

**Preliminary Comments from Members of the Chartered SAB on the SAB
Draft report entitled *Peer Review of EPA's Draft National-Scale Mercury Risk
Assessment (08/05/11 Draft)*.**

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Comments from lead reviewers

Comments from Dr. Elaine Faustman

1. Were the original charge questions to SAB adequately addressed?

Yes, the ad hoc Panel has produced an extraordinarily clear and targeted review of the National-Scale Mercury Risk Assessment Supporting the Appropriate and Necessary Finding for Coal and Oil-Fired Electric Generating Units—March 2011.” They have provided specific statements on what sections they agree with and what sections require clarification and they have addressed 14 charge questions, many with several components. They have done this in a timely manner. The panel had a significant number of internationally recognized experts in MeHg and this reviewer was impressed with the depth and breadth of the Panel expertise and their response to these detailed questions. Kudos to the Panel!

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

The Panel is very clear that although supportive of the overall approaches to the technical document they require extensive clarification. I was exceptionally impressed with their thoroughness and only in a very few cases have I requested an additional note with some specific charge questions—please see below. This reviewer also noted that in a few cases an overemphasis of a particular point was made and suggested use of the appendix rather than the body of the Panel report to address these comments.

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

Yes, the Panel’s report is very clear and logically constructed. Due to the large number of charge questions and sub- questions I have specifically addressed my responses to this question by each charge question listed below.

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

Yes, the Panel’s conclusions and recommendations are very well supported by the body of the Committee’s report. In a few situations, this reviewer recommended moving forward some of the exact language from the body of the report to the Executive Summary and Letter to the Administrator. The ad hoc Panel clearly states in their general comments and in their executive summary and letter to the administrator that the technical documentation needed to explain the rationale and technical details are not contained within the document and thus it fails to demonstrate the “scientific credibility” of the overall design of the risk assessment (Charge question 1). The Panel also clearly states that when additional details were provided at the public meeting that the Panel agrees with the approach taken by the agency. Nevertheless they clearly indicate that these details are needed within the document.

Comments on the Executive Summary:

Another example of a very clear statement by the Panel is given in:

Executive Summary-Page 2, lines 10 to 14: “However the Panel considers the integrity of the risk assessment to be dependent in part on a transparent description of the analysis, and the Technical Support Document needs to be strengthened to provide this description. Responses to charge questions indicate where improvement needs to be made, and the Panel’s support for the risk assessment is contingent upon these issues being addressed.”

Executive Summary –Page 4, line 1. This reviewer asked that the Panel clarify what they are requesting for the use of the 75th Percentile fish tissue methyl mercury value, especially as it relates to the Panel statement regarding underestimation. Please clarify by adding some of the text language from the body of the report to this section of the executive summary.

Executive Summary—Page 3 lines 1-2—Panel should define “integrative metric” of risk.

It was unclear to this reviewer what “updated figures in the revised report are being requested—do these need to be attached or more specifically referenced in the report at this section?”

Specific comments on the Panel’s report by charge question:

Charge question 1:

Panel report-Page 6-7: This reviewer was surprised when reading the Panels response to Charge question 1 that no mention of the clarifying role that the extra materials presented in the face to face meeting had on the overall Panel agreement with the overall design? This reviewer would suggest adding such a reference here, perhaps before lines 20-23 on Page 7?

Charge question 2:

Panel report-Page 7-9. The panel did an excellent job in discussing the robust and detailed literature on MeHg effects. They gave a convincing discussion of various critical endpoints and provide a strong rationale for the use of the HQ. Their decision to recommend additional references but not re-calculation of the HQ is sound. Although it may be obvious, the Panel refers to the HQ as an integrative measure, thus it would be good to add a statement such as: The HQ is considered an integrative measure as it looks at the weight of the evidence and determines a quantitative value that is based on the most sensitive endpoints across multiples studies and endpoints.” This statement could go at Page 8, line 7. This reviewer also liked the suggestion that the IQ discussion be considered as supportive of the HQ rather than replacing it.

Charge question 3: This reviewer felt that the Panel comments were very clear and on target.

Charge Question 4: The Panel provides clear statement about their support for the use of the HUC 12 as it represents “true watershed delineations” and has a similar physical scale to the mercury air maps. They also indicate where additional information is needed. For example, they recommend that the authors of the report prepare a summary table describing the characteristics of the watersheds where fish were collected.

The Panel also mentions the potential significance of watersheds with limited fish sampling and

the issues surrounding the combining of small lakes under the HUC 12 designation. They clearly indicate suggestions on how the EPA should approach such a situation and point to a reference by Wiener et al 2006 that illustrates dramatic differences in how fish MeHg content can vary. The Panel cautions against using a single fish MeHg value.

Question 5: Again, the Panel is very clear in discussing the report and in this case identifying potential areas of uncertainty. They indicate when actions are needed. For example the Panel discusses various sources of uncertainty and potential bias since the fish tissue determinations are more robust in the East. It is a bit unclear what the EPA should do about these limitations and this reviewer would recommend adding a concluding statement on Page 12 at lines 20-21 to summarize their recommendations. The Panel's recommendations in the following paragraph are clear that they are not suggesting use of empirical models to improve the density of fish methyl mercury estimates for this report but for future considerations.

Question 6: The Panels discussed detailed issues regarding the representativeness of the fish used for estimating the 75th percentile tissue values. The panel illustrated the potential for bias and suggested the inclusion of more details regarding the sources and contributions to uncertainty. Of significance, the Panel recommended that the EPA conduct a sensitivity analysis using the median fish tissue concentrations. This request was documented. The Panel also recommended that the Technical Support Document clarify the representativeness of the 75th percentile "represents available fish tissue data that reflects the fish in the watershed and which are consumed. Again this is a supported suggestion.

Question 7: The Panel discussed the references that formed the basis for the fish consumption estimates and noted that other references by the same authors, Berger et al may also be helpful. The panel suggested some caveats that need to be included i.e. non-representativeness of spot sampling, seasonality of fishing in certain regions and need to clarify whether estimates were for as caught or as prepared estimates. Overall the Panel asked for clarification of details and not significant revision of this section.

Question 8: The Panel stated that they were supportive of the use of 25 persons per census tract intersecting the watershed. They requested several additional minor clarifications. This reviewer had an additional issue: Since many sites with water location are desirable, how frequently are the subsistence fisher people using the lakes as residents or non-residents in the nearby census tracts. This would potentially bias the estimates of potential subsistence fishing populations.

Question 9:

The Panel is supportive of the proposed use of Mercury Maps as an approach for this risk assessment. They cite recent research that also indicates the utility of the maps and statements on Page 18 lines 5 to 12 are especially relevant. The Panel may want to move this paragraph forward as part of the executive summary as it speaks to the essential component of this approach. This reviewer found that the Panel also addressed subsets of the charge question in a clear manner. The panel clarified that they do not need to see alternative models run as part of this assessment.

Question 10: The Panel is supportive of the technique used to exclude watersheds with

significant non-air contributions and their statements are clear in this charge response. The Panel requests inclusion of potential sources of uncertainty especially within the TRI databases. The panel lists two additional criteria for consideration at the end of this section. This reviewer would ask the Panel to clarify what they are asking EPA to do with these considerations? Just list or analyze?

Question 11: The Panel discussed the importance of considering alternative concentration-response functions in their models. The Panel identified three sub-questions to this question and provided clear answers to all. The Panel was clear that while nutrients in fish may moderate the impacts of methyl mercury effects that these effects which have been largely identified in marine fish and for IQ changes. These effects are much less clear for the lakes and rivers addressed in this technical document and for the spectrum of other health endpoints the panel is recommending to EPA to emphasize in their use of the HQ approach. The Panel clearly indicated that they were supportive of listing such potential uncertainties in the appendix to the document however not to change the modeling approaches.

The Panel discussed the issue of Selenium in their document however this over-emphasis on selenium was unclear to this reviewer and she would suggest a short section in the appendix to discuss potential uncertainties that this could be addressed there. The less than clear conclusion that this Panel member received was that we do not know enough about Selenium in general to modify our models and even more we know less about the effects of selenium in the lakes that we addressing in this document. If we only have a very few Western samples it seems highly unusual that we will have significant MeHg and Selenium values at the same locations to make any significant science based model adjustments at this time.

Question 12: The Panel recommended expansion of the Technical document's discussion of variability and uncertainty based on Figures 3 and 4 presented at the Panel's public meetings. This recommendation appears to be well-founded and clear. Additional requests were suggested however the Panel clarified that they considered the approach presented in the Technical Support Document sound and reasonable. The Panel needs to clarify the necessity of making all of these changes. To this reviewer this seems to be a very significant request and in contrast to the statement that the Panel considered the approach to be sound and reasonable (Page 25, lines 6 and 7).

Question 13: The Panel clearly indicates in great detail their responses regarding the analytical results. In particular they state at the start of each sub charge question what the Panel found and then follow with specific suggestions. This reviewer found this section to be very clear. For points regarding populations at risk, Pages 32 and 33 this section could refer to the earlier comments about the surveys on subsistence fishing populations (Question 8).

Question 14: The Panel indicated that the Technical Report need to more clearly state its key findings. This reviewer found that the Panel's statement on Page 33 lines 39 to 44 to be especially clear and felt that this should serve as an example to the Technical Panel but should also be repeated in the letter to the administrator and the executive summary. Very clear statement!

Question 15: Addition by the Panel however this reviewer liked the statement discussed above,

Page 33 lines 39 to 44 as a better bottom line.

Editorial comments:

Clarify some of the report language to be more direct:

Letter to the Administrator-Page 1 line 34: Change “The SAB finds it difficult to evaluate the risk assessment based solely upon information...” to the following: “The SAB could not evaluate the risk assessment based solely upon information provided in the...”

Letter to the Administrator-Page 2 line 14: Change “Despite a generally favorable review regarding the design and approach, the SAB strongly advises EPA...” to say “The SAB strongly advises EPA to revise the Technical Support Document to”.

Page 6 line 29-30 Remove “do a much better job of explaining” and replace with “explain”.

Executive Summary –Page 2, line1: Remove the words “in general”.

Format of report changes for Panel response to questions 12 and 13.

Comments from Dr. Eileen Murphy

Were the original charge questions to the SAB committee adequately addressed?

Yes. This was a very well-written, concise and understandable report. The charge questions were clearly presented and addressed for the most part. The panel heard presentations by EPA that went into greater detail on methods that EPA used in its modeling efforts, but the panel did a good job explaining this and actually presented some of that material in their report (i.e., schematics on page 24). However, I found the graphs in the report (Figure 1 on page 13 and Figure 2 on page 14) difficult to read due to unclear axis titles and chart titles. Better chart labeling is needed for both of these graphs to make them more understandable to the readers.

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 apparent in the report.

Is the committee's report clear and logical?

The report was well-written, thorough and easy to follow. I found the Executive Summary to be particularly well-written. I read the full report first in order to understand the full charge questions and the panel's responses and wondered how the panel would be able to summarize 14 complex, multi-faceted charge questions into a concise summary. By grouping the recommendations by topic area (rather than by the individual charge questions), they provided an understandable and concise summary of their recommendations. The letter to the Administrator was short and to the point, focusing on the major recommendations and referring her to the full report for more details.

Are the conclusions drawn or recommendations provided supported by the body of the committee's report?

Yes.

Comments from Dr. Paige Tolbert

The following comments are provided in my role as discussant/quality reviewer of the report by the SAB Mercury Review Panel reviewing EPA's "Technical Support Document: National-Scale Mercury Risk Assessment Supporting the Appropriate and Necessary Finding for Coal- and Oil-Fired Electric Generating Units (March 2011)."

Quality Review Question #1: whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

Response:

The SAB Panel has adequately addressed the original charge questions posed to them by EPA.

The Panel has provided a thorough response to the charge questions, and has proposed many helpful suggestions. EPA has requested peer review of the linkages of the key data inputs and their integration into the risk assessment, as well as review of several of the specific data inputs. Overall, the panel found that the methodology for conducting the mercury risk assessment were sound and appropriate; the panel's criticisms for the most part relate to the write-up of the work, not the actual work performed. The panel found that aspects of the work that are presented in a vague or ambiguous manner in the document were presented clearly and in a compelling way at the June public meeting with EPA staff about the report and the panel asks that the report be revised to include these clarifications. The requested revisions are straight-forward and should require minimal additional time and effort by EPA staff. In addition, the panel notes a number of aspects of the risk assessment that are conservative and likely lead to underestimation of risk, strengthening the overall finding of the EPA risk assessment. The final charge question was modified somewhat at the prerogative of the panel, but the modification gets at the same basic issue and should be useful to EPA; the panel finds that pending incorporation of its recommendations the document will provide an objective, reasonable and credible determination of the potential for a public health hazard from mercury emitted from U.S. EGUs despite the uncertainties inherent in the analysis.

Quality Review Question #2: whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report

Response:

I did not find technical errors, omissions or issues that are inadequately dealt with in the report.

Quality Review Question #3: whether the Committee's report is clear and logical

Response:

I find that the Panel's report is clear and logical. The report effectively communicates the Panel's assessment of the draft report with respect to EPA's charge questions.

Some very minor editorial comments:

Page 22, lines 5-12 and lines 14-21: Nearly identical text repeated.

Page 25, line 4: Not clear what is meant by: "data and methodological sources variability and uncertainty."

Page 29, line 4: Not clear what is meant by: “the source of U.S. EGUs should be specified.” – should this be source of information on U.S. EGUs? Or location of U.S. EGUs?

Quality Review Question #4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee’s report

Response:

The conclusions drawn and recommendations provided are supported by the body of the Panel’s report. Overall, the Panel’s conclusions and recommendations are scientifically sound and well-justified.

Comments from Dr. Jerald Schnoor

I have reviewed the SAB Mercury Review Panel Draft Report on EPA's Draft National Scale Mercury Risk Assessment. I believe the committee has done a good job of responding to the charge questions. The report is well written and makes good points which should improve the EPA's Mercury Risk Assessment.

The Quality Review Questions were the following:

Question 1: Were the original charge questions to SAB adequately addressed.

The SAB Committee answered all 14 charge questions and even added a 15th question (in lieu of a sub-question posed by EPA). I believe that all of the charge questions have been adequately addressed.

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

I found no technical errors or omissions in the report.

Question 3: Is the Committee's report clear and logical?

Yes, the report is clear and logical. Specifically, I agree with the point made in the Executive Summary and in response to Charge Question #2 that IQ loss as a critical health endpoint should be down-played and most of the discussion moved to the Appendix. While it is true that neurobehavioral risks to small children are potentially the most critical health endpoints (such as attention span, fine motor function, language skills, verbal memory, and visual-spatial skills), they are likely not linearly related to absorbed dose or blood level concentrations. Neither is IQ loss. From my perspective, a better critical health endpoint would simply be the prediction of blood levels of mercury in women of childbearing age, but this is quite well reflected by use of the RfD and Hazard Quotient (HQ) which EPA uses in its draft report.

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

Yes, the conclusions and recommendations contained in the response to charge questions are supported in the body of the SAB's report. In particular, I agree with the sentiment expressed in response to charge question #14. There, the SAB Committee asks three important questions including, "What is the nature and magnitude of the potential risk to public health posed by current U.S. EGU mercury emissions?" Having skimmed the EPA's Draft National-Scale Mercury Risk Assessment report, I came away also wanting to know exactly what it means. I think the public will have the same reaction.

EPA needs to explain their findings in simple language. After all, mercury is possibly our largest chemical health risk affecting people in the U.S. according to NHANES. Fully

1-in-14 women of child bearing age have mercury in their blood streams that exceed the reference dose, the level at which most people could be exposed without risk (Schober et al., *JAMA*, **2003**, 289, 1667-74; Jones et al., Natl. Cntr. Health Statistics, *NCHS Data Brief* No. 52, December, **2010**). That is a lot of people. Presumably it is a much greater percentage for subsistence fishers.

Yet, I think people may draw some comfort from EPA's risk assessment report. Only 2,400 out of 88,000 watersheds (HUC-12) are affected by EGU deposition as a major fraction of the total, and the total Hg deposition attributable to EGUs was only 2% of the mean, 1% of the median, and 11% of the worst watershed (99th percentile). The numbers need to be put into some perspective of how many people this might affect, i.e. the proportion of subsistence fishers who may exceed the reference dose as a result of EGU emissions. I do not find that in EPA's report.

Perhaps the bottom line is that mercury really is a global pollutant and, due to improvements in emissions between 2005 and 2016, our U.S. EGU emissions and related Hg-deposition really is becoming dwarfed by other global sources. If that is the conclusion, let's say it plainly.

Comments from Dr. John Vena

Science Advisory Board (SAB) review of the SAB Mercury Review Panel's draft report entitled Peer Review of EPA's Draft National-Scale Mercury Risk Assessment (08/05/11 draft).

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

I extend my compliments to the Panel for their careful review of the draft report, comprehensive response to each of the 14 Charge Questions and thoughtful development of recommendations. I concur with the Panel and support their position that the risk assessment document needs revision to address the numerous and detailed recommendations of the Panel for SAB support.

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

None that I can tell based on my expertise.

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

The cover letter is concise and very effectively highlights the issues and responses. The executive summary is well done and provides an excellent overview of the responses to each of the issues. A brief summary at the end of the conclusions and recommendations would be helpful to the reader, perhaps a detailed list by charge question of recommended changes.

Page 6 line 25 it lacked details? Such as??? List the details that were lacking...

A summary of conclusions and recommendations from all 14 charge questions at the end of the report would be beneficial to the reader. It should be explicitly stated what changes are necessary for the document to be acceptable to the panel. It was difficult for me to identify each of the recommendations in the midst of the text of the charge questions. Do a text search for the word "recommended" and it is evident that they are scattered throughout the document.

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

Yes. In my opinion the report is very well written, comprehensive in responses to each of the Charge Questions.

Comments from other SAB Members

Comments from Dr. Ingrid Burke

1. Were the original charge questions adequately addressed?

Yes, clearly.

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

Not that I can see!

I will merge my answers to 3 and 4 below.

3. Is the Panel's draft report clear and logical? and
4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

I am not sure that the Letter encapsulates the Panel's sense of IQ loss as an endpoint. The letter reads: "The SAB views IQ loss as a possible secondary public health endpoint, among others...". The spirit of the rest of the document, both in the Executive Summary ("the Panel had little enthusiasm for the use of IQ loss"), and under Question 2 (There are significant concerns about the use of IQ...) is considerably more negative. I think the language in the letter needs to be strengthened to match the rest of the report. One has the sense that the letter is being diplomatic, when really, the Panel doesn't think IQ should be used, period.

The line "the panel had little enthusiasm" is probably accurate, but I think that a more objective representation would be better. "The panel did not consider this to be a sensitive..." would be better.

I think the methodological issues associated with the 75th percentile and small sample sizes goes on too long (pages 12-15 in the report).

Page 20, I am thinking that high-dust areas, where there is substantial erosion, should be included under "other criteria" watersheds. Arid regions that are cultivated or grazed hard, other mineral exploration (or coal mining!) surely have higher mercury concentrations.

5. Miscellaneous, unimportant things to be cleaned (grammar and syntax):

I haven't had this trouble reading one of these yet – seems like it needed a bit more technical editing. I stumbled a lot in many parts just getting through the syntax.

- letter, page 2, line 3, needs a comma after "adequate"

- letter, page 2, line 10, delete "a" after "inform"

- letter, page 2, line 16. "choices"? I think a term that reflects more EPA logic would be better. "assumptions"?

- Summary, page 1, line 5, either (EGUs)COMMA or (EGUs), which require...

-Summary, page 1, line 17 “depositing” not quite right. “That is deposited”?

- summary, page 2, line 22. “at watersheds” doesn’t make sense. I think it might mean “at the scale of watersheds”? Or “in watersheds”?

Summary, page 2, line 41. Seems like there’s a noun missing. “IQ loss is not a sensitive response to “.... Does not respond sensitively? Is not a sensitive response variable or endpoint”. Is not sensitive to?”

Summary, page 3, line 11. This conflates reality (real deposition) with the scale of measurement (finer watersheds). Using a certain resolution does not increase homogeneity of deposition. Re-phrase.

Summary, page 5, line 24, “in the opinion of”. Can we change to assessment or evaluation or something that represents objective judgment better?

(I have more of these but am running out of typing time to meet the deadline!)

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Comments from Dr. Terry Daniel

General comments

The SAB panel's review of the EPA's mercury risk assessment report is well organized and clearly written. While the Panel has generally been very clear about the need for the incorporation of additional material in the report—especially the additional material that was presented in presentations and discussions by EPA staff—it is important to reinforce the fact that the review and conclusions presented depended upon the additional information. The letter and the executive summary should be especially clear in this regard. Toward this end, a sentence should be interjected in the Executive Summary, P2, L12 similar to the following (in blue)

This review was based on the text of the report and the additional information provided by the above cited presentations and discussion provided by EPA staff. Responses to charge questions indicate where improvements need to be made, and the Panel's support for the risk assessment is contingent upon these issues being addressed.

Specific Quality Review questions

1. Were the original charge questions to SAB Panel adequately addressed?
Yes
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
3. Is the Committee's report clear and logical?
In general the review is quite clear and logical. There are, however, two specific points that were confusing, at least for a reader of the review who had not read the subject EPA report. First, the interpretation of the "75th percentile fish tissue value" was not clear. Initially this reviewer took the percentile criterion to refer to the distribution of methylmercury concentrations found in tissue samples at a sampled site. Later references seemed instead to refer to the population distribution of sizes of fish at each sample site. Secondly, the accepted criterion of a 1 or 2 point drop in IQ as representing a significant public health concern would be made more clear for many readers if the criterion were noted to be based (presumably) on means (not scores for individuals), especially if that were accompanied by a report of the applicable standard error.
4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?
Yes, although the requirement that additional information be incorporated into a revision of the EPA report should be reinforced at several places in the review.

Some editorial suggestions

P12/L17 (body of the review)

Rather, the EPA might consider use of empirical modeling to improve the density of fish methylmercury concentrations in future assessments.

[This sentence must be about increasing “samples” and not about increasing “density of fish methylmercury.”]

P22

[There is high redundancy between the first and second full paragraphs.]

Comments from Dr. George Daston

1. Were the original charge questions adequately addressed?

I believe that the charge questions have been 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?

I did not note any technical errors or omissions. I am curious as to whether a one point decrease in IQ is possible to measure accurately. I am not an expert in IQ measurement, but it seems to me that there must be a small but known variability in the measurement, and I would be surprised if a one point difference was not in the range of variability. If so, it is difficult to justify this level of decrement as having biological meaning.

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

I found the report to be logically presented and easy to follow. There was good consistency between the body of the text, the Executive Summary and the cover letter.

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

I believe that the Committee's conclusions and recommendations are supported by the text. Given that the committee pointed out several times that the report contained omissions in methodology and data that were only clarified during oral presentations, does the Committee feel that it needs to re-review the report when those oral comments, which seem vitally important, are committed to paper?

Comments from Dr. David Dzombak

1. Comment on whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

The charge questions were adequately addressed.

2. Comment on whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report.

I found no technical errors or omissions in the report, or issues that were inadequately addressed.

3. Comment on whether the Committee's report is clear and logical.

In my view, the clarity of the letter to the Administrator and the report Executive Summary could be improved with some modifications which are discussed below. Also, the Introduction in the report should be modified to provide a better overview of the charge to the committee, and how the report is organized.

Letter to the Administrator

With 15 specific charge questions, it is reasonable not to list them all in the letter to the Administrator, but the brief summary of the charge to the committee should be expanded somewhat to give a clearer indication of the scope of the committee's work, and the relationship of the risk assessment plan and the Technical Support Document. The charge is summarized in two sentences: "The SAB was asked to comment on the risk assessment, including the overall design and approach, as well as various technical aspects. The SAB was also asked to comment on the extent to which specific facets of the assessment were well characterized in the Technical Support Document." It should be explained that the "various technical aspects" are specific methodologies for the risk assessment components presented in the Technical Support Document.

Without a better understanding of the charge to the committee, two important statements in the letter to the Administrator seem contradictory. In lines 34-36 of page 1 of the letter, it is stated that "The SAB finds it difficult to evaluate the risk assessment based solely upon information provided in the Technical Support Document. Important elements of the methods and findings are missing or poorly explained." Leading off with this comment indicates that the SAB finds the risk assessment quite deficient. However, three lines later, lines 39-41, it is stated that "The SAB finds that the design of and approach to the risk assessment are able to provide an objective, reasonable, and credible determination of the potential for a public health hazard from mercury emitted from U.S. EGUs." These two statements appear to be contradictory. Perhaps this could be fixed by inverting the order in which the statements are presented, and explaining that the shortcomings are with respect to insufficient detail for

particular components of the Technical Support Document which gives the specific methodologies for the risk assessment.

Executive Summary

The specific charge questions need to be presented in the Executive Summary. The report is divided into subsections corresponding to specific charge questions or groups of charge questions, and the relevant charge questions should be given as each of these subsections are introduced. As currently presented, it is unclear what constitutes responses to specific charge questions, and what the questions are. For example, in line 18 of page 2 it is stated: "In response to the first charge question ...", but the first charge question has not been stated.

Introduction

The brief "General Comments" section following the Introduction reads in part like an Abstract for the report, and in part like the concluding portion of the Introduction. I recommend that this section be modified and incorporated into the Introduction, with removal of the "General Comments" heading. I suggest that this new concluding paragraph of the Introduction provide a better overview of the charge to the committee, and a description of how the report is organized (by charge question).

4. Comment on whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The main conclusions drawn and recommendations made as presented in the letter to the Administrator and the Executive Summary are supported by the body of the report. As discussed above, however, I recommend some modifications to the letter to the Administrator and to the Executive Summary to clarify the charge to the committee and the overall view and recommendations of the committee regarding the draft Technical Support Document.

Comments from Dr. Bernd Kahn

My response to the four quality review questions, respectively, are yes, no, yes, and yes. The review is well written, and I have no specific corrections to submit.

I suggest, however, that the Mercury Review Panel consider pointing out that the chain of reasoning by which EPA connects mercury releases by electrical generating units to reduction in IQ in persons consuming mercury-bearing fish is highly tenuous (i.e., flimsy), at least on the basis of the information discussed in the panel review. This seems unsuitable for a risk assessment that can be expected to be strongly challenged politically and in the courts.

The EPA presentation depends on (1) relating mercury releases by U.S. EGUs in specified years to methylmercury concentrations in edible fish tissue in specified drainage basins for the same period (I assume) by means of a computer model; (2) relating fish consumption rates by studied non-U.S. population groups that consume methylmercury-bearing fish to their average IQ level as compared to the IQ level of a non-exposed population group; and (3) applying these statistics of methylmercury consumption rate vs. IQ level decrease to a most-exposed-persons group of subsistence fishers and consumers in each of the drainage basins.

The transport model for mercury in its various forms is surely complex and highly uncertain. It includes air dispersion, mixing, and deposition (wet and dry); collection by, dispersion in, and deposition from, streams; and uptake and retention by various fish species. It must involve much data integration, averaging, and approximating and yield highly uncertain outputs. Data sets are not representative of the U.S. in being mostly from the east, and are said to be insufficient for eastern states with major sources. Most importantly, the output suggests that the methylmercury levels in fish attributed to EGUs constitute only a few percent of the measured values, so that the model stands internally unconfirmed.

The basis for relating mercury consumption in fish to loss of IQ level appears to be a few studies in other parts of the world. Apart from the question of transferability of IQ measures among various cultures is the possibility that cause and effect are actually reversed, i.e. lower IQ level leads to more methylmercury consumption (I assume these were not before and after measurements, but rather comparisons of populations).

With regard to the most exposed persons, have these been identified in the pertinent high-methylmercury watersheds and their consumption of high-methylmercury fish quantified; or were the contributing factors of identity for critical persons, numbers of fish caught and eaten by them, weight of specific part of fish consumed, and methylmercury concentrations in these portions, simply assembled from different studies.

These apparently weak links (and probably others that II did not think of) should be reconsidered in a revised document.

Comments from Dr. Nancy Kim

The report was clear and well written. The panel did an excellent job.

1. Were the original charge questions to the Panel adequately addressed?

Yes.

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

No.

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

Yes, the report was well written and generally easy to understand.

Body of the report

Page 7, line 6 – 12. The last few sentences of this paragraph are not easy to read and are not readily transparent. They should be rewritten.

Page 7, line 34. Add a phrase after underestimation to identify what is being underestimated.

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

Yes

Minor comments

Letter to the Administrator

Page 1, line 38. Suggest reordering to: a sufficient understanding of the risk assessment to conduct its review.

Executive Summary

Page 4, line 18. Without more details the first sentence is difficult to understand unless the whole report is read. Suggest expanding the sentence.

Body of report

Page 7, line 5. Add s to compare.

Page 8, line 15. Insert the between been and most.

Page 18, line 7. Remove extra that.

Page 25, line 4. Need to insert of between sources and variability.

Page 26, line 6. Insert that were between factors and between and remove was.

Comments from Dr. James Hammitt

Comments on Hg risk assessment

1. Were the original charge questions to adequately addressed?

Yes.

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

I am concerned by the discussion of whether IQ loss is a critical health endpoint and the claim that it "would be a less sensitive endpoint than the HQ, which is based on the current RfD for methylmercury" (p 7, l 4). The document could be improved by defining what is meant by critical health endpoint and how one compares sensitivity across endpoints. One convention is that the most sensitive endpoint is the one that shows a statistically significant response at the lowest dose. But that does not seem to be the concept implicit here, as IQ loss is generally estimated as a linear, non-threshold function of MeHg exposure and the panel discusses the question of whether a predicted loss per individual of 1 or 2 IQ points is a "credible decrement" (p 9, l 15). The panel also seems to endorse the use of a continuous, regression-based response measure in its discussion of developmental delay (p 8, l 30). Using a non-threshold dose-response function, the question of sensitivity depends on the magnitude of response that is judged significant and the corresponding rationale. The discussion (p 8, ll 8-16) of the relative sensitivity of various tests is similarly confusing because it does not address the question of how sensitivity is compared across tests that measure different outcomes.

The document would also be improved by more explicit attention to the dynamics of the response of MeHg concentrations in fish tissues to changes in atmospheric Hg deposition. As noted, the assumption that fish-tissue concentrations are proportional to atmospheric deposition (in water bodies without important other Hg sources) applies to steady-state conditions (e.g., p 17, l 30). Given the complexity of the process between atmospheric deposition to soil and water in a watershed, runoff, methylation, and bio-concentration up the food chain, it may take many years to reach steady state after a change in deposition rate. If so, the response time between change in EGU emissions and fish-tissue concentrations seems very relevant to characterizing "the nature and magnitude of the potential risk to public health" associated with current and projected 2016 EGU emissions and the apportionment of risk between EGU emissions and other Hg sources (which are the goals of the risk assessment; p 5, ll 26-31). The discussion of response times for Hg deposited directly to aquatic systems (p 8, ll 6-12) suggests the assumption of steady-state may be adequate in this context, but that point should either be made more explicit or the plausibility of non-steady-state conditions associated with runoff of Hg deposited to non-aquatic parts of the watershed should be discussed.

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

Yes.

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

Yes.

Minor comment:

The references are incomplete, at least Strain et al. (2008) is missing.

Comments from Dr. Cecil Lue-Hing

SAB. Homework Review Notes. Mercury Risk. For Telecon Sept. 7.2011.

General Comments

The Panel conducted an excellent review of the TSD and other relevant literature and documents provided by the EPA.

The Panel offered a wide ranging array of recommendations, suggestions, and numerous other statements. These statements were not defined as recommendations, suggestions or findings.

Letter to the Administrator

The letter is concise, and incorporates the issues of importance. The letter takes issue with the lack of a transparent description of the methods and findings of the risk assessment, and conditions the SAB's support of the risk assessment – *contingent upon development of a revised document that addresses these issues.*

Comment: This statement contingency is appropriate for the letter. However, it should be stated how it will be determined if these risk assessment issues are satisfactorily addressed, not necessarily in the letter, but elsewhere in the Executive Summary and the Body of the report.

Executive Summary

Format OK

Page 2, line 12-14, states – *Responses to charge questions indicate where improvements need to be made, and the Panel's support for the risk assessment is contingent upon these issues being addressed.*

Page 6, lines 31-33, states – *The Panel's support for the risk assessment is contingent upon a development of a revised document that addresses these issues.*

Comment – Since this risk assessment revision appear to be a point of strong interest by the Panel, the mechanism for determining if these issues are addressed need to be stated, in the body of the report, and or in the Executive Summary for example, a) will the revised risk assessment need to be reviewed by the SAB, or, b) is the revision expected or intended to be done on the honor system, such that no additional review by the SAB is needed?

The Body of the Report

The Panel's Recommendations & Pseudo-recommendations?

The Panel has offered a rich source of advice in the form of recommendations, intermixed with suggestions, requests, and other less specific statements such as, the Panel indicated, the EPA should, it would be useful to, etc., Some examples follow:

- Page 15, lines 5-7; -- it is also requested that the Technical Support Document clarify ---
- Page 15, line 29; -- the Panel indicated that a few caveats should be acknowledged more fully -
- Page 15, line 32; -- the Panel suggested that the Technical Support Document acknowledge ---
- Page 16, line 5; --- the Panel requested that this information be clarified ----
- Page 31, line 22; --- It may be useful to note why the average deposition rate is lower ----
- Page 32, line 7; --- EPA should consider whether it is better to use a 25% range or use the 10 nearest ---

Page 32; line 15; --- It would be helpful to have more information on the gold-mining ----

Comment: While all of these “non-recommendations” statements are meritorious, they do not convey any meaningful measure of seriousness or urgency. The Panel should indicate how it expects or wishes the EPA to react to them, since the EPA could easily not regard them as recommendations or suggestions to be acted upon.

It is noteworthy that also on page 32, in the midst of these non-specific, pseudo-recommendations on the page, we find at line 31, --- *The Panel recommended that language be added regarding the change in the percentage of watersheds* ----

Another example on page 33, line 27, --- The section should be revised to explicitly respond to each----

Comment: Would it be better to say --- The Panel recommends that the section be revised to explicitly respond -----?

The Panel recommends vs. the Panel recommended:

On page 28, line 10; we find --- *the Panel recommended* that EPA explain these differences and that EPA consider ---

Also on page 28, line 30; we find --- *the Panel recommended* that EPA clarify the text to improve -----

The past tense suggests that these recommendations were also made elsewhere in the Panel’s report – if this is the case, a reference should be made as to where these recommendations were previously made, e.g., the Panel recommended (Section X etc. -----) that EPA clarify ---

Editorial Comments

Page 14, lines 9-11; - It is not clear what is meant by the statement --- *result in a conservative estimate of the number of watersheds at risk* --- Does conservative mean, an overestimate of watersheds at risk or an underestimate of watersheds at risk?

Responses to the General Quality Review Questions

1.

Were the original charge questions adequately addressed?

Yes – They were adequately addressed. See comments under The Body of The Report.

2.

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

None that I found

3.

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

Yes – See comments under – The Body of the Report

4.

Are the conclusions drawn or recommendations provided supported by the body of the committee's report?

Yes.

Comments from Dr. Judith Meyer

Mercury Risk Assessment Quality Review – Judy Meyer

Page, line number

1. Were the original charge questions to the SAB Committee adequately addressed?

In general YES, but see following two comments.

Section 2.3: Reference to the previous discussion on use of the IQ loss benchmark should be included in this response to the charge question. If someone were to just read (or quote) this section, it should be more apparent that the Panel did not find IQ loss appropriate for a primary endpoint.

34, 7: A reader is left wondering what the original charge question was. I think that the original charge question should be included so that one can evaluate whether the changes made were appropriate. I realize the original question is in the appendix, but I think it also belongs here. I don't think I have read a report where the committee answered a question they asked rather than the one EPA asked.

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

NO

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

YES. I particularly appreciated the clear statements about how Agency presentations were necessary for the Panel to be able to evaluate the document and therefore the need for increased clarity in the document.

ES4, 5: What's a high end-consumer? A person who consumes a lot? Is there a percentile (e.g. above 50th percentile)?

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

In general, YES, but see the following two comments.

ES 1, 29: This is outside my area of expertise, but a change of 1 IQ point seems fairly stringent.

What is the measurement error for an IQ test? Is it really less than 1 IQ point? I would think the standard would be something more closely approximating the measurement error. At the very least, some justification for this standard and the Panel acceptance of it seems warranted. In the text of the report, the Panel notes that this benchmark is based on what has been observed in the lead literature. A phrase noting that in the Executive Summary would help justify that 1 point loss.

When I read the letter (p. 2, line1), I interpreted what was written as SAB endorsing the loss in IQ as appropriate. That is very different from what is written in the Executive Summary (2, 41-44). The letter needs to better reflect what is in the Executive Summary and report.

Editorial suggestions

Ltr, 1, 42: considers rather than considered to be consistent with rest of sentence.

p. 14, lines 5 & 6 & 14 & 17 & 20; p. 17, 20 – should use present and not past tense. Panel recommendations are written in past tense in several places. This strikes me as strange since the document is the Panel's recommendations so it should be in the present tense.

The Table of Acronyms seems in the wrong place. Or is it supposed to be another appendix? If so, that title is needed.

Comments from Dr. L.D. McMullen

I feel the panel did an excellent job of answering the charge questions and providing additional information to EPA.

1. Were the original charge questions to adequately addressed?

Yes and provided additional information on the topic of the question.

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

This is not my area of expertise, but I did not find any errors or omissions

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

I thought that the style of having the charge question followed by the response provided for easy reading and helped the reader to keep track of the topic of the response.

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

I feel the conclusions and recommendations were well supported.

I also feel the letter to the administrator did a good job of summarizing the subject and the Executive Summary did a good job with a paragraph on each of the charge questions.

A very good report by the panel.

Comments from Dr. James Mihelcic

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

The Committee has adequately addressed all fourteen charge questions.

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

I did not see any technical errors or omissions in the report.

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

The report is clear and logical. It was organized and to the point.

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

The recommendations are supported by the body of the Committee's report.

Comments from Dr. Keith H. MooYoung

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

Yes, the charge questions to the SAB committee were addressed. The SAB committee commended the SAB Mercury Risk Assessment Report for the consistency, rigor and comprehensive nature of the written report.

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

This is not my area of expertise. However, I saw no error or omissions in the report.

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

Yes, the report is clear and logical. The report is well summarized.

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

Yes, the conclusions drawn and recommendations support the body of the committee's report.

Comments from Dr. Amanda Rodewald

1. Were the original charge questions to adequately addressed?

Yes, the questions were well addressed.

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

No, not that I could find.

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

Yes.

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

Yes

Other comments:

Regarding Charge Question 2, the wording in the Executive Summary suggested to me that the Panel ultimately did not endorse use of any critical health endpoints, given that they recommended that IQ be de-emphasized and moved to an appendix and recommended no specific alternatives. This was a different impression than I got after reading the full response on pages 8-9. Also, it seems that the Panel could better acknowledge that the Agency discussed the shortcomings of IQ in the Appendix and text of the original technical support document.

From the text in the Executive Summary on page 3-4, I was not entirely clear if, in the end, the Panel agreed with the use of 75th percentile given their expressed concern that over half of the watersheds had very few fish samples (and 29% with only one sample, as stated on page 12), which would render the 75th percentile estimate a serious underestimate of exposure and one with "considerable uncertainty". The full response on page 13-14, though more detailed, still was somewhat vague in terms of the final recommendation. For example, the Panel recommended that the Agency conduct a sensitivity analysis, but specifically how should they use those results (i.e., what result should trigger action or modification of the approach?). I understand the desire and/or need to slightly hedge statements, but this one left me unclear about the real intent of the Panel.

Minor: in the original technical support document, on page 18, there should not be a question mark following the italicized text for Stage 2.

Comments from Dr. James Sanders

1. Were the original charge questions adequately addressed?

Yes, the charge questions were adequately addressed.

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

No. However, there are some issues with the letter to the Administrator that should be addressed, which are noted below.

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

The report is clear and concise. I have some reservations that the Panel's concerns are in places understated. For example, the general comments on p. 6 state that the Panel had difficulty evaluating the report, and it was only after additional information and discussions with EPA staff that sufficient information was available for evaluation. This is stated clearly in the document, but to this reviewer's opinion, this lack of information and transparency was not dealt with critically enough throughout the review. The Panel concludes that an extensive revision will be necessary to address the Panel's concerns, yet this conclusion is buried in the last paragraph of the letter to the Administrator--and the language used there is not strong enough. That paragraph begins, "Despite a generally favorable review..." I strongly recommend that the Panel consider the language used throughout the review, for example that on p. 2 and p. 6, for use in the letter to the Administrator. In addition, as is the case in the review's body, this paragraph should be moved up in the letter, perhaps becoming paragraph 3.

A further comment on the letter. The sentence on the use of IQ again does not convey the Panel's determination that this measure is not well suited for this risk assessment. The comments in the body state that the Panel had little enthusiasm for this measure and recommended that it be de-emphasized. This recommendation is not what is found in the letter.

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

Yes.