whether there are sufficient data
11 (both quantity and quality) for different types of cases to fully implement this framework. It will be
12 important to ensure that the models and data used in each assessment type address the appropriate spatial
13 and temporal scales of the problem. Principles of landscape ecology and environmental heterogeneity
14 must be incorporated explicitly into this framework, but it is not clear that the proposed framework is
15 dynamic enough to do this. Further, the three types of stressors (chemical, physical, biological)
16 identified in the “Condition Assessment” compartment of the EPA’s preliminary framework need to be
17 considered in terms of cumulative effects, both direct and indirect (e.g., trophic cascades). The
18 combined use of field data along with bench_top data and models is recommended for that purpose.
19 Guidance and case studies need to consider both data-rich and data-poor situations to ensure that the
20 approach is protective of populations and communities of organisms and, where applicable, of
21 endangered species.

22 *Recommendations*

- 23
24
25 • Models and data used for each type of assessment in the integrated framework should address the
26 appropriate spatial and temporal scales of problems.
- 27
28 • In the integrated framework, the EPA should consider the cumulative effects, both direct and indirect
29 (e.g., trophic cascades) of the three types of stressors (chemical, physical, biological) in “Condition
30 Assessments.”
- 31
32 • The guidance and case studies developed for the integrated framework should consider both data-
33 rich and data-poor situations to ensure that the approach is protective of populations and
34 communities of organisms and, where applicable, of endangered species.

35 36 **3.2.2. Consideration of Climate Change and Ecosystem Services**

37
38 Each of the assessment processes in the proposed integrated framework must be considered in the
39 context of changing climate, particularly with respect to increased variability. Many of the assessment
40 endpoints used for condition assessments are subject to change as sensitive species are eliminated and
41 replaced by those less sensitive. Not only will populations and ecosystems change, but as temperatures
42 increase, so will sensitivity to other stressors, including chemicals. The combined effects of increased
43 temperatures and changing precipitation patterns is a special concern in the context of the delivery and
44 responses to a multiple stressor environment (see the special issue of the *Journal of the North American*
45 *Benthological Society* 2010, 29(4) on the topic of bioassessment under a changing climate). [The SAB is](#)

1 | concerned about exclusive reliance on the use of indices for such assessments because this may result in
2 | loss of critical data (Chapman 2011; Green and Chapman 2011).

3 |
4 | Consideration of ecosystem services endpoints is implicit but not explicit in the EPA’s proposed
5 | integrated assessment approach; explicit assessment end-points are needed. It is unclear why the EPA
6 | Office of Research and Development (ORD) strategy for incorporation of ecosystem services into
7 | assessments has not been mentioned in the Plan development process. Incorporation of ecosystem
8 | services is an important aspect of the integrated assessment approach and previous SAB reports on the
9 | EPA Ecosystem Services Research Program (U.S. EPA SAB 2008; 2009) identified some of the
10 | challenges that face the RAF with regard to integrating across EPA programs.

11 | *Recommendations*

- 14 | • Each of the assessment processes in the proposed integrated framework should be considered in
15 | the context of changing climate, particularly with respect to increased variability.
- 16 |
17 | • Ecosystem services endpoints should be explicitly incorporated into the integrated assessment
18 | framework.

19 | **3.2.3. Use of Adverse Outcome Pathway and Adaptive Management Approaches**

20 |
21 |
22 | The development and application of adverse outcome pathway (AOP) approaches is strongly
23 | recommended as part of the integrative framework. An AOP is “a conceptual construct that portrays
24 | existing knowledge concerning the linkage between a direct molecular initiating event and an adverse
25 | outcome at a biological level of organization relevant to risk assessment” (Ankley et al. 2009). When
26 | developing AOPs, it is important to identify specific sublethal measures associated with linkages
27 | between the molecular initiation events (Ankley et al. (2009) refer to the initiating event as “anchor 1”)
28 | and adverse outcomes at the individual and population levels of biological organization (Ankley et al.
29 | (2009) refer to the adverse outcome as “anchor 2”).

30 |
31 | The integrated assessment framework could address the long term perspective and “cultural” changes
32 | that are needed within the EPA to implement the framework. This can be viewed in the context of
33 | adaptive management. Adaptive management requires a long-term commitment to a specific goal, which
34 | in this case is the maintenance of specific ecosystem services. Long-term management of ecological
35 | systems will require a planning time frame that enables consideration of the dynamics of those systems,
36 | often years and decades in scale. Management of major systems such as the Great Lakes and estuaries
37 | such as the Puget Sound and Chesapeake are examples of systems that require such long-term
38 | commitments. Mining and energy extraction can require a century or more of management from the
39 | exploration of a site to the final remediation and closing.

40 |
41 | For large-scale systems managed at time scales equal to or longer than a decade, climate change will
42 | have to must be incorporated into the risk assessment and adaptive management framework.
43 | Consideration of such persistent multi-decadal changes to ecological systems has a number of
44 | implications: (1) managing to some ideal reference or baseline state is unrealistic; (2) ecosystem services
45 | are the entity to be preserved, although the species that provide those services are likely to change; (3) a

Comment [LJ28]: Johnson – I am not comfortable with this statement. I am of the opinion that indices have their place, along with other types of metrics; we should not rely exclusively on either type of data, but rather, should use both when appropriate. I would prefer to reword this statement as proposed. We have considerable data from across the Great Lakes basin coastal areas that include both species-based indicators as well as some composite metrics that are well-linked to individual and composite measures of stress.

Comment [LC29]: Conquest – I either am not familiar with, or have forgotten, what “anchor 1” and “anchor 2” refer to. So an individual reading this for the first time would presumably also be in the dark. Do these terms come out of Ankley et al 2009? Please clarify.

1 long-term monitoring and response system, innate to adaptive management systems, will have to
2 become the norm across the EPA, and National Pollution Elimination Discharge System (NPDES)
3 permits, Total maximum daily load (TMDL) guidance and restoration activities, and other long-term
4 programs must be managed within the context of climate change to meet the goals of legislation; and (4)
5 adaptive management in the context of climate changes means placing the most current science and
6 techniques at the Regional and Program level so that improved processes become operational. Delays in
7 implementing management under climate change simply increase the uncertainty that implemented
8 regulations are effective in managing vital ecosystem services.

9 10 *Recommendations*

- 11
- 12 • The development and application of adverse outcome pathway (AOP) approaches is strongly
13 encouraged as part of the integrated assessment framework.
- 14
- 15 • Adaptive management approaches could be implemented in an integrated assessment framework but
16 the EPA should adopt planning time frames for long-term management of ecological systems to
17 enable consideration of the dynamics of those systems under changing climate.
- 18

19 **3.2.4. Consideration of Multiple Stressors**

20

21 The SAB notes that the risks of multiple stressors to multiple endpoints have been calculated for
22 landscapes for over 15 years by groups across the world (e.g., Walker et al. 2001; Moraes and Molander
23 2004; Pollino et al. 2007; Gibbs 2007; Apitz 2011; Bartolo et al. 2012; Glendining and Pollino 2012;
24 Chen et al. 2012). This work has been poorly acknowledged throughout the Plan. As part of a research
25 effort in the U.S. Forest Service, Bayesian networks increasingly are showing their worth as a tool for
26 both assessing impacts and adaptive management (Marcot et al. 2001; 2006a,b; Nyberg et al. 2006).
27 Drawing on this work and on the regional risk assessment model, Ayre and Landis (in press) have
28 demonstrated that risk assessment can be successfully combined with the Bayesian approaches in a
29 forest management context. It is critical that the EPA take advantage of this ongoing research conducted
30 outside of the agency to improve the risk assessment process.

31 32 *Recommendation*

- 33
- 34 • To improve the risk assessment process, the EPA should take advantage of multiple stressor research
35 conducted outside of the agency. In particular, the SAB notes that Bayesian networks are
36 increasingly showing their worth as tools for assessing impacts and adaptive management.
- 37

38 **3.2.5. Importance of Social Science**

39

40 The SAB notes that engagement of social scientists is essential for successfully implementing ecological
41 risk assessment. A leading risk assessment journal, *Risk Analysis*, publishes a large number of articles in
42 the social sciences addressing such topics as stakeholder communication, risk perception, decision-
43 making, and expert elicitation. The EPA currently employs few experts in these areas. Having access to
44 this additional expertise would facilitate the EPA's communication of ecological problem(s) and risk
45 assessment results to informed professionals, stakeholders, and the general public.

The application of social science tools can be best illustrated by developing a series of case studies illustrating the utility of the social sciences in environmental assessment and adaptive management. A similar approach was used to create and critique case studies for the EPA’s Framework for Ecological Risk Assessment (U.S. EPA 1992).

Recommendation

- The SAB recommends developing a series of case studies to illustrate the utility of the social sciences in environmental assessment and adaptive management.

3.3. Use of a Weight-of-Evidence (WOE) Approach in Ecological Risk Assessments

Charge Question 3. Although ecological risk assessments often involve multiple lines of evidence, no guidance exists on how to weigh those lines of evidence to make inferences. The RAF Action Plan proposes that EPA develop such guidance. Please comment on the scientific merit and limitations of using a weight-of-evidence approach in decision-making and offer any guidance on weighing ecological risk assessment lines of evidence.

3.3.1. Scientific Merit of Using a Weight-of-Evidence Approach

The SAB strongly supports development of EPA guidance for weighing and integrating multiple lines of evidence to make inferences in ecological risk assessments. The scientific merit of WOE is clear and evidenced by the large number of scientific publications and its consistent and continuing use in ecological risk assessment. For instance, in 2002 a series of articles on WOE were published in the journal *Human and Ecological Risk Assessment*. Numerous articles on WOE have since been published in a wide variety of journals and books. Reviews of WOE approaches (e.g., Burton et al. 2002a; Weed 2005; Linkov et al. 2009) uniformly recommend its use, particularly in ecological risk assessment, but also note the need for transparency and guidance in its use.

The EPA has recognized that “today’s environmental challenges are increasingly subtle and complex”, and that research must not be just inter-disciplinary but in fact trans-disciplinary, “combining perspectives to form entirely new concepts and reach new levels of scientific understanding” (Anastas 2012). It has also been recognized both inside and outside of the EPA that the WOE approach has merit; this merit has been affirmed by the SAB in previous advice to the agency (U.S. EPA SAB 2007).

However, a scientifically rigorous WOE approach must rely less on best professional judgment (BPI) and more on statistically based decision points. This will not be possible without EPA WOE guidance that is program specific and that ideally provides structured decision-making frameworks. Specific recommendations are required regarding the use of WOE.

In the future, as we gain a better understanding of how to relate scale in time and place to stressor intensity, develop mechanistic processes linking stressors with responses, and develop a better understanding of baseline ecological conditions, the use of WOE should not be as necessary as it is today. As discussed below, there can be much argument over how much weight to give certain LOE or how to integrate the various LOE into a decision-making framework. As a better understanding arises

Comment [LJ30]: Johnson – This section is really packed with information and is really useful, but it seems disproportionately long compared to the other responses, and there is some redundancy across the different parts. To keep readers from getting bogged down, could this section be shortened up a bit.
Also – there are recommendations listed under some of the sections and not others...is that an omission or deliberate?
In the Adaptive Management section, the first part includes general comments...I think the definition of WOE under 3.3.2 should be covered under general comments, as opposed to Limitations.

Comment [JM31]: Meyer – I don’t think we need to introduce yet another acronym.

1 concerning multiple and complex stressors, and as these are related to life history parameters (see the
2 response to Charge Question 7), there should be less argument over the strongest LOE and the optimal
3 integration process.

4 3.3.2. Limitations of Using the WOE Approach

5 *Challenges inherent in using WOE*

6
7
8
9 A uniform definition of WOE does not exist. The following WOE definition of Burton et al. (2002b) is
10 perhaps the best one at present because it does not unduly limit the concept: “a process used in
11 environmental assessment to evaluate multiple lines-of-evidence concerning ecological condition.” The
12 SAB has also previously described ecological risk assessment as “a process, not just a technique” (U.S.
13 EPA SAB 2007).

14
15 The challenges inherent in using WOE for decision-making are well known (Batley et al. 2002; Burton
16 et al. 2002a,b; Wenning et al. 2005). More instructive and consistent guidance is needed for using WOE
17 approaches. WOE approaches are most often based on **best professional judgment BPJ** and vary widely
18 in their scientific rigor and statistical credibility (Burton et al. 2002a). Consequently, they may not
19 reduce uncertainty as they are meant to, and may in fact confound effective decision-making. WOE
20 depends to a certain extent on **best professional judgment BPJ**, which varies depending on the
21 professionals making judgments (e.g., Bay et al. 2007; Thompson et al. 2012). The EPA has identified
22 **best professional judgment BPJ** as a source of uncertainty (U.S. EPA 2010b), and lack of agreement
23 among experts about WOE extends beyond the environmental sciences (Large and Nielssen 2008). Bay
24 et al. (2007) suggest that uncertainty related to the use of BPJ must be recognized in ecological risk
25 assessment and will be less important at the extremes (e.g., sites that are clearly contaminated and toxic,
26 and those that are clearly not) than between the extremes. They recommend three steps to reduce
27 uncertainty in the integration and interpretation of multiple LOE:

- 28
29 1. Key elements of the assessment strategy should be determined during the problem formulation
30 phase of the ecological risk assessment. This could involve developing: the relative weight of
31 each LOE; the method of combining multiple LOE using techniques such as scores, ranks, and
32 logic frameworks; and criteria for determining the ecological risk assessment conclusions.
- 33
34 2. Guidance should be developed on the specific methodology/methodologies for measuring and
35 assessing each LOE.
- 36
37 3. Training, including guidance documents, should be provided for individuals interpreting both
38 individual LOE and the overall WOE.

39 *WOE interpretations in the context of risk assessment*

40
41 The term weight of evidence (WOE) appears to have a variety of interpretations in the context of risk
42 assessment. It begins with the general idea that more than a single line of inquiry is desirable when
43 assessing risk. At issue is how to integrate and synthesize evidence from different studies. The studies

Comment [LJ32]: Johnson – Move definition and introduction to WOE just below here.

Comment [LJ33]: Johnson - Are these recommendations from the Committee? if so they should be formatted like the others in the document, and the recommendation to provide case studies should be included.

1 might not all measure the same thing (e.g., chemical responses, individual organism responses,
2 community responses).

3
4 Rothman and Greenland (2005), based on the classic paper by Hill (1965) on causes of occupational
5 diseases, listed ~~nine the following~~ causality criteria ~~formulated in the context of potential carcinogens~~
6 ~~and disease. These:~~

- 7 ~~1. Strength of the association (stronger associations support the notion of causality);~~
- 8 ~~2. Consistency (more studies find similar results);~~
- 9 ~~3. Specificity (specific exposures exert specific effects and, at the same time, certain exposures can~~
10 ~~lead to multiple effects);~~
- 11 ~~4. Temporality (exposure should precede the effect);~~
- 12 ~~5. Biological gradient (a dose response relationship lends evidence to causality);~~
- 13 ~~6. Plausibility (knowledge of biological processes involved lends evidence to causality);~~
- 14 ~~7. Coherence (other observed biological effects lend evidence to a causal association);~~
- 15 ~~8. Experimental evidence (e.g., does the amount of a toxicant in a body of water decrease following~~
16 ~~changes in practice by an industrial plant?); and,~~
- 17 ~~9. Analogy (does a similar agent exert similar effects?);~~

18
19
20 ~~The above criteria were originally formulated in the context of potential carcinogens and human disease,~~
21 ~~but they~~ can also be interpreted in terms of ecological risk assessment. ~~Simply contemplating all the~~
22 ~~items on this list serves as a reminder that m~~Many factors are involved in trying to quantify the process
23 of linking exposure to something (e.g., a toxicant, a management practice) and a resulting effect. The
24 EPA has incorporated these useful concepts into its stressor identification ~~E~~evaluation guidance (U.S.
25 EPA 2000) and CADDIS (Causal Analysis / Diagnosis Decision Information System) approach
26 (~~Cormier and Suter 2009~~U.S. EPA 2010a).

Comment [LJ34]: Johnson – suggested edits to tighten up this section.

27
28 The EPA has used a WOE approach for human health risk assessments (e.g., carcinogens and
29 toxicology) (U.S. EPA 2005). However, it seems unlikely that ecological risk assessments are as
30 amenable to formalization as human cancer risk assessments. Many ecological risk assessments are
31 inherently unique, and a high degree of flexibility will remain desirable for the foreseeable future to
32 address the nuances associated with particular assessments. As noted in the response to Charge Question
33 2, adverse outcome pathways (AOPs) should be a key component of ecological risk assessment. The
34 overall goal should be to protect populations and communities, not individuals (an exception is the
35 protection of individuals in an endangered species). However, this goal must include protection of the
36 ecosystem services provided. Thus, measurement endpoints must include responses that affect or could
37 potentially affect those services (e.g., cancers in edible crabs that reduce consumer interest in this food
38 source are indicative of anthropogenic ecosystem degradation if the cancers are related to human
39 activities).

Comment [LJ35]: Johnson – This is a very nice introduction and overview to WOE...why not put this up at the top of this section and call it something like General Comments?

40
41 SAB has previously recommended: development of a consistent approach to interpreting LOE and WOE
42 in ecological risk assessments, both to reduce uncertainty and to facilitate the use of this information in
43 decision-making; use of Bayesian analysis and causal argumentation to develop hypotheses or risk
44 questions focused on causal relationships and WOE; and, development of “case studies and/or standards
45 of practice for interpreting lines of evidence and weight of evidence with an emphasis on application in

1 decision-making” (U.S. EPA SAB 2007). The SAB continues to advise the EPA to apply these
2 recommendations as the Plan is developed and implemented. The SAB also notes that the EPA guidance
3 document on generic ecological assessment endpoints (GEAEs) for ecological risk assessment (U.S.
4 EPA 2003) states that “as the GEAEs are applied to ecological risk assessments, the experiences should
5 be documented and published as case studies.” The SAB supports the development of such case studies.
6 In particular, we recommend that the case studies focus on whether some LOE carried more weight than
7 others, or whether they were ignored or too difficult to interpret or use. This information will assist in
8 future weighting of ecological risk assessment LOE. Case studies should cut across different EPA
9 regulatory programs in which WOE is used and should emphasize statistics, not just best professional
10 judgment-BPJ, for decision-making. As further discussed below, the SAB particularly recommends that
11 the EPA develop case studies illustrating the use of Bayesian approaches. Such approaches will provide
12 more flexibility and more convincing outcomes than reliance on best professional judgment-BPJ.

14 3.3.3. Guidance on Weighting Ecological Risk Assessment LOE

15
16 WOE is an approach to evaluating and integrating multiple sources of evidence, rather than a single
17 technique. As such, WOE should follow certain principles, but not a particular recipe nor algorithm.
18 Any effort that applies WOE to reach conclusions should be completely transparent with regard to the
19 different sources of evidence considered and any qualitative (e.g., expert opinion) or quantitative
20 weighting schemes used. This point is discussed by Swaen and van Amelsvoort (2009) in the context of
21 evaluating epidemiology data for cancer risk assessment. Data quality and the reliability of different
22 studies should also be considered in a WOE approach. Weed (2005) points out that applying an arbitrary
23 weighting scheme without a solid theoretical foundation to integrate different LOE into a single risk
24 score may not actually improve decision-making.

25
26 A well developed WOE framework would enable ecological risk assessors to assign quantitative weights
27 to results from different studies (with associated estimates of uncertainty) and to combine them into an
28 assessment of a defined risk. Thus far, this has been largely done in epidemiological contexts, but
29 having quantitative results from adaptive management experiments based on sound principles of
30 statistical design would make it easier to construct WOE arguments on ecological risk.

31
32 The most specific WOE approach is meta-analysis. This approach is used when different studies have
33 provided estimates of the same effect (an admittedly well-focused set of circumstances). The estimated
34 effects coming out of the different studies are assigned a weight inversely proportional to the variance
35 associated with the effect and combined together to form a weighted average effect (with a weighted
36 variance). In this manner, the presence of many studies with almost-nearly statistically significant results
37 can lead to an overall statistically significant result.

38
39 Other useful statistically-based WOE approaches have been reported (Bailer et al. 2002; Burton et al.
40 2002b; Grapentine et al. 2002; Reynoldson et al. 2002; Kapo and Burton 2006; Kapo et al. 2008). These
41 approaches address many weaknesses of qualitative approaches and provide a solid basis for EPA
42 guidance that could be structured to address unique program needs.

43
44 The WOE process should be described in the problem formulation stage of a risk assessment and ensure
45 credible stakeholder input and a transparent understanding of what constitutes reference condition,

1 restoration goals, remedy objectives, and/or ecological impairments in the context of site spatial and
2 temporal variations. This point was highlighted in the SAB report on improving the ecological risk
3 assessment process, which resulted in the current RAF process (Dale et al. 2008). The SAB provides the
4 following recommendations with regard to weighting ecological risk assessment LOE:
5

6 *Recommendations*

7

- 8 • In general, a comprehensive set of LOE should be utilized in the WOE process. The LOE should
9 adequately characterize physical, chemical and biological conditions. This will ensure a cumulative
10 evaluation that considers commonly occurring stressors such as habitat, water flow and nutrients.
11 The weight given to particular LOE is likely to be very case-specific, and quality of the data
12 underlying a particular LOE should factor into assigned weights. Beyond that, LOE that are clearly
13 linked to population or community attributes should receive greater weights than those that are not.
14
- 15 • Arbitrary numerical weightings should not be assigned to LOE because site- and situation-specific
16 considerations will affect weightings. WOE assessments need to be “flexible, transparent and
17 defensible...[with] sufficient flexibility to accept all relevant evidence and generate creative
18 solutions to difficult problems” (Suter and Cormier 2011). The SAB agrees with the EPA that
19 “weighing of evidence should be considered during each problem formulation, and a method for
20 weighing evidence should be included, as appropriate, in the analysis plan” (U.S. EPA 2010**b**).
- 21 • Multicriteria decision analyses (~~MCDA~~) should be further investigated as recommended by Linkov
22 et al. (2011): “Each WOE method is based on a unique rationale and capable of considering a
23 different scope of LOEs. Thus, each method has specific benefits and drawbacks. The different
24 nature of methods means that one cannot *a priori* determine the superior method for a particular
25 application. One must consider the method employed in addition to the evidence.”
26

27 **3.3.4. Probabilistic Basis for the WOE Approach**

28

29 The evaluation of WOE has progressed over the years but as it is currently practiced, WOE is a
30 qualitative tool without a probabilistic basis. A WOE is essentially a Bayesian approach without a
31 realization of the calculation. Evidence should be taken that can differentiate between alternative
32 hypotheses. As discussed by Newman et al. (2007), there are ways to perform specific calculations and
33 to use Bayesian networks to improve analyses conducted within risk assessments.

34 Bayesian networks can be tied directly to the cause-effect conceptual model that should be generated for
35 every risk assessment. Bayesian networks have long been used in this manner to create diagnostic tools
36 for medicine (Ben-Gal 2007). Jaworska et al. (2010) have suggested that Bayesian networks be used to
37 optimize testing methods specifically targeted to mammalian testing for carcinogenicity, but their broad
38 outline should be applicable to testing approaches for environmental toxicity and for protocols used to
39 determine causation when environmental degradation is observed. Huang et al. (2010) have reported on
40 the use of Bayesian approaches for analyzing gene expression data in the public domain to create an
41 automated diagnostic data base for human health. Environmental toxicology research is also providing
42 data on gene expression that may also be used for prediction of effects.
43

1 One question concerning the use of Bayesian tools and networks is how to effectively communicate the
2 results to managers and decision-makers. Fenton and Neil (2010) used a case study comparing the risks
3 of alternate medical diagnosis and a Bayesian network to demonstrate how this can be done. Given the
4 experience in medical diagnosis, a Bayesian approach would be an extension of the basic WOE in
5 deciding between alternative hypotheses and in the diagnosis of causality.

6
7 *Recommendation*

- 8
9 • Specific quantitative (i.e., statistical) guidance, with associated case studies, on interpreting LOE and
10 WOE in ecological risk assessments should be developed for use by EPA risk assessors and risk
11 managers. Case studies should cut across different EPA regulatory programs in which WOE is used.
12 In particular, the SAB recommends that more emphasis be placed on the use of Bayesian approaches
13 (e.g., to assess the probability that a certain state of ecosystem services is the desired state of
14 ecosystem services; to develop the best possible information for decision-making in the face of
15 uncertainty, for instance for data-poor case studies). It is critically important to show success in case
16 studies under data-limited conditions to convince non-scientists (e.g., managers) of the utility and
17 value of WOE and of ecological risk assessment.

18
19 **3.4. Communication of Ecological Assessment Issues and Results to Decision-Makers and**
20 **Stakeholders**

21
22 *Charge Question 4. The RAF Action Plan calls for the development of methods for better*
23 *communication of ecological assessment issues and results to decision-makers and*
24 *stakeholders. This applies to communicating ecological assessment issues during both*
25 *planning of assessments and presentation of results. In part, this may be a matter of the*
26 *inability of assessors to communicate the significance of the loss of species, changes in*
27 *community structure, and other endpoints. The RAF has developed a communication*
28 *technical panel project description. Please comment on whether the RAF's planned project is*
29 *an appropriate way to proceed, and what obstacles might exist to either interpreting or*
30 *utilizing ecological information in risk assessment. Please include any observations on why*
31 *ecological risk assessment has or has not been well incorporated into decision-making in*
32 *general.*

33
34 **3.4.1. Comments on RAF Communication Technical Panel Project**

35
36 <<Comment from the Chair: This section is somewhat long.>>

37
38 ~~The SAB commends the EPA Risk Assessment Forum for recognizing importance of developing~~
39 ~~science policies to improve risk communication and undertaking a new project in this area.~~ The one-
40 page RAF Communication Technical Panel project description provided to the SAB indicates that the
41 Panel intends to: (1) gather data through surveys and interviews of EPA risk assessors and decision-
42 makers to explore how ecological risk assessments are used in agency decision-making; and (2) develop
43 guidance for risk assessors and decision-makers on how to better communicate and enable the use of
44 ecological risk assessment information.

Comment [PC36]: Chapman – Does not fit with the rest of the section.

1 The SAB has been given a minimal amount of detail upon which to base this review. However, the
2 available information indicates that the RAF Communication Technical Panel’s approach to data
3 collection is quite general, and the scope of the proposed investigation is somewhat one-directional and
4 narrow (i.e., it is not designed to provide exchange of information about communication issues
5 important to participants involved in each step of the risk assessment and management process). Such a
6 narrow focus on better communication in risk assessment is not consistent with recommendations from a
7 variety of panels, committees, advisors (NRC 1994, 1996, 2009) that have emphasized that multi-
8 directional communication is a critical part of risk assessment. The SAB has previously advised the EPA
9 that early and continuing engagement of risk assessors with decision-makers and stakeholders is
10 important in order to determine what is valued, and outcomes are desired (U.S. EPA SAB 2007).
11

12 Because of the limited scope and focus of the EPA’s proposed data collection effort, the SAB finds that
13 the current approach being taken by the RAF Communication Technical Panel is not likely to achieve
14 the stated goals of raising confidence in and promoting full use of ecological risk assessment across EPA
15 programs, and meeting the managers’ needs for useable ecological risk assessment information to
16 support decisions. The SAB recommends that the scope of the Technical Panel’s project cover each step
17 of the risk assessment and management process, not just the handoff of the ecological risk assessment
18 from assessor to manager. Communication should be required and documented improved as an essential
19 core activity of the ERA process element << *Comment from the Chair: clarification needed to define*
20 *core process element*>> that runs from problem formulation, through analysis and remedy selection to
21 final communication of the decision and proposed management strategy to stakeholders. There is no
22 indication that the RAF Communication Technical Panel project will address the role and responsibility
23 of management to frame the problem correctly, or that the project will focus on how a well-
24 communicated assessment can improve the communication of the management decision, particularly
25 with regard to the importance or value of the impaired endpoint.
26

Comment [BGR/37]: Biddinger - Believe the revised text should clarify the point.

27 ~~The RAF Communication Technical Panel’s work plan does not appear to deal with the difficult~~
28 ~~ecological risk assessment questions of identifying standards for acceptability and communicating~~
29 ~~variability and uncertainty.~~ The RAF Communication Technical Panel should explore the questions of
30 what constitutes successful communication and what the criteria are for measuring that success. One
31 communication recommendation in the EPA Colloquium Report was to enhance communication among
32 risk assessors, and that does not seem to be a part of the Plan. Establishing a formal exchange among
33 EPA ecological risk assessors would be a valuable way to transfer experience and practice among the
34 agency assessor community.
35

Comment [PC38]: Chapman – Deleted to shorten.

36 ~~The RAF Communication Technical Panel project does not appear to recognize that different~~
37 ~~communication strategies may be needed for different target audiences. For example, vulnerable~~
38 ~~populations may require specialized communication strategies.~~ The RAF Technical Panel should expand
39 the scope of the project to address the need to develop a variety of risk communication strategies to
40 reach different audiences. In this regard, ecosystem services might be recognized as more or less
41 valuable by different audiences and thus become a critical element of targeted communication strategies.
42 Therefore, concerted cross linkage between the Communication Technical Panel and the separate
43 Technical Panel on Ecosystem Services is advised warranted.
44

Comment [PC39]: Chapman – Deleted to shorten.

1 Finally, the methodology of the Communication Technical Panel survey to develop a basis for designing
2 better communications seems at best to be a preliminary approach that will not provide the information
3 needed by the EPA. The use of surveys/interviews of both risk assessors and decision-makers (i.e., risk
4 managers) asking high level questions such as “is ecological risk assessment information being used
5 for....?” will likely lead to many yes, no and maybe answers. The description of the proposed survey
6 contains insufficient detail to fully understand the extent to which the surveys are meant to delve into the
7 questions posed by the RAF with regard to how to communicate the *significance of the results*, such as
8 the loss of species, changes in community structure, and other endpoints. Such surveys are very labor
9 intensive and are more likely to reinforce the need to act, but not get at the matter of what to change and
10 how to make a change. The original EPA colloquium was a survey of sorts and already has indicated the
11 need for change. The Communication Technical Panel would be better advised to analyze the risk
12 assessment process by deconstructing specific decisions with a cross disciplin~~ary~~ary team.

13
14 The Communication Technical Panel can test what it might expect to get in a survey by looking at the
15 results of a similar effort undertaken by the SAB, which was a survey across EPA regions and programs
16 to assess the question “Is science integrated into decisions?” The results of the SAB survey provide
17 information about the interface of assessors and managers as well as the challenge of bringing science to
18 bear on agency decisions. Ecological risk assessment and associated science are a subset of the SAB
19 study. A description of the survey and recommendations to strengthen science integration for EPA
20 decision-making are provided in the SAB report, *Science Integration for Decision-making at the U.S.*
21 *Environmental Protection Agency* (U.S. EPA SAB 2012).

22 *Recommendations*

- 23
24
- 25 • The scope of the RAF Communication Technical Panel’s project should be broadened to include a
26 focus on improved communication across the entire risk assessment and management process.
27 Communication should be elevated to an essential core process activity element with its own
28 performance standards and success criteria. The Technical Panel should not focus on just
29 communicating the current process and the outputs it generates, but consider process redesign to
30 make effective communications an integral component of the ecological risk assessment process.
31
 - 32 • The focus of the RAF Communication Technical Panel’s work should be broadened to address better
33 communication performance by all participants including ~~r~~ risk assessors, managers and key
34 stakeholders. As been noted previously, a multi-dimensional approach to effective communication in
35 the risk assessment process is needed to improve the impact of risk assessment in the risk
36 management process. In addition, a range of communication strategies or techniques needs to be
37 made available to both risk assessors and risk managers. Establishing technical platforms for peer
38 networks to exchange experience and practices may go a long way toward advancing
39 communication in risk assessment.
40
 - 41 • The RAF Communication Technical Panel should focus on developing guidance/support tools that
42 can be adapted customized to the need of specific regulatory application-decisions. The Panel’s work
43 should recognize that communication strategies may vary with the ~~decision~~ type of regulatory
44 application. The EPA makes a broad range of decisions across its programs and regions and different
45 management and supporting assessment processes are used within EPA program offices for a given

1 regulatory category (e.g., waste management has RCRA and CERCLA). These decisions are
2 supported by a variety of assessment-decision processes. It should be no surprise that the risk or
3 hazard assessment methods and their outputs that support these varied processes would also vary.
4 This suggests that, for ecological risk assessment to ~~be used more fully and~~ have maximum impact
5 on agency decisions, the question of how to improve that outcome must be addressed at the level of
6 the specific decision process.
7

- 8 • The focus of the RAF Communication Technical Panel’s work should be broadened to recognize
9 that communication strategies may vary with the intended audience. Communication strategies
10 should be adapted to the intended stakeholder audience. It is important to keep in mind that one is
11 not only communicating to the decision-maker, but also assisting the decision-maker in being able to
12 communicate how an assessment drives the proposed actions that will be required. Knowing why
13 the risk matters to the receiving audience is as important as quantifying the risk.
14
- 15 • The RAF Communication Technical Panel should actively reach out to other RAF Technical Panels
16 (e.g., Ecosystem Services) as sources of information to enhance better communication of risks and
17 impacts. There is an obvious and strong linkage between risk communication and some of the other
18 policy areas addressed in the Plan, such as ecosystem services and the integrated assessment
19 framework. Results of an ecological risk assessment consist of the scientific facts, but generally lack
20 the interpretation of how humans will be affected. The key to effective communication may lie in
21 understanding and communicating why the risk matters and how managing it will provide a valued
22 benefit.
23
- 24 • The RAF Communication Technical Panel should actively engage experts in communication to
25 inform its efforts. The Technical Panel should consider incorporating external technical input to their
26 process from social scientists, ethicists, marketing professionals, and media specialists who have a
27 good understanding of risk communication and broader environmental concerns. Particularly good
28 resources might include environmental non-governmental organizations, university extension
29 professionals, and academic communities that have considerable expertise communicating the value
30 of ecosystems and their services to the public (e.g., State University of New York Stony Brook
31 School of Journalism Center for Communicating Science;
32 <http://www.centerforcommunicatingscience.org/>; and the Ecosystem Commons
33 <http://ecosystemcommons.org/>; <http://ecosystemcommons.org/soapbox/Madsen>).
34
- 35 • The RAF Communication Technical Panel should conduct a more thorough analysis of the
36 communication issue, not just a survey of assessors and managers. A systematic evaluation of the
37 challenges and opportunities for better communication across a range of different decision types will
38 provide a better basis for developing performance standards and guidance.
39

40 The following is just one such approach illustrating steps the Technical Panel might take in this kind of
41 evaluation:
42

- 43 1. Create a matrix of decision types (programmatic, regional, etc.) and identify: (a) those decision
44 types where EPA staff or interviewees indicate that ecological risk assessment is having the

- 1 | ~~correct~~appropriate impact; and (b) one decision type where there is clear indication that
2 | ecological risk assessment is being grossly under-utilized.
3 |
- 4 | 2. Create a work team with representation from all staff and technical responsibilities involved in
5 | the specific decision process. This work team should include assessors and decision-makers and
6 | ~~even~~ real or mock stakeholder representatives.
7 |
- 8 | 3. Provide the team with a detailed case study problem and have it “table top” the decisions while
9 | fully discussing: (a) how ecological risk assessment information, or more broadly “science,” can
10 | support ~~a~~ better decisions; and (b) how and when ecological risk assessment can be better
11 | communicated. Use this exercise to discuss the manager’s information needs, useable
12 | information format, and the importance of context in communicating the ecological risk
13 | assessment output, but more importantly in shaping the ecological risk assessment through the
14 | problem formulation. The exercise should involve all aspects of the decision process including
15 | the selection of the technology or remedy and communicating the decision. The exercise should
16 | be facilitated by a non-participant in the assessment-decision exercise. The team should have a
17 | clear charge, information reporting requirements and sets of questions that need to be addressed
18 | at each stage of the decision process.
19 |
- 20 | 4. After running several of these exercises, evaluate the results and determine whether a
21 | protocol/process template can be developed for independent use by others (e.g., EPA Program
22 | Offices and Regions). If such a template cannot be developed, run several additional “exercise
23 | sessions” with different decisions. At the end, the goal is to create a self-assessment tool that
24 | can be used by a program or regulatory group to apply to its specific regulatory
25 | ~~application process~~ in order to identify how ecological risk assessment can have more impact on
26 | a specific decision, and how better communication of ecological risk assessment information
27 | and science can facilitate those results.
28 |
- 29 | 5. Finally, if the EPA wants to build general guidance, the SAB suggests developing a document
30 | built on understanding gained from the case study problem and also creating a “go-by” tool that
31 | risk assessors can use to improve communication as they are participating in the ERA process.
32 | The tool could be simply a check list of considerations and questions that are clustered
33 | according to the typical steps in most decision processes, including problem formulation,
34 | assessment design, risk analysis, options selection and decision communication. Development
35 | and use of such a self-guided process to improve performance would go a long way to elevate
36 | both consistency and alignment of decisions and science.
37 |

38 | The SAB is both supportive of EPA’s efforts to improve the communication of ecological risk
39 | assessment information and interested in the direction that the EPA is taking in the RAF Communication
40 | Technical Panel project. We stand ready to provide future advice as the EPA completes work on this
41 | important project. When the Ecological Assessment Action Plan has been refined to provide more
42 | detail, or after the initial path of data collection, it may be useful to receive additional advice from the
43 | SAB.
44 |

Comment [JM40]: Meyer – The previous comment was that the proposed approach would not work. It is not consistent with this comment to state that the SAB is supportive of the direction EPA is taking in the RAF communication project

3.4.2. General Observations on Incorporation of Ecological Risk Assessment into Decision Making

The SAB was asked to comment on why ecological risk assessment has or has not been well incorporated into decision-making. There are likely many reasons why ecological risk assessment output has not, in the view of risk assessors, had an optimal impact on decisions. Not all of these reasons have to do with effective communication. Focusing principally on the aspect of improving success through better communication, the SAB suggests that the EPA Risk Assessment Forum think more broadly about communication throughout the entire assessment-management process.

As stated previously, the communication of the risk output is not the only point of communication that could be improved. The risk assessor and the manager overseeing the decision process need to clearly understand what data are required for the decision, or from which the decision could benefit, and how the data inform the selection of alternatives. A robust communication process that leads to a clear understanding of the context for the decisions, and how various data or ecological risk analysis improve or support the decision at hand, will go a long way to better alignment of assessment and decision. As discussed in section 7.1.2 of the EPA Colloquium Report (U.S. EPA 2010b), the risk assessor needs to understand all aspects of the context of the problem and decision in order to help managers do the “balancing act” required in specific regulatory application contexts.

Unfortunately, ecological risk assessment still finds limited use even in the EPA. ~~For example, a recent SAB report on methods for the treatment of vessel ballast water (U.S. EPA SAB 2011) recommended including risk assessment in the processes of determining the appropriate ballast water treatment methodology and in managing the treatment. That SAB recommendation apparently was not implemented.~~ There are many barriers to the use of ecological risk assessment in decision-making. The barriers to be overcome include making stakeholders or decision-makers comfortable with quantitative assessments and providing realistic training so that EPA staff can apply risk assessment to decision-making processes. Further information about the limitations or barriers to fuller use of ecological risk assessment by the EPA is provided in Landis (2009).

3.5. Incorporation of Ecosystem Services into Ecological Risk Assessment Methods

Charge Question 5. Ecosystem services can be used to describe potential outcomes of environmental management decisions in terms that can be more effectively communicated to decision-makers and the public. RAF expects to produce guidance on how to relate ecological risk assessment endpoints to ecosystem services. This information will be used to update the EPA guidance document Generic Ecological Assessment Endpoints (GEAEs) for Ecological Risk Assessment (U.S. EPA 2003). Please consider Appendix B (page 52) of the generic ecological assessment endpoints guidance document and the project description of the RAF Technical Panel on Ecological Services Assessment Endpoints and comment on whether they capture the full range of opportunities to incorporate ecosystem services into EPA’s ecological risk assessment methods.

The concept of ecosystem services has emerged as a means of conveying the total integrated direct value of the environment to human well-being by including both market and nonmarket goods and services.

Comment [JM41]: Meyer - Much of the material in this section is repetitive of what is in the earlier section (3.4.1). Can't the two be combined and shortened?

Comment [JM42]: Meyer - I don't think this is true. I think the response letter received by the SAB noted how and where a risk assessment approach is being used.

Comment [BGR/43]: Biddinger - Ecosystem services as being applied don't assume the value of nature to other ecological components other than humans in doing the valuation. This is a principle criticism of the concept that it leaves out the essential value of natural systems.

1 | The ecosystem services paradigm has been operative for some time (citation?) and its integration with
2 | ecological assessments is both fundamental and overdue. Thus the SAB finds that its inclusion in the
3 | Plan is appropriate. The use of ecosystem services endpoints affords the opportunity to move ecological
4 | risk assessment from identifying *what* is at risk to *why* that risk matters to humans. This will help EPA
5 | managers more clearly communicate outcomes in terms of the benefits/values derived from the
6 | ecosystem attributes that are protected and support an understanding of why decisions were made. The
7 | concept of ecosystem services can be easily grasped by all stakeholders from scientists to managers to
8 | policy makers to informed public. It can also help managers better understand the trade-offs in their
9 | decisions, although assessing trade-offs among services is one of the most difficult aspects of its use as
10 | an endpoint in risk assessment. Often, optimizing delivery of a given service may reduce or impair
11 | another (Mooney 2010). Agriculture provides a primary example. The enhanced provisioning of food
12 | can result in loss of clean water and stress to biodiversity that supports other services. Incorporating
13 | ecosystem services into risk assessment is of high priority. It takes advantage of the expertise being
14 | developed around ecosystem services in ORD, and therefore should benefit both ecological risk
15 | assessment and the ORD program. Incorporating ecosystem services is also likely to stimulate progress
16 | on the first science policy initiative in the Plan, namely incorporation of systems analysis into ecological
17 | risk assessment.

Comment [BGR/44]: Biddinger - Can we add some early citation that precedes the MEA 2005?

19 3.5.1. Comments on RAF Ecosystem Services Technical Panel Project

20
21 The Plan is vague on how the ecosystem services activity will be implemented. It says that an RAF
22 Ecosystem Services Endpoint Technical Panel has been created whose findings will be incorporated in
23 the EPA guidance document on ecological assessment endpoints; the brief project description from the
24 Technical Panel does not provide much additional information. The Panel's project description indicates
25 that the products to be developed include: (1) a white paper interpreting conventional measurement and
26 assessment endpoints in the context of ecosystem services; (2) a case study(s) of applying the ecosystem
27 services concept in ecological risk assessment; and (3) an addendum to the RAF Generic Ecosystem
28 Assessment Endpoints guidance (GEAE) (U.S. EPA 2003). The addendum would expand the GEAE
29 document to include a broader range of ecosystem services and more explicitly address linkages
30 between the original GEAEs and services. It is not clear that the development of "case studies and
31 guidance on how to relate ecological endpoints to ecosystem services" will be successful in achieving
32 the desired goals of incorporating ecosystem service endpoints into the ecological risk assessment at
33 problem formulation, analysis, and risk characterization. Greater detail is needed to evaluate the
34 potential success of this activity. In the EPA's presentation to the Committee, the SAB was pleased to
35 learn that considerable progress has been made in developing the white paper on the use of ecosystem
36 services as an endpoint in ecological risk assessment. The decision to incorporate several case studies
37 into this document will increase its value. There is some concern that the document may stress concepts
38 at the expense of application. It will be most valuable to the community of practitioners if application is
39 stressed, for example, how endpoints could be created and applied in different situations. The SAB
40 encourages the EPA to complete this white paper and recommends that, in addition, the authors consider
41 submitting a briefer version to a peer-reviewed publication that would make it available to a wider
42 audience.

43
44 It would have helped the SAB to have had a copy of the white paper in hand to better evaluate the
45 direction this effort will take the agency. It would be beneficial for the RAF Ecosystem Services

1 Endpoint Technical Panel to engage the SAB to make suggestions on the guidance being developed.
2 One SAB concern that might be assuaged by having the white paper available is the limited view
3 implied by the statement (on page 1 of the Ecosystem Services Endpoint Technical Panel presentation)
4 that the value to the EPA of integrating ecosystem services into ecological risk assessment is “Improved
5 means of communicating risk and informing risk management decisions.” The SAB notes that
6 integration of ecosystem services can also help in designing an ecological risk assessment that is well
7 aligned with the decision context and those aspects of the decision that matter to the public. Integration
8 of ecosystem services can also be used to inform the selection of technologies and remedies by
9 expressing the reduction of risk in terms of benefits that can potentially be valued in monetary terms. In
10 addition, tying the ecological risk assessment to ecosystem services should help managers communicate
11 with stakeholders. This may have been implied in the statement in the EPA’s presentation to the
12 Committee, but ~~that~~ is not clear without the details that are likely to be provided in a white paper. The
13 SAB recommends that the white paper include evaluation of the use of [information related to](#) ecosystem
14 services endpoints throughout the entire risk assessment and risk management decision process. By
15 considering the entire range of process steps, it seems likely that using ecosystem services as endpoints
16 will help achieve the goals defined in Charge Question 4, namely making ecological risk assessment
17 more frequently used and more useful to managers in making the their decisions.
18

19 The white paper could benefit from describing how the concept of ecosystem services is being used in
20 other agencies and other countries. Many natural resources agencies (e.g., U.S. Forest Service) routinely
21 include ecosystem services in their management strategies (e.g., Agee 2003; Ager et al. 2007; Barbour et
22 al. 2007). The RAF should investigate lessons that can be learned from their experiences. There is a risk
23 and threat assessment literature that routinely incorporates ecosystem services in its calculations (Marcot
24 et al 2006a; Apitz 2012; Glendinging and Pollino 2012). The RAF should assess how the agency’s
25 proposed guidelines compare with those efforts and results. The international community is also using
26 ecosystem services in risk assessment (e.g., SETAC Symposium, Ecosystem Services: From Policy to
27 Practice, http://sesss05.setac.eu/programme/presentations/?contentid=565&pr_id=470&last=487), but it
28 is not clear that insights from this work are being incorporated into the documents being developed by
29 the RAF.
30

31 *Recommendations*

- 32
- 33 • More information is needed to evaluate [the](#) potential success of the RAF Ecosystem Services
34 Endpoint Technical Panel project. However, the SAB encourages the EPA to complete the
35 ecosystem services white paper and recommends that, in addition, the authors consider submitting a
36 briefer version to a peer-reviewed publication that would make it available to a wider audience. The
37 decision to incorporate several case studies into this document will increase its value.
38
 - 39 • The SAB recommends that the ecosystem service white paper include an evaluation of the use of
40 [information related to](#) ecosystem services endpoints throughout the entire risk assessment and risk
41 management decision process. Considering the entire range of process steps will help achieve the
42 EPA’s defined goals, namely making ecological risk assessment more frequently used and more
43 useful to managers in making the their decisions.
44

- The ecosystem service white paper should include a description of how the concept of ecosystem services is being used in other agencies and other countries. Many natural resources agencies (e.g., U.S. Forest Service) routinely include ecosystem services in their management strategies

3.5.2. Definition of Ecosystem Services Endpoints

The SAB was also asked to comment on the range of ecosystem services described in Appendix B of the EPA's generic ecosystem assessment endpoints guidance. Neither the GEAE nor the Colloquium Report, *Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward* (EPA 2010) captures the full range of concepts embodied by the term ecosystem services. More current ecosystem services concepts and definitions, provided below in Table 1 (Millennium Ecosystem Assessment, 2005; U.S. EPA SAB 2011), need to be incorporated into the EPA's guidance, replacing older terminology and meaning (e.g. Appendix B Table B-1 of the GEAE). This would provide the EPA with continuity of thought and concepts with the published literature on ecosystem services, and would provide clarity as to what constituted ecosystem services. The term "ecosystem services" is used frequently in the Colloquium Report, but there is no list of services or discussion of the broad range of tangibles and intangibles included in the term.

It is difficult to judge how the proposed addendum to the table in Appendix B of the GEAE will build on the material that is now in the guidance document. Presumably, the text of the white paper will provide further explanation and support. If the RAF has not already considered and rejected revising the original GEAE guidance, the SAB recommends considering updating the original guidance rather than producing an addendum. If both an original and an addendum are in circulation, a practitioner could mistakenly use only one, which could lead to errors.

The current GEAE document lists ecosystem functions as a possible endpoint, but only for wetlands. Some evaluation of the experience in using this endpoint would be a valuable aspect of the EPA's proposed analysis because there is more experience in using structural rather than functional endpoints. Section 4 of the GEAE proposes that there be a place (e.g., a website) where experiences with these and other endpoints could be posted. This is a useful suggestion.

The incorporation of ecosystem services into ecological risk assessment at the EPA should be straightforward. There are a number of examples from work outside of the agency that can be used as models (see above). In addition, Suter et al. (2005) have presented an approach for endpoint definition that can easily be applied to ecosystem services. They define an endpoint as an entity plus its attribute(s). Although they did not single out ecosystem services in their paper, this foundation is applicable. For example, a common ecosystem service is the persistence of commercial and sports fisheries. With that as the ecosystem service, the attributes would be those entities that embody that service. For example, in the Willamette River in Oregon, fisheries are defined by the Oregon Department of Fish and Wildlife as ~~a the~~ number of ~~each~~ salmonid species for each of the segments of the river and their tributaries. The specifications for the types of fish and the numbers are the attributes of the commercial and sport fishing ecosystem service. For the South River of Virginia that same service is defined by the Commonwealth of Virginia as a certain number of trout in one part of the river and by the number of sunfish and bass in other segments. The ecosystem service of flood control can be defined

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1 by the number and extent of floods. Water quality and quantity have attributes that are mandated by
2 local, regional and federal standards.

3
4 The SAB recommends that when the RAF Ecosystem Services Endpoint Technical Panel completes its
5 listed objectives at the end of fiscal year 2012, it consider looking at the other policy focus areas in the
6 Plan to determine where ecosystem services information should be incorporated into those other topics.
7 Although this is not currently part of the Technical Panel's charge, the linkage with communications is

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Table 1. Global status of provisioning, regulating, and cultural ecosystem services (Millennium Ecosystem Assessment 2005)

Service	Sub-category	Status	Notes
Provisioning Services			
Food	Crops	+	Substantial production increase
	Livestock	+	Substantial production increase
	Capture fisheries	-	declining production due to overharvest
	Aquaculture	+	substantial production increase
	Wild foods	-	declining production
Fiber	Timber	+/-	forest loss in some regions, growth in others
	Cotton, hemp, silk	+/-	declining production of some fibers, growth in others
	Wood fuel	-	declining production
Genetic resources		-	lost through extinction and crop genetic resource loss
Biochemicals, natural medicines		-	lost through extinction, overharvest
Freshwater		-	unsustainable use for drinking, industry, and irrigation
Regulating Services			
Air quality regulation		-	decline in ability of atmosphere to cleanse itself
Climate regulation	Global	-	net source of carbon sequestration since mid-century
	Regional and local	-	preponderance of negative impacts
Water regulation		+/-	varies depending on ecosystem change and location
Erosion regulation		-	increased soil degradation
Water purification and waste treatment		-	declining water quality
Disease regulation		+/-	varies depending on ecosystem change
Pest regulation		-	natural control degraded through pesticide use
Biological control, trophic structure		+/-	trophic-dynamic regulations of populations
Pollination		-	apparent global decline in abundance of pollinators
Natural hazard regulation		-	loss of natural buffers (wetlands, mangroves)
Supporting Services			
Soil formation		+	Weathering of rock and erosion
Photosynthesis		+	
Primary production		+	net primary production has increased
Biodiversity		-	loss of species
Nutrient cycling	Nitrogen	-	large-scale changes from general eutrophication
	Phosphorus	-	
Water cycling		-	major changes from structural changes in rivers, water withdrawal, and climate change
Habitat, refugia		-	habitat for resident and transient populations
Cultural Services			
Spiritual and religious values		-	rapid decline in sacred groves and species
Aesthetic values		-	decline in quantity and quality of natural lands
Recreation and ecotourism		+/-	more areas accessible but many degraded

Status indicates whether the condition of the service globally has been enhanced (+) or degraded (-) in the recent past.

obvious, and other important linkages with topics like such as strengthening the EPA's protective goals and applying systems and integrated approaches may be uncovered. The RAF Ecosystem Services Endpoint Technical Panel could act as a cross review group with expertise in ecosystem services that could contribute to the other tasks.

Recommendations:

- The EPA should incorporate more current ecosystem services concepts and definitions (e.g., Table 1) into the GEAE document replacing older terminology and meaning.
- The EPA should consider updating the original GEAE guidance rather than producing an addendum. If both an original and an addendum are in circulation, a practitioner could mistakenly use only one, which could lead to errors.
- EPA guidance should include evaluation of experience in using the functional wetlands endpoint because there is more experience in using structural rather than functional endpoints.
- When the RAF Ecosystem Services Endpoint Technical Panel completes its listed objectives at the end of fiscal year 2012, it should consider looking at the other policy focus areas in the Ecological Assessment Action Plan to determine where ecosystem services information should be incorporated into those other topics

3.6. Use of Adaptive Management for Testing and Revising Risk Management Actions

Charge Question 6. In its 2007 report, Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in environmental Decision-Making, the SAB recommended that EPA use adaptive management to address uncertainties in decision-making. The application of adaptive management in risk assessment and risk management is discussed in section 6.3 of the EPA colloquium report, integrating Ecological Assessment and Decision-making at EPA: A Path forward, and the RAF Action Plan proposes the development of adaptive management as a tool to methodically improve risk management decisions. Please comment on how adaptive management approaches can be developed to provide optimal value for EPA programs.

3.6.1. General Comments on Developing Adaptive Management Approaches

Adaptive management is a process intended to reduce the uncertainty in the decision-making process through the use of monitoring efforts and the iterative evaluation of the data from these monitoring programs. The NRC (2004) identified six elements as key principles of adaptive management:

- (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;

- 1 (5) ongoing monitoring and evaluation are necessary to improve accuracy and completeness of
2 knowledge; and
3 (6) management actions are revised with new cycles of learning.”
4

5 Adaptive management has not been adopted as a formal policy in EPA programs; however, its concepts
6 have been adopted by other regulatory agencies responsible for the management of environmental
7 concerns.
8

9 Both the SAB and the RAF have previously considered the use of the adaptive management approach, at
10 least in part. In its 2007 report, *Advice to EPA on Advancing the Science and Application of Ecological*
11 *Risk Assessment in Environmental Decision-Making*, (U.S. EPA Science Advisory Board 2007) the
12 SAB recommended that the EPA use adaptive management to address uncertainties in decision-making.
13 Subsequently, in its 2010 Colloquium Report, the EPA RAF concluded that “Adaptive management is
14 potentially a highly useful strategy, but its implementation would require changes in fundamental
15 agency science policies and practices.” The SAB provides the following comments and
16 recommendations concerning development of adaptive management approaches to provide value for
17 EPA programs.
18

- 19 • The six elements of adaptive management that were identified by the NRC (2004) and described in
20 section 6 of the RAF Colloquium Report seem-are consistent with the general risk assessment
21 framework typically employed in conducting an ecological risk assessment in accordance with
22 existing EPA policy (U.S. EPA 1992; 1998). The SAB therefore concludes that the use of adaptive
23 management approaches is a logical recommendation and an appropriate application in the risk
24 assessment framework. Adaptive management offers an opportunity to improve practices in
25 ecological risk management and to document successes so that decision-makers have greater
26 appreciation for the practice of ecological risk management.
27
- 28 • The SAB notes that one of the six adaptive management elements, ongoing monitoring and
29 evaluation, is a key aspect of adaptive management that is not always fully implemented in the risk
30 management framework and the evaluation of mitigative actions. This is likely due to a lack of
31 regulatory authority or cost considerations, but the importance of these activities as a means of
32 “uncertainty” evaluation and a measure of “validation” of the risk assessment or the “efficacy” of
33 mitigation actions should not be overlooked. Monitoring and evaluation should be incorporated in
34 any risk management activities. The SAB notes that Bayesian approaches, causal argumentation, and
35 probabilistic risk assessment would facilitate the development of hypotheses that could be evaluated
36 as part of the adaptive management process
37
- 38 • Incorporation of adaptive management principles into the EPA’s risk assessment framework is an
39 appropriate goal for the agency. However, it is recognized that implementation of this goal may be
40 quite difficult given the complexity of consistent and continuous ecosystem monitoring and
41 evaluation over appropriate time scales and the scope and magnitude of resource limitations
42 currently facing the EPA. Nonetheless it is a goal to be aspired to and implemented with time.
43
- 44 • Incorporation of the adaptive management approach into the risk assessment framework may be
45 particularly useful for addressing certain technical concerns (e.g., climate change) or programmatic
46 issues facing EPA programs (e.g., Office of Pesticide Programs, Superfund, Office of Air)-facing the

1 | **EPA.** However, the adaptive management approach may not be appropriate for all of the complex
2 “risk assessment applications” throughout the various EPA programs using the risk assessment
3 framework.
4

Comment [JM45]: Meyer - The parenthetical phrase just lists program offices – this is not a listing of issues. It is not clear what is meant here.

- 5 • Comments from EPA staff suggest that the adoption of all the principles in the adaptive management
6 approach may involve the need to understand the mechanism(s) of “why we see what we see.” This
7 may require more than just an understanding of the “validation” or “lack of validation” of the
8 management actions taken. EPA staff is concerned that this interpretation of adaptive management
9 may be more onerous than is actually needed. The SAB appreciates the EPA’s concern in this regard
10 and suggests that recommendations for the use of adaptive management principles should indicate
11 that “aspects of the adaptive management approach” are appropriate for inclusion in the risk
12 assessment process.
13
- 14 • Risk assessment is, by its very nature, an iterative process and this is consistent with the adaptive
15 management approach. The approach can be described as “*Plan, do, check, adapt*,” one must always
16 look back to check that actions had their intended consequences. It is difficult to predict at the
17 problem formulation phase of any risk assessment all of the issues or concerns that may arise;
18 therefore, changes in approach may be needed and appropriate. This appears to be a key principle of
19 the adaptive management approach and one that should garner greater focus in the implementation
20 of the risk assessment framework.
21

22 *Recommendations*

- 23
- 24 • The SAB recommends that EPA take action to implement the goal of incorporating adaptive
25 management principles into the agency’s risk assessment framework. However, the SAB recognizes
26 that implementation of this goal may be difficult given the complex problems and the scope and
27 magnitude of resource limitations currently facing the EPA.
28
- 29 • Monitoring and evaluation should be incorporated into the EPA’s risk management activities.
30 Monitoring and evaluation are an important means of “uncertainty” evaluation and a measure of
31 “validation” of a risk assessment or the “efficacy” of mitigation actions.
32

33 **3.6.2. Importance of Applying Statistical Design Principles in Adaptive Management**

34
35 Adaptive management effectively occurs when natural resource managers apply the principles of
36 rigorous statistical design of experiments to evaluation of management actions. In the best cases, this
37 can result in powerful “management experiments.” Such management experiments may have to occur at
38 large temporal or spatial scales, and therefore require careful thought and planning. In order to compare
39 selected practices or policies, one must be able to state management questions in terms of testable null
40 hypotheses about the system being managed. This usually requires a good deal of knowledge about the
41 particular ecological process(es) being studied.
42

43 As part of any project design, there need to be clearly defined study objectives. One has to decide what
44 the different “treatments” being compared are; in adaptive management these could be different risk
45 management practices or policies. There may be ancillary variables (“covariates”) that also affect the
46 response; if so, they must be recorded and included in the data analysis. One has to think carefully about

1 the experimental units to which the different “treatments” are being applied. For example, in comparing
2 different fishery management practices, an experimental unit might be a large region to which a
3 particular management practice has been assigned. Inferences are the most solid when true random
4 assignment of “treatments” to experimental units can actually be done, although this is ~~probably~~ not
5 always the case.

6
7 There may be a need to separate experimental material into “blocks” (e.g., in space or time) such that
8 there is more homogeneity within blocks, more heterogeneity between blocks, and each “treatment”
9 occurs once in each block. An example is a boat using 3 different types of fishing gear meant to decrease
10 accidental seabird bycatch, in a set time period, in randomized order. Another is using different forest
11 management practices (the “treatments”) in a relatively homogeneous area of land.

12
13 The concept of a “control” also requires some thought. ~~For example, in~~ ecological studies where few
14 areas are really pristine, the concept of regional reference sites as “controls” has been used.
15 Statistical replication is necessary in order to get useful inference from the results. This means multiple
16 experimental units must receive the same “treatment.” For example, in comparing different fishery
17 management practices, at least two regions would need to be subjected to each management practice. In
18 the forest management example mentioned above, several large blocks of land would be required; ~~and~~
19 each block would have the different forest management practices occur within it. One can ~~take~~obtain
20 measurements on the same experimental unit over time or space; that can add useful information, but
21 that would not be statistical replication in the sense of adding more true experimental units.
22 Accumulating lots of data points is not necessarily the same as adding more statistical replicates.
23 The usefulness of the subsequent data analysis depends upon measuring meaningful responses at
24 appropriate scales and using a good sampling design, paying attention to the original objectives. Quality
25 control at every step of the way is crucial.

26
27 It is also important to consider “What, When, Where, and How.” “What”² refers to the response
28 variables being monitored; these must be decided with care. Sometimes the response variables are
29 obvious from knowledge of the process being studieds, sometimes they are not (see comment about pilot
30 studies, sample size and power analysis below). “When” and “where” refer to the temporal and spatial
31 aspects of monitoring, and “how” to the actual method of obtaining the data. In the context of adaptive
32 management, this could be carefully designing a long-term, ~~or~~ large, or multi-stage monitoring study,
33 with chosen milestones when actual hypothesis testing or estimation of important parameters occurs.

34
35 Paying attention to Type I and Type II errors and their costs is also important. In classical statistics, a
36 Type I error occurs when data lead one to reject a specified null hypothesis (i.e., a hypothesis of “no
37 difference”, or “no change”) in favor of an alternative hypothesis, when the null hypothesis is actually
38 the true state of nature. A Type II error occurs when data result in the failure to choose the alternative
39 hypothesis when the alternative is actually the true state of nature. In adaptive management, attention
40 must be paid to the costs of making each type of error. Pilot studies can yield valuable information in
41 this regard before a large experiment or massive monitoring effort takes place. Pilot studies can also aid
42 in sample size determination, or even in the choice of response variable (e.g. one which has the most
43 statistical power to detect a certain level of change). Results from hypothesis tests or estimation of
44 certain effects can then be incorporated into future decisions. While there are limitations to applying
45 statistical design of experiments principles when comparing management practices, one can still strive to
46 meet such principles.

Adaptive management requires scientists to look at every ecological monitoring effort as an experiment, through the prism of statistical design, and to implement that monitoring using rigorous statistical principles. This is not a trivial effort. Perhaps the biggest point in favor of an adaptive management approach is that by applying statistical design principles to assess and compare ecological risk management practices, any subsequent weight-of-evidence arguments would then incorporate rigorous quantitative results, with associated estimates of uncertainty. This is a big advantage of using the adaptive management approach.

Recommendation

- In order to implement effective adaptive management approaches, the EPA should apply principles of rigorous statistical design.

3.7. Strengthening the EPA's Ecological Protection Goals

Charge Question 7. The RAF Action Plan indicates that there is little consensus in EPA about goals for the protection of ecological systems, and that important and well-developed ecological science principles (e.g., systems analysis, landscape ecology, ecosystem services, and adaptive management) have not been systematically integrated into the agency's science policy framework. Are there aspects of ecological risk assessment science that make the information difficult to communicate, use, and process by decision-makers? What recommendations does the Committee have to strengthen EPA's ecological protection goals? Please comment on how ecological assessment science can be used to strengthen EPA's ecological protection goals.

The EPA should strengthen its ecological protection goals. This need is particularly urgent because the ecological protection goals are likely to provide important context and guidance for the development of ecological assessment approaches used by the agency. As mentioned in the Plan, increasing the representation and influence of ecological scientists in the agency is likely to be crucial to strengthening and sustaining ecological protection goals over the long term.

Comment [JM46]: Meyer - This is a very strong statement, but I don't think we are clear in what we mean by "ecological protection goals." What are the goals that need to be strengthened? Do we mean strengthened or more clearly articulated.

Incorporation of ecosystem services into the ecological assessment process is an effective strategy to strengthen the EPA's ecological protection goals, given that an ecosystem services framework explicitly recognizes the interdependence of the ecosystem and human health. This framework could be further expanded to include environmental justice which recognizes that poor ecological conditions and/or health can exacerbate exposure and the magnitude of negative impacts on vulnerable populations.

The concept and application of ecosystem services has been an important component of recent global efforts by United Nations agencies to reduce excess nutrients delivered to coastal zones and the negative environmental impacts associated with these excess nutrients, which are primarily harmful algal blooms and hypoxia. Ecosystem services have been particularly important in conveying risks of continued increases in hypoxia from excess nutrients. For example, very preliminary estimates indicate a possible 0.5% loss of global ecosystem services due to hypoxia. These services are valued at approximately 200 billion in 1994 dollars (citation needed). The factors that will lead to long-term sustainability of ecosystem services are central to development of management strategies for reducing nutrient loadings and consequently hypoxia (STAP 2011). The consequences of oil spill impacts on estuarine and bay habitats, linking ecosystem structure to function, have recently been discussed (NRC 2012). Thus, the

1 concept of ecosystem services could provide an overall framework for assessment and lead to increased
2 effectiveness and responsiveness of the EPA to the social, economic, and ecologic components of risk
3 assessment. Other clear examples linking ecosystem health to human health also exist. The assessment
4 of the Milltown Reservoir on the Clark Fork River, Montana and the assessment of the Coeur D'Alene
5 River in Idaho (NRC 2005) are two examples. Damaged ecosystems are a bellwether to damaged human
6 health. EPA ecological risk assessors should make a more direct case connecting human health to
7 ecosystem health and follow this with development of relevant ecosystem evaluation methods.
8

9 Many of the risk assessment practices recommended in the 2007 SAB report on advancing the science
10 and application of ecological risk assessment and in Dale et al. (2008) would lead to the development of
11 stronger ecological protection goals at the EPA. Implementation of these recommendations would bring
12 about stronger protection of ecosystem structure and function. Ultimately, the recommendations would
13 not only lead to more robust assessments, but also better understanding of ecosystem structure and
14 function. This understanding, in turn, would lead to better predictability of effects and wider
15 applicability of ecological assessments in similar situations. Some key recommendations are provided
16 below.
17

18 Recommendations

- 19
20 • Scale, both in time and space, should be explicitly considered in the problem formulation stage of
21 ecological risk assessments. Aspects such as life history and scope-for-growth analyses are
22 important because the use of r , the intrinsic rate of natural increase, ultimately is useful in predicting
23 if a population, subject to stressors of a variety of types, will grow, stabilize or shrink ~~in the present~~
24 ~~conditions~~.
- 25
26 • Ecological risk assessments should link biomarkers of exposure to biomarkers of effect, ~~whether~~
27 ~~they be metabolic costs (scope for growth), ultrastructural modifications of critical organs (e.g., gill~~
28 ~~clubbing), or net reproductive output over several generations.~~
- 29
30 • As previously discussed, post-remedial assessments and adaptive management programs should be
31 incorporated into the risk assessment and management process in order to adjust the remediation
32 approaches should this be necessary after the assessment.
33
- 34
35 • Success stories, in which environmental cleanup has led to cleaner air and water, should be
36 developed and used to enhance the communication process between risk managers, assessors and
37 environmental scientists. An overarching recommendation of the SAB is that risk assessment teams,
38 assessors and managers use better communication techniques to educate ~~management managers,~~
39 ~~policy makers,~~ and the general public.
40

Comment [JM47]: Meyer – We have been asked if the RAF Plan does an adequate job of responding to the recommendations in the earlier SAB report, and we have said that it does. Hence this statement is unclear. Are we saying that the Plan does not address these recommendations and if it did, then that would lead to stronger ecological protection goals? Then we make further recommendations in the next section. Are we saying these are the recommendations from the earlier report that it is most important to address? Some clarification of this whole paragraph is needed.

Comment [PC48]: Chapman – Not just in present.

Comment [PC49]: Chapman – Mixing apples and oranges here. Either first clearly give examples of those of exposure then those of effect or leave short as is.

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APPENDIX A: THE CHARGE TO THE SAB



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

January 20, 2012

OFFICE OF SCIENCE ADVISOR
Risk Assessment Forum

MEMORANDUM

SUBJECT: Transmittal of RAF Ecological Action Plan and Charge to the SAB EPEC

FROM: Edward Ohanian, Chair
EPA Risk Assessment Forum

TO: Thomas Armitage
EPA Science Advisory Board Staff Office

The RAF Ecological Action Plan, prepared following deliberation on SAB recommendations, is attached for transmittal to the SAB EPEC for their review and comment. Also attached is a charge to the EPEC offering guidance for their review scheduled for February 22 and 23, 2012. We are looking forward to the outcome of this timely meeting regarding SAB/EPEC's feedback on the Action Plan.

Thank you for your assistance in this endeavor.

Attachment

Science Advisory Board (SAB) Ecological Processes and Effects Committee (EPEC) Draft Report (5/9/12) to Assist Meeting Deliberations. Do Not Cite or Quote. This draft report is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered SAB, and does not represent EPA policy.

Charge to the SAB Ecological Processes and Effects Committee for the Advisory on the EPA Risk Assessment Forum's Ecological Assessment Action Plan

February 22 - 23, 2012

The Risk Assessment Forum (RAF) in the EPA Office of the Science Advisor has developed an Ecological Assessment Action Plan identifying six high priority overarching science policy initiatives and seven specific technical practice initiatives to improve the quality, scope, and application of EPA's ecological assessments. The initiatives in the Ecological Assessment Action Plan address high priority recommendations in the report of an EPA colloquium, [Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward](#). The EPA colloquium, which included ecologists from across the Agency, was held in response to a 2007 SAB report titled, [Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision-Making](#) and the National Research Council (NRC) report *Science and Decisions: Advancing Risk Assessment* (National Research Council, 2009).

Summary of RAF Ecological Assessment Action Plan

The following science policy initiatives [are proposed by the RAF in the Ecological Assessment Action Plan](#) to transform and improve the Agency's Ecological Risk Assessments ~~are proposed by the RAF in the Ecological Assessment Action Plan~~:

- ***Develop Guidelines for Application of Systems Approaches to Ecological Assessments and Integration of Different Types of Assessments to Solve Broad Environmental Problems***

The design and conduct of complex large-scale assessments currently facing EPA (e.g., global change, sustainability, estuarine and coastal hypoxia, integrated nitrogen control, hydraulic fracturing of deep geologic formations for methane extraction, mountain top mining, and deep sea oil spills) requires a broad assessment framework. The RAF recommends that EPA develop a systems approach to ecological assessments that includes multiple media and endpoints as well as integration of different types of assessments described in Cormier and Suter (2008)¹ and in chapter 3 of the EPA colloquium report [Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward](#). The framework focuses on resolving environmental problems by integrating different types of assessments: (1) condition assessments to detect chemical, physical, and biological impairments; (2) causal pathway assessments to determine causes and identify their sources; (3) predictive assessments to estimate environmental, economic, and societal risks, and benefits associated with different possible management actions; and (4) outcome assessments to evaluate the results of the decisions of an integrative assessment.

- ***Improve Communication of Ecological Assessment Issues and Results***

The RAF Action Plan calls for the development of methods for better communication of ecological assessment issues and results to decision-makers and stakeholders. This applies to communicating ecological assessment issues during both planning of assessments and

¹ Cormier, S.M., and G. Suter. 2008. [A Framework for Fully Integrating Environmental Assessment](#). *Environmental Management* 42:543-556.

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presentation of results. In part, this is a matter of the 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 standards 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 EPA guidance for communicating ecological risks. A Risk Assessment Forum panel is studying this issue.

- ***Incorporate Ecosystem Services and Benefits in Ecological Risk Assessments***

The outcomes of research into ecosystem services and benefits are potentially transformational for environmental sciences and decision-making. Ecosystem services can be used to describe potential outcomes of environmental management decisions in terms that can be more effectively communicated to decision-makers and the public. A Risk Assessment Forum panel is addressing this issue and expects to produce case studies and guidance on how to relate ecological risk assessment endpoints to ecosystem services. This information will be used to update the EPA guidance document [Generic Ecological Assessment Endpoints \(GEAEs\) for Ecological Risk Assessment](#) (U.S. EPA, 2003).

- ***Strengthen Science Policies that Promote Agency-wide Ecological Protection Goals***

There is little consensus in the Agency about goals for protection of ecological systems or the importance of ecological effects. In addition, important and well-developed ecological science principles (e.g., systems analysis, landscape ecology, ecosystem services, and adaptive management) are unfamiliar and have not been systematically integrated into the Agency's science policy framework. If the Agency is to successfully incorporate ecology, it must consider ways to elevate representation and influence of ecological scientists in its programs, regions, and Intra-Agency science policy development and coordinating bodies.

- ***Incorporate Adaptive Management as a Formal Science Policy for EPA***

Adaptive management is a process that determines the outcomes of actions and uses that information to improve assessments that inform decisions, thereby improving the efficacy of those decisions. Adaptive management has not been adopted as a 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 RAF recommends the development of adaptive management for testing and revising risk management actions.

- ***Develop Weight-of-Evidence as an Option for Inference in Ecological Assessments***

Although ecological assessments often involve multiple lines of evidence, there is no guidance on how to weigh those lines of evidence to make inferences. The SAB identified a need for guidance, case studies, and standards of practice for weighing multiple lines of evidence to support decision-making. The weight-of-evidence should be used and fully documented during problem formulation, data analysis and interpretation, and risk characterization. The RAF recommends development of guidance on the use of weight-of-evidence.

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The following specific technical practice initiatives are also proposed by the RAF in the Ecological Assessment Action Plan:

- **Training and Improved Access to Information for Ecological Assessment** - Risk assessor and manager training and increased access to information will lead to improved quality of risk assessments.
- **Quality Assurance and Data Quality Objectives for Ecological Assessment** - Quality assurance and data quality objectives for ecological risk assessment will formalize ecological assessment standards.
- **Assessing the Risks of Multiple Stressors** — Development of Guidance is proposed for assessing the risks of multiple stressors.
- **Receptor-specific and Stressor-specific Guidance** — Development of Guidance is proposed for common receptor and stressor-specific assessments.
- **Life Cycle Analysis for Product Safety Evaluations** — Development of Guidance is proposed for assessing new chemicals and other products using a life cycle approach. This will improve the quality of assessments and decisions.
- **Uncertainty Characterization and Communication** - Guidance is proposed for characterizing uncertainty and preparing risk communication information.
- **State-of-the Science, Best Practices Reports, Exemplary Case Studies, and Success Stories** - This initiative will provide timely information on best practices to risk assessors.

Overarching Charge Question

Charge Question 1. Overall technical merit of the proposed science policy and technical practice initiatives.

The RAF Ecological Assessment Action Plan proposes six high priority overarching science policy initiatives and seven specific technical practice initiatives to improve the quality, scope, and application of EPA's ecological assessments. Please comment on whether the initiatives proposed in the Plan are a) responsive to SAB and NRC recommendations; and b) reflect the most important set of activities needed to address the key scientific and technical challenges ~~to~~for advancing the application of ecological risk assessment in environmental decision-making. Please also consider whether there are other key science policy or technical practice initiatives that should be considered for inclusion in the Plan.

Specific Charge Questions

Charge Question 2. Importance of developing an integrated assessment approach.

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The RAF Action Plan proposes that EPA develop a systems approach to ecological assessments that includes multiple media and endpoints as well as integration of different types of assessments as described by Cormier and Suter in [A Framework for Fully Integrating Environmental Assessment](#), *Environmental Management* 42:543–556, and in chapter 3 of the EPA colloquium report [Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward](#). The framework focuses on resolving environmental problems by integrating different types of assessments: (1) condition assessments to detect chemical, physical, and biological impairments; (2) causal pathway assessments to determine causes and identify their sources; (3) predictive assessments to estimate environmental, economic, and societal risks, and benefits associated with different possible management actions; and (4) outcome assessments to evaluate the results of the decisions of an integrative assessment. Please comment on how guidance for an approach to assessment that integrates different media and endpoints and different types of assessments might contribute to better decision making (e.g., assessment of complex issues, cumulative risk assessment and sustainability analysis).

Charge Question 3. Use of the weight-of-evidence approach in ecological risk assessments.

Although ecological assessments often involve multiple lines of evidence, no guidance exists on how to weigh those lines of evidence to make inferences. The RAF Action Plan proposes that EPA develop such guidance. Please comment on the scientific ~~benefits~~merit and limitations of using a weight of evidence approach in decision making and offer any guidance on weighing ecological risk assessment (ERA) lines of evidence.

Charge Question 4. Communication of ecological assessment issues and results to decision-makers and stakeholders.

The RAF Action Plan calls for the development of methods for better communication of ecological assessment issues and results to decision-makers and stakeholders. This applies to communicating ecological assessment issues during both planning of assessments and presentation of results. In part, this may be a matter of the inability of assessors to communicate the significance of the loss of species, changes in community structure, and other endpoints. The RAF has developed a communication technical panel project description. Please comment on whether the RAF's planned project is an appropriate way to proceed, and ~~the-what~~ obstacles ~~that~~ might exist to either interpreting or utilizing ecological information in risk assessment. Please include any observations on why ERA has or has not been well incorporated into decision making in general.

Charge Question 5. Incorporation of ecosystem services into ecological risk assessment methods.

Ecosystem services can be used to describe potential outcomes of environmental management decisions in terms that can be more effectively communicated to decision-makers and the public. RAF expects to produce guidance on how to relate ecological risk assessment endpoints to ecosystem services. This information will be used to update the EPA guidance document [Generic Ecological Assessment Endpoints \(GEAEs\) for Ecological Risk Assessment](#) (U.S. EPA, 2003). Please consider Appendix B (page 52) of the generic ecological assessment endpoints guidance document and the work plan for the RAF Technical Panel on Ecological Services Assessment

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Endpoints and comment on whether they capture the full range of opportunities to incorporate ecosystem services into EPA's ecological risk assessment methods.

Charge Question 6. Use of adaptive management for testing and revising risk management actions.

In its 2007 report, [*Advice to EPA on Advancing the Science and Application of Ecological Risk Assessment in Environmental Decision-Making*](#), the SAB recommended that EPA use adaptive management to address uncertainties in decision-making. The application of adaptive management in risk assessment and risk management is discussed in section 6.3 of the EPA colloquium report [*Integrating Ecological Assessment and Decision-Making at EPA: A Path Forward*](#), and the RAF Action Plan proposes the development of adaptive management as a tool to methodically improve risk management decisions. Please comment on how adaptive management approaches can be developed to provide optimal value for EPA programs.

Charge Question 7. Strengthening EPA's ecological protection goals.

The RAF Action Plan indicates that there is little consensus in EPA about goals for the protection of ecological systems, and that important and well-developed ecological science principles (e.g., systems analysis, landscape ecology, ecosystem services, and adaptive management) have not been systematically integrated into the Agency's science policy framework. Are there aspects of ERA science that make the information difficult to communicate, use and process by decision makers? What recommendations does the committee have to strengthen EPA's ecological protection goals? Please comment on how ecological assessment science can be used to strengthen EPA's ecological protection goals?