

**Preliminary Comments from Members of the Chartered SAB on the SAB
Draft Report SAB Review (7-24-12 Draft) of the EPA’s Ecological Assessment
Action Plan (Quality Review Draft)**

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Comments from lead reviewers

Comments from Dr. Joseph Arvai

General comments:

I appreciate that a great deal of work went into the EPA's Ecological Assessment Action Plan and the accompanying SAB review. The topic of the report and the SAB review are extremely important for EPA and I applaud the agency and the SAB for its work in this area.

However, I found both the report and the SAB review to be quite difficult to read and, at times, quite frustrating in terms of the material discussed and the recommendations put forward.

My main concern with the plan is that it does not elucidate why an ecological assessment action plan is needed, nor does it provide any indication as to how such an action plan will be used/implemented by the agency. This, in my view, granted the SAB license to wax poetic about all kinds of things the EPA could do as part of an "ecological assessment action plan" without a lot of consideration as to why such recommendations would be needed, or how they might be used.

For this reason, I found myself questioning many of the recommendations and disagreeing with others.

1) Were the charge questions to the committee adequately addressed?

Yes and no.

Yes, in that the responses to the charge questions were extremely thorough clocking in at 26 pages long, not including the executive summary, for a report that was only 4 pages long.

No in the sense that the responses to the charge questions read like a bit of a grab bag of ideas, concepts, arguments, and supporting information. It seemed as though the SAB viewed its report as a means of expanding upon (maybe even rewriting) the report itself, rather than just responding to the charge questions.

Based on how much disparate information was provided in the SAB response, it's not clear to me how much of it (1) is responsive to realities and constraints at the agency, and (2) will be useful for agency decision makers.

For example, the SAB suggests that the EPA look at what other countries are doing with respect to ecological risk assessment. This seems to me like a bit of wild goose chase in that different countries, and indeed more local or provincial/state jurisdictions, look at ecological systems and ecological risks in wildly different ways. It's not clear to me what the EPA would learn from such an exercise other than, wow, things sure are different in other places.

The suggestion that the EPA look at what other agencies with the US (USFS, NOAA) are doing in the arena of ecological risk assessment is a good one with a caveat. Namely, this recommendation can be more easily supported if the mandates of the comparison agencies (or sub-processes therein) match those of the EPA.

In another part of the report, the SAB suggests that the EPA prepare a publication based on the plan for peer review. Again, it's not clear to me why the EPA should do this in light of resource constraints at the

agency and in terms of providing benefits or added value to the EPA. Perhaps the SAB thinks there is a good reason for taking such a step and I concede that I may simply be missing it. If so, it should be much more clearly articulated in its report.

By way of a third example, the SAB calls for greater inclusion of insights from the social sciences. However, the level of detail that follows this recommendation is quite low.

Calling for more social science in ecological risk assessments is low hanging fruit and, as such, lots of people like to talk about it. But, the amount and type of social science that is needed will be driven by the decision contexts for which the analyses are used. Simply calling for more input from the social sciences is, in my view, not terribly informative for the EPA in the absence of more information regarding *what kind of social science information is needed* and, importantly, *why it is needed (from the standpoint of informing decisions)?*

2) *Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?*

There were a few instances where I was left wondering about the recommendations provided by the SAB. For example:

- In response to one of the charge questions, the SAB suggests that (1) a weight of evidence (WOE) approach, (2) communication, and (3) incorporation of ecosystem services be given high priority in terms of advancing the agency's goals in the near term. What is the rationale for these three priority areas (over others)? Moreover, a more compressive and defensible decision making framework would view all three of these issues (as well as others) as connected (in that you can't really have one without the others).
- With respect to the application of a weight of evidence (WOE) approach specifically, the SAB provides a lengthy treatise on the limitations and weaknesses of WOE (pp. 15 – 16), along with expository text that suggests that a WOE approach for ecological risks may not be at amenable for application by the EPA (when compared to health risks).
- But, in spite of this, the SAB provides a series of recommendations (p. 17, p. 18) for the application of WOE to ecological risk. Based on my read, I'm not sure that I am convinced by the EPA's Ecological Assessment Action Plan or the accompanying SAB review that a WOE approach is appropriate.

As I understand it, the aim of the EPA report is to improve the quality, scope and application of the agency's ecological (risk) assessments. To me, this means clearly articulating how information from ecological assessments will be used in the context of informing agency decisions. The parameters of these decision making process set the stage for what kind of information will be necessary from an ecological assessment. WOE approaches are not as tightly linked to decision making process as are other methods (in my view). To this end, I'd urge the EPA and the SAB to look more closely at two sources:

1. *Structured Decision Making: A Practical Guide to Environmental Management Choices* by Gregory et al. (2012); and
2. *Understanding Risk: Informing Decisions in a Democratic Society* by the NRC (1998).

Indeed, I found it quite curious that this latter book was not used (seemingly) in either the Ecological Assessment Action Plan or the SAB's review of it.

The EPA and the SAB might also find useful the work by Willis, Morgan, and colleagues on ecological risk ranking (see *Risk Analysis* 24(2): 363-378).

- The lengthy section on communication (pp. 19-23) seems to be unrelated to any specific decision context. As a result, it's unclear to me how the EPA would benefit from undertaking many of the recommendations (e.g., creating work teams, case studies, etc.). In my view, a better grasp on how to address decisions requiring integrated and multi-criteria analysis would drive better communication (and not necessarily vice versa).
- The SAB provides a lengthy and technically accurate assessment of adaptive management. The SAB remarks (on p. 30), "Adaptive management is potentially a highly useful strategy, but its implementation would require changes in fundamental agency science policies and practices."

I strongly agree with this statement. So much so that I wonder if strict adaptive management as it is discussed on pp. 31-32 (under the heading of Applying Statistical Design Principles...) is even *possible* at the EPA. The rigorous requirements around hypothesis formation and testing, controls, and importantly allowing for failure (so that learning can take place) present – in my view – too high a bar for the EPA to cross.

For more information see: Deconstructing Adaptive Management: Criteria for Applications to Environmental Management in *Ecological Applications* 16(6): 2411-2425.

3) *Is the draft report clear and logical?*

The draft report is very clearly written, and it is quite methodically argued.

However, as I note above, I'm not sure that it will be as helpful to the EPA as the SAB might like given that it does not seem to be sensitive to (1) required inputs to decision making, and (2) the realities and constraints at the agency. Likewise, neither the SAB's recommendations nor the report itself adequately set the stage for why an Ecological Assessment Action Plan is needed in the first place. In my view, this represents a shortcoming of the plan, more than the SAB report.

4) *Are the conclusions drawn or recommendations provided supported by the body of the draft report?*

There were several instances where I was left asking myself why the SAB ventured into certain areas in its review. In my mind, the answer is that the SAB did the best job it could given the vagueness of the EPA's Ecological Assessment Action Plan itself.

In my view, the central problem I have with The Plan and the SAB's response can be summed up in the sentence (p. 33), "The EPA should articulate and elucidate its ecological protection goals."

In my view:

- By having more clearly articulated goals, the EPA will be able to better define the kinds of decisions it needs to make.
- By having a better understanding of the kinds of decisions it needs to make, the EPA will be better able to collect information via ecological assessment to support those decisions.
- Depending upon the nature of these decisions, different branches of the ecosystem sciences will have to be engaged. The same is true for the social and behavioral sciences, as well as for different stakeholders.

- In pulling these groups together to jointly work through a decision, improved communication will be driven by the needs of the decision making process.

Comments from Dr. John Giesy

Note: Page numbers, where they occur in my review refer to the pages in the PDF, not the pages in the following report.

Overall Conclusion:

In general I found the report to be well done. It is concise and addresses all of the charge questions in a very organized and logical manner. It is complete enough to be useful to the EPA as they go about designing the strategy for implementing the proposed suggestions. I think the report is acceptable in its present form. As I read the report, I have made some comments and suggestions to be considered by the committee. Much of what is suggested in the report from SAB has been suggested before. The lack of progress on some of these topics is as much a function of existing legislation and the difficulty of some of the assessments. But more than anything the overriding reason more of the suggestions from the SAB have not been implemented is that most of those suggestions relate to the fact that most of those suggestions have been in technical areas related to science and most of the impediments to their implementation are related to social, political and economic issues. Therefore the suggestion for more integration of the social sciences into the risk assessment process is paramount.

The suggestions I have made are all optional and do not need to be implemented, but some of them might result in correcting some perceptions and others might add more specific guidance that the EPA can use.

1) Were the charge questions to the committee adequately addressed?

Yes. The report gives excellent guidance on how to proceed with the exercise by the Risk Assessment Forum (RAF). The report points out that some of these initiatives will be more relevant to Ecological Risk Assessments (ERAs) than assessments of risk to human health. Furthermore, the SAB report appropriately prioritizes the issues to be addressed first.

There are some redundancies in the report that are repeated in responses to the various charge questions. These may be unavoidable and necessary for each section to stand alone. Some examples of these redundancies are: 1) to include more social scientists and 2) make use of Bayesian methods.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

No. The report is very comprehensive. This is due to the fact that the SAB has been making the recommendations upon which the proposed exercise is based for some time. Especially since the genesis of the entire initiative is the SAB report.

3) Is the draft report clear and logical?

Yes. The report is well organized around the charge questions and easy to read and understand. The text is free of errors of grammar and syntax.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes. The report gives solid guidance and gives appropriate references to help the agency implement the suggestions.

Personally, I think that the potential for Bayesian decision trees and statistical analyses is a bit oversold. While these methods are useful under some conditions, the need to have appropriate distributions selected are a limitation, especially when sample sizes are small, which is exactly when these methods are most useful and likely to be applied. I am somewhat fearful that when these types of analyses of successive sampling are applied that the practitioners get a false sense of the robustness, accuracy and precision of the predictions and statistical inferences drawn. Even though it is easy to bootstrap up to 10,000 or 100,000 observations, if the population of actual observations was only 4, the security is a false security. I would like to retain the suggestion of the application of Bayesian approaches (I use them myself) but add a codicil of caution about assumptions and limitations of the approaches. I have seen some real horror stories in Ecological Risk assessments when default assumptions of distributions of parameters (such as square or triangular distributions are assumed for the initial assumed distributions for parameters).

I think that the report does a good job of calling out some of the difficulties and limitations of achieving some of the goals outlined in the proposals. While it is certainly possible to make improvements, some of the deficiencies exist because of the difficulty of implementing them. It is not that people do not think about life cycle assessments, or multiple stressors or ecosystem services, they do. In risk assessments these issues are often articulated in the problem formulation stage, but it is simply impossible, with current understanding, to make explicit statements about some of these issues. I agree that a more holistic approach that considers the various interactions, uncertainties and trade-offs would be an improvement, but it is often difficult to do more than enumerate these implicitly.

I have similar reservations about adaptive analyses and use of adverse outcome pathways. While useful for some things, both of these have inherent limitations that will limit their applicability under certain situations.

There is a large difference between “lines of evidence (LOE)” and “weights of evidence (WOE)”. The report calls this out, but I think it can be made more explicit. As it is, it reads as if these terms can be used interchangeably—they can’t. I agree with the report in that I think a LOE approach is useful and should be encouraged. I have researched many of the WOE approaches that have been implemented (see State of Massachusetts guidelines for ecological risk assessment. Personally I think that application of explicit weighting factors gives a false sense of sophistication and certainty. While I agree with the guidance provided by the SAB, I think that section 3.2.1 can be revised to be clearer. I suggest a short description of LOE and WOE and a contrasting between the two would be helpful. I also suggest adding some citations to this section to provide more specific guidance on this issue (Fairbrother, 2003).

The discussion of WOE approaches on page 26 (section 3.3.2) is good.

The first whole paragraph on page 22 makes a number of statements about use of appropriate models, quality of data, including different types of stressors. I found this paragraph to be obvious and full of jargon. After reading it I was left wondering if there was any value added by this paragraph or any specific guidance to be gleaned by EPA from it. I do not think so. The suggestion of the use of case studies is a good one, but this was already part of the study plans.

In section 3.2.2, the need to consider climate change in assessments is made. First, this will be difficult to do, so a statement to do it is somewhat glib. But, I am more concerned about some of the statements about the need to consider greater “variability” that will occur due to climate change. I am not comfortable with the assumption that variability will increase. In fact, I doubt that this is true. But if it is, the report needs to identify some proof to support this statement. This will be different in the future than they are now and these differences will be region specific. But how does this relate to variability? I think that this is speculation and not supported by any empirical evidence and should be removed from the report. Just make the point that climate change and potential scenarios need to be considered when assessing risks of the stressors.

I think too much emphasis is placed on the “ecosystem services”. I know that this is a current catch phrase, but in reality it is just another way to say that in the problem formulation valued structural or functional features of an ecosystem need to be articulated and these “assessment endpoint” related to measurement endpoints that can be quantified. I have looked back at the EPA report on quantifying Ecosystem Services and for the life of me cannot see how this is different from the valued attributes that must be identified currently in risk assessments. To simply state that ecosystem services need to be considered in ERAs is not very helpful. I suggest punching this up with specific suggestions of how this can be done.

In section 3.2.3 it is suggested to apply the concept of adverse outcome pathway analyses. While this is sometimes possible, I and many of my colleagues do not subscribe to the theory that there is a small number of discrete and identifiable pathways of adverse outcome. I know that this is a current catch phrase, but without additional clarification and discussion, this is a glib suggestion that provides no real guidance to EPA. Similarly, the term adaptive management is a recent area of investigation. While it is important to consider potential long-term events when construction risk assessment scenarios, I do not find either of these terms particularly useful and suggesting that they be applied without giving more explicit suggestions is not useful. I see these as jargon and basically throwaway suggestions. I think that this section needs more support and justification with some more specifics. As it stands it is not useful. It is good that some references are supplied as examples of how multiple stressors can be addressed. But in general, I think that this section relates to a general more holistic approach and the life cycle approach. I think that this is already implicit in the feasibility portion that is included in most ERAs. While not a bad idea to suggest that this be included in ERAs, I am not sure that it is not already part of the process. I would like to see some specifics called out that would be added to the existing ERA guidance that is not already included.

On page 25 line 38 the report states that the SAB endorses a WOE and LOE approach. It goes on to give some guidance on the use of WOE and especially expert judgement, which is good. But I disagree with the statement that when more is known there will be less need to WOE. I do not think that this is true, but if it is the report needs to provide more specific support of this statement. I suggest that as the data set becomes richer with greater understanding of pathways there will be more need to an assessment of LOW and that WOE will also not be lessened in the future. I think this should be removed from the report. I would like to see more specific guidance on types of WOE that are available and which should be considered for further development.

Starting in section 3.3.2 and continuing for several sections avoid stating sentences with a call out to a citation to literature. Use subject-verb syntax.

In section 3.3.2. I think it is misleading and confusing to state that a meta-analysis is a WOE approach. I disagree. I think it is better to keep the concept of weighting LOEs separate from meta-analyses.

The recommendations in this section are good. They are clear and I think accurate and good guidance to EPA.

I liked the suggestions made in section 3.3.3 on probabilistic approaches to the WOE process. This is very germane to the WOE and gives EPA good guidance.

There is a big difference between the application of Bayesian networks based on previous information and statistical inferences based on Bayesian approaches. I think it would be good at some point in the report to describe Bayesian approaches better and put in a reference to the recent special issue of *Integrated Environmental Assessment and Management* (IEAM).

The recommendations on the exercise to improve communication are fine as written.

The section (3.5) on ecological services is fine and provides a good analysis of the plan put forward by EPA and provides good guidance on how the concept of ecological services can be implemented into the future risk assessment guidance and specifically into the study plan.

Section 3.6. The analysis of Adaptive Management is accurate and the recommendations appropriate and achievable. However, while the recommendations are correct, the recommendations relative to reference areas and experimental designs rely only on Type 1 models, when a type II model (regression) with a range of magnitudes of control might also be appropriate. This approach often has greater statistical power and is more amenable to address cofactors and confounding factors. Also, the monitoring can be a function of time as well as space. That is adaptations to a particular control might be implemented if the trajectory of the measurement endpoint was on what was predicted or wanted. Thus, it would be good to consider other statistical models than a simple type I comparison of alternative practices.

Section 3.7 s fine as written.

Additional Specific comments:

The cover letter is well organized and written and succinct while providing an overview of the guidance provided.

The report is well focused and provides useful input at a time when the plans have been articulated, but the project has not yet been undertaken. Thus there is no report to which to respond, only three short outlines of the tasks to be completed.

The tasks to be completed by the RAF are based on six transformative areas within risk assessments. The working group is to prepare some white papers on the key areas and then take on the tasks of developing guidance. One is to implement a “weight of Evidence Approach” into risk assessments and to harmonize the approach across the agency. Currently US EPA Risk Assessment Guidance (1998) identifies specific properties of functions to be protected and develops assessment endpoints that are then related to “measurement endpoints”. However, these endpoints are not explicitly related to ecosystem services. The RAFA will undertake the task of establishing methods to achieve these sorts of linkages while applying a “systems level approach”. The working group is to further develop risk assessment methodologies to deal with multiple stressors. The working group is further to develop an approach to identify adaptive manage strategies to cope specifically with global climate change. Initially the RAF working group is to take on three specific tasks, to 1) develop a weight of evidence approach, 2) determine how to best relate assessment endpoints to ecosystem services and finally to develop methods and guidance for communicating the results of ERAs to risk managers and the lay public.

Reference:

Fairbrother A. 2003. Lines of evidence in wildlife risk assessments. *Hum Ecol Risk Assess* 9:1475-1491.

Comments from Dr. Duncan Patten

1. Were the charge questions adequately addressed?

The panel did an excellent job of addressing the charge questions and raising important issues. Emphasis on topics such as ecosystem services and WOE are well done.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

Not specifically, however, I believe some of the discussion of adaptive management was narrower than it might be, both in general and how it applies to ecological assessment.

3. Is the draft report clear and logical?

It is quite clear and as I read it, I found myself marking important topics or recommendations as they seem to appear clearly emphasized.

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

The recommendations clearly follow on the preceding text but I still am concerned that the panel limits itself to a “big three” issues to emphasize in the letter to the administrator and later in text. By doing this, the panel seems to “down play” the importance of other topics.

General comments

Overall the report is well prepared and important issues are highlighted. When reading it I regularly marked what I thought were very good points, points that the panel emphasized. These do not need to be brought up here.

One issue that the panel needs to justify is not placing adaptive management as one of the primary recommendations (only three are highlighted). Adaptive management is a fundamental structure for developing the assessment action plan and issues with it that are brought up should be considered critical to development of the assessment plan.

Below are some other points.

Letter to Administrator

First page, lines 26-27. What does this sentence mean?

Executive Summary

Page 3, lines 1-2. Why isn't Adaptive Management part of top issues?

Page 3, lines 14-16. Sentence not clear.

Body of Report

Page 10. Liens 5-8. Again, why is adaptive management not one of the important issues? This omission needs to be defended.

Page 12, lines 17-19. Is SAB just adding questionable complexity by bringing up AOP, or does ORD bring this topic up? Does it belong here?

Page 12, line 35. The implication of bringing up climate change here is that the ORD report never does. If it does, then this should be pointed out.

Page 13, line 9-11. This statement implies that adaptive management isn't long term or can't be long term.... Is that what was meant?

Page 14, line 41. First mention of LOE (I think) and thus spell it out.

Page 15. This is a good discussion of WOE approach.

Page 20. Bottom paragraphs include recommendations which precede the recommendations section which follows. Should this be corrected?

Page 21, Line 35 paragraph. How does this recommendation to use expert opinion fit with SAB concern for use of expert judgments presented earlier in the report?

Page 22, line 23 #2. This recommendation is basically a form of adaptive management... might this be recognized as such?

Page 23, 3.4.2. To push for more recognition of use of adaptive management, this is one section where one could emphasize the use of adaptive management in decision making.

Page 26. 3.5.2. This discussion is appropriate and well done as some of the earlier discussion seems to confuse ecosystem services endpoints with ecological assessment endpoints.... Make sure this is clear....

Page 29. 3.6.1. OK to use NRC six elements but should also recognize that this is only one of many "definitions" or explanations of adaptive management. Many are context oriented.

Page 31. 3.6.2. This section seems to be written by one member of the panel who has a relatively narrow perception of adaptive management. Does the whole panel agree with this discussion of statistical design principles in AM? In this section the emphasis on need to use a null hypothesis approach seems to avoid the potential need to do some small tests or experiments to improve the original conceptual model that is a foundation of adaptive management. See page 32, line 40 where pilot studies are suggested and these can be used to improve the conceptual model that is driving AM.

Comments from Dr. James Sanders

1. Were the charge questions adequately addressed?

Yes, the EPEC did a very good job of responding to the questions presented to them.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

No.

3. Is the draft report clear and logical?

Yes, for the most part. The EPEC is to be commended for developing a very clear and concise report. I have only a few comments and suggestions that might improve the document overall.

Letter to the Administrator: The letter is short and readable, and provides good context for the body of the report. I suggest a word change, from and to but, on P2, line 30 (The SAB supports the goal...assessment framework, BUT recognizes that implementation...).

Executive Summary: For the most part, the summary is very clear, and is aligned with the body of the report. I suggest the following:

P4, lines 8-10. This summary does not match the degree of concern shown in the report body concerning what the result of the planned communication project will be. In this summary, the SAB finds that the project could lead to short-term improvements, with little concern noted. Section 3.4.1 shows a greater level of concern, and consideration should be given to rewriting this summary sentence. I point to the sentences found in the Letter concerning communication, on page 2 of the letter, for use here. I would suggest a rewritten sentence something like: The SAB finds that, WHILE the proposed project could lead to short-term improvements...the SAB also finds that this effort is a preliminary approach that will not provide all of the information needed by the EPA to develop better communication methods (lifted from the letter, page 2)

Report Body: Clear overall with the exception of the comments below on prioritization (P 9). I have the following comments:

P.7, line34. I would delete the reference to the Committee, and say, "the background documents provided included the 2007 SAB report...".

P.9, lines 44-45 and P 10, lines 1-9. I understand that the request for prioritization did not come through the charge questions, but rather during discussions with EPA staff. I think this is a valuable exercise, but believe that further information is necessary. Why were these three initiatives chosen? I do not feel that the sentence that they "had the greatest likelihood of advancing the agency's goals" is an adequate explanation. Could EPEC provide a little more context for why these three were chosen, what components within these initiatives were most attractive, or how they are most likely to advance the agency's goals?

P 27, line 8. I suggest that you delete for example and begin the sentence “In the Willamette River...”

P 27, lines 20+ and P 29, lines 1-21. There is a formatting issue here around Table 1

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes.

Comments from other SAB Members

Comments from Dr. George Alexeeff

1. Were the original charge questions adequately addressed?

The strength of the SAB review was the clearly articulated references to the charge questions. There were seven charge questions to be considered by the Science Advisory Board. These can be briefly summarized into the general area of *technical merit*, and the specific areas of *developing an integrated assessment approach, use of the weight-of-evidence, communication of ecological assessment issues, incorporation of ecosystem services, use of adaptive management, and strengthening EPA's ecological protection goals*. Each of the charge questions were thoroughly addressed and carried forward in the review to the executive summary and the letter to the Administrator. Recommendations are provided in the review on how each of the 6 specific areas can be improved. The SAB identified 3 of the specific initiatives which they felt would best advance the agency's goals. Thus, the charge questions were thoroughly addressed.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

I did not identify any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report.

3. Is the Panel's draft report clear and logical?

The Panel's report is clear and logical.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The conclusions of the report are supported by the body of the Committee's report. I suggest that one recommendation be clarified. On page 9 lines 13-18, the review recommends that "identification of vulnerable population for environmental justice purposes can be facilitated by using cumulative risk assessment that explicitly account for both background and source related exposure and their impacts on ecological services." Further, page 32, lines 33 to 35 states: "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." While the recommendation seems reasonable, the recommendation should be clarified. Is the recommendation suggesting that Ecological Assessments include a discussion on impacts to vulnerable populations? A clearer statement on how environmental justice is to be integrated into the plan would be helpful. Further, it would be helpful to provide a reference or two regarding environmental justice and vulnerable populations.

Regarding the discussions of communication and integration into risk management, I think the review missed the opportunity to integrate several of its recommendations. While one can focus on communication methods and techniques, it is most important to focus on the message. As stated on page 23, "ecological risk assessment finds limited use even in the EPA." The answer

may in part rely on developing a clear and simple understanding of the importance of ecosystem services and then communicating that message in the risk assessments. The review could mention the importance of developing a clear message of the value of and threat to ecosystem services, the relevance of ecosystem services to the human population, and that such information should be included in the agency's ecological risk assessments.

Comments from Dr. Thomas Burke

1. Were the charge questions adequately addressed?

Yes

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the draft report?

No

3. Is the draft report clear and logical?

Yes, very well presented

4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes

Specific comments:

The draft and letter are well done and provide strong recommendations. I do have a few points that I might be considered during the upcoming discussion.

1. I suggest that a bullet be added to the letter and executive summary to emphasize the importance of problem formulation and scoping. This is nicely stated on page 9 of the Draft report and I think it is an important component of successful science integration.
2. I also suggest greater emphasis of the importance of developing improved capacity for monitoring and sampling to support ecological assessment. Regions and programs have very limited support for monitoring which is essential to problem identification, model validation, and ultimately the success of adaptive management.
3. The importance of the human impact is buried on page 21. This should receive greater emphasis, including a sentence on the complementary potential of health impact assessment. It is time to build a better bridge between these two worlds.
4. Finally, I am a little concerned about the strong wording of the WOE recommendations. While I agree with the need for more rigorous statistical methods, I am concerned that the approach may become too formulaic and be saddled with the controversies now facing health risk assessment. To state that a rigorous approach “must be based upon statistically based decision points” may

cause unanticipated delays in decision making or tie the hands of managers, particularly at the state and regional level.

Comments from Dr. George Daston

We were asked to address four specific questions as part of the quality review.

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Question 1: The charge questions posed to the review panel were all adequately addressed in a very transparent way.

Question 2: The committee urges EPA to use a weight-of-evidence approach in ecological risk assessment, but does not provide enough guidance on how EPA should ensure consistence in a WOE approach. The committee advocates the use of a number of different tools that could be used in a weight-of-evidence approach, including Bayesian analysis, the adverse outcome approach (which at its heart is a means of establishing biological plausibility for causality, thereby supporting WOE) and meta analysis, but does not provide much guidance as to how or when to use which tool. Regardless of which tools are used, I was surprised that there was little discussion on the communication of the certainty (or lack thereof) of risk assessment results. This seems to me to be an important aspect of risk communication, particularly in those instances where WOE approaches are being taken because of data paucity.

Question 3: I found the report to be clearly and logically presented.

Question 4: I found the conclusions of the report to be well documented and supported.

Comments from Dr. Otto Doering

This review is a very good effort to better bound and bring more specificity to EPA's Ecological Assessment Plan

I believe that the charge questions were more than adequately addressed. I do not know of technical errors or omissions or issues not adequately addressed. Given the complexity and breadth of the topic, I found the review clear and logical. The conclusions and recommendations were supported by the body of the review.

Several points that were particularly important in the review:

In several places the review urged the use of illustrations or case studies. These would serve not only to illustrate the method or protocol intended, but also to bring definition and clarity. For example, p 15, line 5 – the statement that a uniform definition of WOE does not exist. Illustrations and case studies can be used in the process of defining WOE on the basis of the level of utility and efficacy required. This then makes clear the context being used for this approach.

The concern that the EPA approach was somewhat myopic (p. 8, line 28) is something that needs to be remedied. Both in terms of ecosystem services and in the associated risk analysis, EPA may well best move forward by borrowing heavily from others as suggested in the review.

A systems-level approach (an integrated approach) is especially important at the Problem formulation stage (p. 9, lines 33-36). If there is no integrated approach at this first stage, the assessment has a higher probability of going off track.

Adding the climate change dimension for longer term assessments is realistic and necessary, but brings a higher cost in adequate resources to undertake the task. The suggestions with respect to Communication are equally important, but also represent substantial resource requirements. This is not that both of these do not need to be done, but to recognize the resource requirement necessary to undertake them.

Comments from Dr. Michael Dourson

1) Were the charge questions to the committee adequately addressed?

The questions appeared to be adequately addressed.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Not of which I am aware, but this is not my area of expertise.

3) Is the draft report clear and logical?

Very much so. In particular:

- Page 4, lines 14 to 23 and lines 32 to 39.

Well written. I completely agree.

- Page 8, Section 3.1.

Very nicely written; these conclusions of the panel seem well wrought.

- Page 13, lines 23 & 24. “It is critical that the EPA take advantage of this ongoing research conducted outside of the agency to improve the risk assessment process.”

Amen. EPA is not at the forefront anymore in several areas of risk assessment. Moreover, many outside groups have expertise in risk assessment and are solving local, regional and national problems. EPA needs to work with outside parties to effect solutions to some of these complex problems... or they can watch from the sidelines.

- Page 16, lines 13 to 15. “Thus, measurement endpoints must include responses that affect or could potentially affect those services (e.g., cancers in edible crabs that reduce consumer interest in this food source are indicative of anthropogenic ecosystem degradation if the cancers are related to human activities).”

Nice example; now I better understand the concept of ecosystem services.

- Page 21. Recommendations.

The panel's recommendations are spot on. I particularly like the first specific example on page 22.

- Page 29. Section 3.6.1.

The panel's thoughts on this section appear to be very reasonable.

However, in a few places the panel could perhaps be more clear, in particular:

- Page 2, lines 6 & 7. “The EPA should also carefully review 6 related activities occurring in other countries, including Canada, Australia, China and the European 7 Union.”

In fact, many groups are also concern about these issues (e.g., Environmental Defense Fund, nearly all US states, and Canadian provinces); EPA should be asked to reach out to these, and other, groups as well. What about a social media request for assistance?

- Page 3, line 15. “A scientifically rigorous WOE approach must rely on statistically-based decision points rather 14 than best professional judgment...”

But is not best professional judgment used as a “prior” in a Bayesian analysis? If so, why is it being downgraded (?) here, especially if Bayesian is being highlighted in lines 12-13 of page 2?

- Page 3, line 18. “There are a number of challenges inherent in using WOE in ecological risk assessments for decision making.”

I know that this is probably hopelessly naive, but is not the ability of a population/ecosystem to thrive a good indicator of multiple LOE in ERA? I know of colleagues that can look at a stream and determine, crudely, its overall health. How is such best professional judgment not a WOE? See for example discussion on page 15.

- Page 12, line 15. Section 3.2.3.

The AOP moniker is getting more play in the human health risk assessment side of the shop, but it needs to be further integrated in the current concept of critical effect and outcomes of clinical significance. What kinds of effects in an ecosystem or population would be a comparable tie in? Reproductive success? Balance among competing populations?

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

They appear to be so, and in some cases are, but this is not my area of expertise.

Comments from Dr. David Dzombak

1. Were the original charge questions adequately addressed?

Yes, the original charge questions are addressed adequately.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Panel's report?

I found no technical errors or omissions.

3. Is the Panel's draft report clear and logical?

The draft report is well written and well organized. It responds to the charge questions adequately. There are two high-level inconsistencies in the report that the panel should consider addressing.

- (a) The panel provides extended discussion on pages 14-17 about the need for EPA to develop specific guidance and a formalized, statistics-based approach for implementation of weight-of-evidence (WOE) decision making. At the same time, within the discussion, it is acknowledged that the science and practice around WOE decision making has not advanced to the point where this is doable. For example, the following statements are made:
 - p.15 – “A uniform definition of WOE does not exist.”
 - p.15 – “WOE approaches vary widely in their scientific rigor and statistical credibility.”
 - p.15 – “WOE depends to a certain extent on best professional judgment, which varies depending on the professionals making judgments.”
 - p.15 – “The term weight-of-evidence appears to have a variety of interpretations in the context of risk assessment.”
 - p.16 – “The EPA has used a WOE approach to conduct human health risk assessments However, it seems unlikely that ecological risk assessments are as amenable to formalization as human cancer risk assessments.”
 - p.16 – “WOE should follow certain principles, but not a particular recipe nor algorithm.”
 The panel urges the EPA to develop a systematic, quantitative approach to use of WOE while at the same time describing how this goes beyond current science and practice and will be very difficult to do. This is not consistent. In essence, the panel is recommending that the EPA advance the science and practice of using WOE in ecological risk assessment, which is valid, but if this is the case I suggest that this be stated explicitly. As currently written, the text implies that EPA is behind in the state of science and practice regarding WOE in ecological risk assessment, which based on the statements cited above does not appear to be the case.
- (b) The report discusses throughout the importance of ecological risk assessment in EPA decision making, but does not discuss explicitly the areas of EPA responsibility and decision making in which ecological risk assessment is most relevant. On page 23, deep within the report, it is acknowledged that “ecological risk assessment still finds limited use even in the EPA” but the reasons for this are not examined. It would be useful to address in the front of the report the primary areas of EPA activity in which ecological

risk assessment has a role. There are many areas of EPA activity in which there will not be an opportunity for ecological risk assessment to be implemented, e.g., because of statutory direction to the Agency to focus only upon human health issues.

4. Are the conclusions drawn or recommendations provided are supported by the body of the Panel's report?

The conclusions and recommendations are adequately supported in the body of the report. The conclusions and recommendations regarding use of WOE in ecological risk assessment should be reconsidered in view of the inconsistency discussed in 3(a) above.

Comments from Dr. James Hammitt

Comments on SAB report on Ecological assessment action plan (8/28/12 SAB mtg)
James K Hammitt

Overall, I judge this to be an excellent SAB report.

1) Were the charge questions to the committee adequately addressed?

Yes.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Some minor issues, see below.

3) Is the draft report clear and logical?

Some minor issues, see below.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Some minor issues, see below.

Comments by page and line number:

p. 3, l 21. What is meant by ‘thresholds for mortality and morbidity’? Perhaps the point is these endpoints are discrete or have a common, clear definition so they can be compared between studies. Human cancer risk assessment usually assumes a no-threshold model, and threshold refers to a dose below which cancer risk is zero.

p. 6, l 23. I am surprised by the phrase ‘Clearly, ecosystem function and services are bound tightly to human health.’ My impression is many people care about ecosystem function and services independent of their relations to human health. Moreover, in some cases ecosystem function conflicts with human health (e.g., mosquito-infested wetlands, top predators). Does the SAB committee mean to suggest ecosystem function is primarily an input to human health? In this case, why not treat it as part of human-health risk assessment (e.g., as part of exposure assessment)? Same concerns apply to p. 34, l 9 where report recommends ‘To strengthen EPA’s ecological protection goals, agency risk assessors should make a more direct case connecting human health to ecosystem function and services and follow this with development of relevant ecosystem evaluation methods.’

p. 15 acknowledges that weight of evidence (WOE) is not well defined and depends on professional judgment. But the executive summary seems to say WOE is better developed (e.g., p. 3, l 11: ‘The scientific merit of using a WOE approach is clear as evidenced in the large number of scientific publications on this subject and in the consistent and continuing use of WOE in ecological risk assessment.’).

p. 17, l 37. Statement that 'LOE that are clearly linked to population or community attributes should receive greater weights than those that are not' should include a qualifier about other things being equal. It seems unlikely this criterion is lexicographically more important than all other criteria.

p. 35, l 25. The introduction of 'r, the intrinsic rate of natural increase' as part of a recommendation seems overly technical. I suggest dropping this technical reference so the sentence reads 'Aspects such as life history and scope-for-growth analyses are important for predicting if a population, subject to stressors of a variety of types, will grow, stabilize or shrink.'

p. 6, l 35 (also p. 9, l 20 and p. 34, l 35) Why the emphasis on 'success stories' for communicating between risk managers, assessors and environmental scientists? Are not stories about failure to consider ecosystem function equally useful?

Comments from Dr. Barbara Harper

- 1) the committee adequately addressed? YES
- 2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report? See below – Natural Resource Damage Assessment (NRDA) as conducted by USFWS is particularly out of sync with current ERA methods and could benefit greatly from learning about ERA state of the art (ERA = ecological risk assessment).
- 3) Is the draft report clear and logical? YES
- 4) Are the conclusions drawn or recommendations provided supported by the body of the draft report? YES

Weight of evidence for exactly what? Aimed at what? A LOAEL, population percentage, other? The term WOE was not well-defined. Maybe it is intended as a general principle of good decision-making, or maybe it was intended to refer to something a little more specific.

Ecosystem services. In Natural Resource Damage Assessment, ERA is seen as completely different from and unrelated to ecosystem services. The Millenium Ecosystem Assessment (MEA) approach to ecosystem services uses 4 service categories – this is useful and amenable to different human populations, EJ communities, or indigenous communities as long as flexibility remains to modify the categories for different habitats, landscapes and ecosystems. NRDA in particular (or USFWS) actively and explicitly prevents ERA from being used in ecosystem service evaluations and injury assessment. Ecosystem services are not just a climate change issue – again, some of these cross-cutting issues are too pigeon-holed, although this may have been for brevity due to page limitations.

Page 24, lines 20–38 also discusses ecosystem services but without reference to the MEA – it would help if EPA knows whether the MEA will be the model (not cited until page 26 line 26, and Table 1). Page 25, line 28 suggests that reduction in risk is an ecosystem service benefit; this is true, but ecosystem services do not flow simply if risks are reduced. This is related to stakeholder involvement. If the decision-maker understands everything that is at risk in a community, it might result in collecting different data, modifying methods, or weighting decision factors differently. This is related to decision stability - good decisions are not just a benefits analysis using a limited set of parameters if they overlook things that are very important to a community or stakeholder group.

Page 28, Table 1. I would caution EPA not to understate the “cultural” services, particularly to indigenous communities, even though they are hard to articulate, harder to quantify, and almost impossible to value enough to play a role in dollar-based decisions. The MEA model gives more weight to the outcomes of well-being, although even the MEA undervalues to role of cultural and amenity services.

Strengthening EPA’s ecological protection goals. Be affirmative; ecological health is not just removal of stressors (even though many national programs address problems and remove

stressors, rather than funding continued improvements). It is stated that “ecosystem function and human health are tightly linked;” I completely agree – EPA’s Sustainable and Healthy Community program can provide support for this linkage. The overall function of integrating ecological functions into the general institutionalized thought process resides not just with ERA practitioners, but also likely in many or all EPA programs; likewise, and all EPA programs probably use ERA outputs of various types.

Omission. The Plan could cite NRDA regulations also, but this is not mentioned at all, presumably because EPA is not a natural resource trustee under NRDA; DOI (USFWS) is and USFWS has quite a different opinion of ERA. There is a huge disconnect between EPA and DOI with respect to methods, level and depth of understanding on ERA, etc. Unfortunately, the usual progression of cleanup (CERCLA) to restoration (NRDA) involves a handoff from EPA to USFWS, with complete disconnects between methods, data, and people; often they don’t even talk to each other.

Social scientists. Caution that social science is a current ill-defined buzzword. More discussion of decision typology or data quality objectives reviews are needed to identify just what kind of additional input would strengthen a particular decision, and what constitutes ‘strong’ decisions. How is ecological information used in different types of decisions or by different audiences? This is also mentioned as ‘better’ decisions (page 22, line 29).

Page 9, 5th bullet. I applaud the recognition that traditional knowledge could be used throughout the entire risk assessment process. This is not simply a communication issue or part of a ‘broad communication strategy’ or holding informational meetings more often. True CBPR will often cause a modification in methods and metrics.

Page 12, Section 3.2.3. I agree that specific sublethal measures need more consistency. I see this both in conventional site-specific ERA and also in NRDA; the latter is particularly problematic since habits have formed around vague regulations issued in 1980 by DOI, and unfortunately this has frozen methods and endpoints for several decades.

Page 16, lines 5-16. The sentence in lines 8-9 is a key point that needs emphasis – ecological risk assessments are tied to local ecologies so flexibility is essential. Lines 10-12 is somewhat arguable – the protection goal may not always be at the population level. Individuals of endangered species must be protected, but tribal communities also protect individuals of heritage species (species of tribal importance for food, fiber, medicinal, or other uses).

Page 16, Lines 8-9 recognize that flexibility is essential, yet line 26 also recognizes that generic endpoints (and generic concentrations) are issued in national regulations. This issue could be expanded to include more discussion of the crosswalk between generic national standards and local ERA. On the other hand, case-specific or location-specific standards may not be accepted in court, so additional input from the EPA enforcement and legal programs might also be beneficial.

Page 22 top; page 19 line 45; page 23 line 37 (and other locations). I am curious why EPA managers do not have confidence in or use ecological risk assessments. I suspect this is not just

a communication issue; indeed, scientists are often cautioned not to assume if we only explained something better everyone would agree with us. Is there space to expand on this? Page 22, line 24 alludes to different consumers of ERA output – assessors, decision-makers, and stakeholders (and I would add the lawyers who have to help managers defend decisions), and the balancing act.

Page 30, line 27-28. Adaptive management costs post-decision money. Long-term monitoring costs may not be included in the original decision funding, so some discussion about how to fund the long-term ‘adaptive’ part of management might help.

Comments from Dr. Bernd Kahn

The review is extremely well written and has no obvious problems.

My response to the four questions is, respectively,(1) yes, (2) no,(3) yes, and (4) yes.

My major concern with the draft report is that it addresses responses to major items such as climate change and fracking that are controversial now and require EPA responses now, by suggesting action plans that need years of study to develop in an effective framework, as indicated in the review. Would it not be desirable also to propose efforts for each of the listed items listed for which an interim goal could be attained within, say one year? In that case, the SAB review could point out that the EPA responses are based on trusted publications currently available, noting that the response is not definitive, but useful in the absence of lengthy ongoing work.

Comments from Dr. Nancy Kim

General Comment

Although this is not my area of expertise, the draft report is understandable, well presented and logical. The format of the draft report helps to highlight the committee's recommendations and make the committee's advice clear.

1. Were the charge questions to the committee adequately addressed?
Yes.
2. Are there any technical errors or omission or issues that are not adequately dealt with in the draft report?
No.
3. Is the draft report clear and logical?
Yes.
4. Are the conclusions drawn or recommendations provided supported by the body of the draft report?
Yes.

Comments from Dr. Cecil Lue-Hing

General Comments

The Panel did a very good job of reviewing the Ecological Action Plan which it found to be generally well designed, but with some deficiencies. The Panel identified these deficiencies and offered some important corrective recommendations.

Specific Comments

Letter to the Administrator

The letter is formatted to be easy to read. It quickly offers an assessment of the Ecological Action Plan with regard to its integrity, content and completeness, and then provides a select summary of important recommendations directly related to the Charge Questions posed by the Agency to the SAB.

The Executive Summary

The Executive Summary is also formatted to be easy to read. Each charge question is thoroughly discussed, and the Panel findings noted. The discussion is then immediately followed by the recommendations related to the respective charge questions before the reader loses focus.

Charge Questions

1) Were the charge questions to the committee adequately addressed?

Yes.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Not to my knowledge.

3) Is the draft report clear and logical?

Yes.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

Yes.

Comments from Dr. James Mihelcic

1) Were the charge questions to the committee adequately addressed?

It is my professional opinion that all seven charge questions were adequately addressed. Important to charge question 1, the EPA report appears to have responsive to the major science policy and other technical practice initiatives recommended by previous SAB and NRC reports. Also, the Draft report provides very specific recommendations related to Charge question 1 that would improve the Action Plan.

2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

I did not identify any errors or omissions or issues that were not adequately dealt with in the draft report.

3) Is the draft report clear and logical?

The draft report is organized well, is clear, and logical. Related to Charge Question 4, on pages 22-23, there is a five-step approach presented in the SAB draft report that illustrates how EPA might evaluate the challenges and opportunities for better communication across a range of different decision types. I felt this text might have been too specific for the SAB Report, given that it is stated by that this is just one possible approach. Suggest authors determine if this is necessary detail, especially since it is only one of several approaches.

4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

The report is strengthened by the easy to read recommendations provided after each charge question was addressed. I felt that the four recommendations provided for charge question 4 appeared to have less supporting material in the text (approximately one page) than provided for the other charge questions (approximately one page). Related to charge question 1, I thought the comment made in the SAB draft report that the U.S. and EPA have lost their former leadership roles is very important, and believe this statement should be included in the letter to Administrator Jackson.

Other comments

- 1) Page 34, line 9 Suggest the following text (in “..... “) be added to end of this sentence so it reads Damaged ecosystems are a bellwether to damaged human health “and economic and social well being”.
- 2) Page 4, line 41, word “charge” needs added so header reads... Incorporation of Ecosystem Services into Ecological Risk Assessment Methods (Charge Question 5)

Comments from Dr. Keith Moo-Young

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

Yes. The original charge questions were addressed. The SAB committee should be commended on the quality of the work. The report is detailed and has very strong recommendations based.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?

No technical error or omissions in the report were found by this reviewer.

3. Is the Committee's report clear and logical?

Yes, the report is clear and logical.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The conclusions and recommendations support the body of the committee's report.

Comments from Dr. Eileen Murphy

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The charge questions were adequately addressed.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?

There were no technical errors or omissions that this reviewer found, though this is not my area of expertise.

3. Is the Committee's report clear and logical?

This is a well-written and logically-organized report.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes, the conclusions in the report are validated by the narrative.

Comments from Dr. James Opaluch

1) Were the charge questions to the committee adequately addressed?

The committee did a good job addressing many of the charge questions, but I believe the report could be strengthened as indicated below.

Charge Question 2

Charge Question 2 asks SAB to “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).”

The response to this part of this charge is very short, and merely indicates that EPA would benefit from an integrated approach. Most of the discussion focusses on issues that should be addressed in such a framework, and that the framework proposed by Corner and Suter would provide a good preliminary framework. The SAB report does not comment on how guidance might “contribute to better decision-making”.

More broadly, I’m not sure that the discussion in Section 3.2.1 specifically addresses Charge Question 2. The response reads like a laundry list of considerations and methods that should be included in a framework, but in my reading the it does not specifically respond *how* guidance for an integrated approach will contribute to better EPA decision-making. For example, the recommendation on page 11 starting on line 23 says “EPA should consider the cumulative effects ...”.

On page 2 line 33, the draft report says “The preliminary framework should be further developed”, but does not provide specific suggestions on how to proceed. The paragraph starting on line 35 makes recommendations for *implementing* the framework, but not on the composition of framework itself. What precisely does the panel mean by “The preliminary framework should be further developed?” Does this refer to the recommendations in the following paragraph? If so, this should be clarified. If not, the report should provide some guidance on the lines along which the framework should be further developed. What elements need further development, and what are some recommendations for doing so. The report might even say that recommendations for further developing the framework are discussed below in Sections ??

Charge Question 3. The material in the response to charge question 3 is good, but it might reformulated and better organized. For example, I recommend that the response on page 14 starting on line 16 more explicitly focus on answering the charge question.

On line 17, the response says “The Scientific Merit is clear”, and the response goes on to cite literature. But it doesn’t explicitly state what is the scientific merit. I think the response to the “Challenges Inherent in WOE” starting on line 11 of page 15 is better formulated as a specific response to the charge question. The scientific merit section should mirror this structure.

The response should say explicitly say that the scientific merit of WOE is that it provides a systematic approach to combine results of multiple studies that focus on various elements of a problem being addressed. There is a vast scientific literature, and the results and conclusion of the many studies vary in their mutual consistency. WOE approaches such as meta-analysis provide tools for a practitioner to systematically draw together results of numerous studies to address a problem. The material starting on line 10 of page 17 should also be moved to this discussion.

I don't follow the statement on page 14 lines 40-41. It is my belief that WOE approaches may well become even more essential in the future as a means of integrating disparate results from an ever expanding body of scientific literature.

The first paragraph under "Challenges inherent in WOE" (page 15, lines 5-9) summarizes what is meant by the WOE approach. This is not a discussion of the scientific challenges inherent in WOE. This should be moved to the beginning of the discussion of WOE. I recommend a separate subsection entitled something like "Summary of the WOE Approach" that would precede the discussion of the scientific merits which begins on line 14 on page 14. Some of the material starting on line 36 of page 15 is also a summary of the approach, and would be better fit in this new subsection.

Charge Question 4

It is essential that EPA get input from social scientists on issues of risk communication. This seems like an obvious place to reinforce the arguments in the report that EPA needs more social science in its program. The recommendation starting on line 35 page 21 focusses on the need to involved experts in social sciences, but I don't see any other discussion of this in the response that supports this recommendation. This section begs for a strong paragraph on the challenges of effective communication, and the importance of involving experts, from which the recommendation would flow. Similarly, it is a challenge to design effective surveys, and experienced survey design experts are required. The paragraph on page 20 starting on line 28 does a good job indicating why the survey employed by EPA is unlikely to be effective. This seems like an obvious place to indicate that survey design experts are required.

The material on pages 22-23 seem rather long for a Recommendation, and is not consistent with the level of detail of the other recommendations. It seems like much of this material should be brought into the prior response to the change question, then briefly summarized in this recommendation.

Page 24, line 1-5. I would argue that communication needs to be a two-way street. In order to resolve barriers to communicating risk assessments we need to understand the needs of the stakeholders and decision-makers and how they process information. Rather than simply trying to make decision-maker comfortable with quantitative risk assessments, we need to understand how they use information, what information is most useful for decision-makers and what form of information would be most useful and acceptable to decision makers. Again, this is an area that requires input of social scientists.

Charge Question 5

The report provides no rationale for the observation/recommendation on lines 46 of page 30 through line 2 of page 31. This seems like an important point, and it would be very helpful to provide reasoned argument for where adaptive management is or is not useful, or at least an example or two of cases where adaptive management would not be appropriate. This would provide useful guidance to EPA for focusing its efforts on adaptive management—where it is likely to be useful and practical, and where it is not.

Should SAB recommend that the white paper on ecosystem services referred to above also include a discussion of how measurement and assessment ends points can be incorporated into an adaptive management framework?

Charge Question 7

I'm a bit confused about what is meant by *strengthening* EPA's ecosystem protection goals. One interpretation of this is to make the goals more ambitious, so that more protection is afforded. But a different interpretation is making the goals more scientifically rigorous or defensible. This might be associated with using endpoints based on ecosystem benefits, rather than less defensible structural ecosystem metrics. For example, the goal for ecological protection of wetlands might be "strengthened" by using endpoints based on ecosystem functions or services of wetlands, as opposed to an endpoint based on acres of wetlands that does not account for their type or "quality". It might be worthwhile to be explicit about what is meant by *strengthening* EPA's ecosystem protection goals.

Page 33, lines 27-29. As EPA's ecological risk assessments evolve towards the concept of ecosystem services, economists and other social scientists would also play a larger role in ecological risk assessments in assessing public benefits from ecosystem protection. This is especially important as we go beyond such service endpoints as human health effects (e.g., number of cancer cases reduced), towards other endpoints like commercial and recreational uses, and especially aesthetic values and non-use values. As an example, wetlands might have an adverse human health effects associated with vector-borne disease, but might provide beneficial services in the form of habitat for migratory waterfowl, nurseries for species of fish, etc. We need to understand human values of the full range of wetland services.

- 2) Are there any technical errors or omissions or issues that are not adequately dealt with in the draft report?

Note that I noticed, other than those noted above.

- 3) Is the draft report clear and logical?

Again, some of my comments above focus on clarity and logic of the report. Otherwise I have no comments.

- 4) Are the conclusions drawn or recommendations provided supported by the body of the draft report?

I noticed a few conclusions or recommendations that are not well supported by the body of the draft report. These are indicated above, in my response regarding the charge questions.