

**Comments from Members of the Chartered SAB on *Drinking Water
Committee's Review of EPA's Microbial Risk Assessment Protocol (1-12-10
Draft)***

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Comments from Lead Reviewers

Comments from Dr. Nancy Kim

1. Were the original charge questions to the SAB Drinking Water Committee adequately addresses?

Yes. The original questions were addressed.

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

No. I did not identify any.

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

Yes. However, I have one suggestion for the committee to consider. The letter, executive summary and the report suggest in several places how EPA should proceed in finalizing the document. One point is made that the document is not a protocol, but an introduction to microbial risk assessment. My impression is that the committee generally favors finalizing this document as an introduction and that EPA subsequently develop a protocol in a series of white papers or as another document. In some places, the document makes this recommendation, in other places it seems to offer options without favoring one option over the other. If my impression is correct (the committee favors finalizing this document as an introduction with a detailed protocol to follow), the report should probably be consistent in its presentation of options. It could provide more than one option, but state that it prefers one (for examples, see page 39, end of first complete paragraph and page 30, end of first full paragraph).

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

Yes.

Editing suggestions. Most of these are minor comments although a few are more substantive.

Letter to the Administration

1. p.2, line 9. I did not find the word concision in the dictionary. Suggest changing the word to conciseness.

2. P.2, line 27. Add the word formulation after the word problem to be consistent with other entries in the review.

Executive Summary of the report.

1. p. 9, line 14. Rewrite of sentence beginning with however. However, the Agency has done a tremendous amount of work on the MRA document and is commended for its leadership in this area. This completion serves...

2. p. 13, line 17. Additional information about this bullet is needed to improve its meaning and clarity.

Body of the report.

1. p. 17, line 4. Suggested revision. Attempts should be made to condense the document to make it more concise....
2. P. 18, line 6. Remove the word discussed at the end of the sentence.
3. P. 18, line 8. I would remove the first sentence of this paragraph. To a reader who was not involved in the detailed review, this sentence appears to be speculative and not necessary for the Committee to make its point.
4. P. 18, line 19. Placing the recommendations in this paragraph in a list, rather than as a long sentence, would highlight the contents and improve readability.
5. P. 18, line 23. Suggested rewrite of sentence. Appendix G should be placed in the document as a separate chapter and undergo a technical statistical review (see response to charge question 4).
6. P. 19, line 13. Add the word a between formulate and problem.
7. P. 19, lines 17 through 21. I found the use of the word protocol in these lines confusing and a reader could interpret this paragraph as being inconsistent with one of the major conclusions and recommendations of the review. The committee concludes that this document is not a protocol and appears to recommend that this document be finalized quickly and a detailed protocol be developed subsequently. However, in this paragraph of the report, the document suggests adding a step by step protocol. I suspect that the word protocol in this paragraph is a missed edit from earlier versions of the committee's report.
8. P. 20, line 11-14. I recommend reviewing the language in these lines since it seems somewhat contradictory to the language in other places that recommends taking many of the appendices and incorporating them into different chapters of the document rather than just capturing the general principles from the appendices.
9. P. 20, line 27. Remove second "of types" at end of line.
10. P. 23, lines 7 and 12. The sentence beginning with "The chapter has a good, concise..." in line 7 and the sentence beginning with "Overall, this chapter is concise..." say the same thing. They should be combined or one removed.
11. P. 23, line 15. Suggested rewrite of sentence, "Exposure assessment is often very venue- and microbe-specific and previous EPA MRA examples, such as that performed on *Cryptosporidium*, could be included here."
12. P. 24, line 3. Suggest replacing the word soft with another, more specific word.
13. P. 24, line 8. Suggested addition. "...i.e. where there is direct contact with raw untreated or with insufficiently treated water."
14. P. 24, line 17. Suggested insert. "...preventing or minimizing human exposure..."
15. P. 24, line 21. The words processes and process are used together. Perhaps the sentence would be clearer if rewritten slightly.
16. P. 25, line 17. Comma needed after ...outbreak).
17. P. 25, line 18. At the end of the sentence, "on this regard" could be replaced with "about this".
18. P. 25, line 22. Change "to occur" at end of sentence to "occurring."

19. P. 25, line 25. Could the logic in the sentence “Pathogens in treated water supplies are far more likely to occur episodically than otherwise because they occur with such a low frequency” be clarified?
20. P. 27, line 15. Suggested edit. Change the end of the sentence from “the needs for data” to “data needs.”
21. P. 27, line 19. Suggest starting a new paragraph with the sentence beginning with “A more thorough discussion...”
22. P. 27, line 27. Something appears missing after the parenthetic. The sentence doesn’t flow.
23. P. 30, line 24. Change data ...is to data...are.
24. P. 30, lines 16 through 20. The last two sentences in the paragraph seem to disrupt the flow and impact of the paragraph. One suggestion is to reverse the order of the last two sentences, but I am not sure that will fix it or that might change the meaning.
25. P. 34, line 10. Suggest replacing the words such information with human health effects information to improve clarity.
26. P. 36, line 24. Suggest starting a new paragraph with sentence beginning firstly. Consider starting remaining paragraphs in this section with secondly, etc.
27. P. 37, line 13. If the committee would like EPA not to use the words static and dynamic, that should be recommended rather than considered.

Comments from Dr. Christine Moe

Comments on DWC Review of EPA's Microbial Risk Assessment Protocol

Christine Moe

March 22, 2010 (World Water Day)

SAB reviewers are asked to comment on:

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.*

The USEPA developed a draft *Protocol for Microbial Risk Assessment to Support Human Health Protection for Water-Based Media* dated July 2009. This document consists of an Executive Summary and five chapters (Ch. 1 Introduction; Ch 2. Planning & Scoping and Problem Formulation; Ch 3. Exposure; Ch 4. Human Health Effects; Ch 5. Risk Characterization). The document also has seven appendices.

1. Addressing the charge questions:

The EPA asked the DWC to address five charge questions that focus on whether the whole microbial risk assessment (MRA) protocol is useful and then whether each of the subject chapters needs improvement. The DWC report starts with an Executive Summary, followed by an Introduction, and then five sections - with each section of the report addressing a charge question. It would be helpful to list all the charge questions in the Executive Summary and perhaps also in the Introduction of the report so that the reader has an overview of the scope of issues that will be addressed by the report.

The Charge Questions from EPA are complex and often involve multiple questions. Overall, the DWC report does a good job addressing each charge question and makes very specific recommendations that should be helpful in revising the document. The only instances where the charge question is perhaps not completely addressed is:

- Question #2, parts "b" through "f" (page 20-21). It is not clear if EPA is just listing bullets "a" through "f" as examples only, or whether the EPA is asking the DWC to comment on these examples. The DWC report comments briefly on bullet "a" (environmentally-based microbial pathogens) on page 22 (lines 21-26) but not on the other examples.
- Question #4 – The DWC does not really comment on the specific dose-response models mentioned in the charge ("advanced and validated threshold, empirical or mechanistic models"). Nor does the DWC comment on other exposure routes ("inhalation and dermal routes") or "in vitro" dose-response protocols.

2. Technical errors, omissions, issues inadequately dealt with:

Overall, the DWC report is very good about raising additional issues that should be included in the MRA protocol. Almost every section of the report includes valuable suggestions about issues for additional consideration.

The DWC report recommends that the EPA add more examples of actual EPA microbial risk assessments to the document (Executive Summary, pg 9. Line 24). This is an important recommendation that should be taken a step further. Not only should the EPA add more examples of MRAs, but for each of these examples, the EPA should explain the strengths and weaknesses of the MRA, where there were information gaps that needed to be addressed by further research, where there were needs to develop better analytical tools or models, etc. Examples are an important way not only to show how to develop an MRA, but also how the results of the MRA were used (or not used) by the Agency for decision-making.

Pg. 29, lines 1-2: Is the DWC suggesting that the MRA protocol should discuss the issue of viable, but non-culturable organisms? This is left as a question in the text.

3. Is report clear and logical:

Overall, the report is quite clear. However, like most documents written by multiple people, this report could benefit from some minor editing and re-organization. There is some **repetition** in the report that could be removed by some re-organization. Examples of this are:

- The report comments several times that the MRA Protocol is not really a protocol (pg. 21 line 28 – pg 22 line 4) and should be re-named and that perhaps there should be two documents – an introduction to MRA document followed by an advanced MRA document or series of white papers.

It is difficult to follow the report's **recommendations on the appendices**. There are times when the report recommends that the materials from the appendices should be added to the body of the report. Yet, the report also recommends putting more advanced and detailed discussions in a second more advanced MRA document or set of white papers (Page 18). There are specific recommendations on page 18, but these are hard to follow. Appendix G is mentioned several times in the report (see also pg 30) – so it is clear that the DWC is concerned about the material in this chapter, but it may be beyond the scope of the DWC review to give more specific guidance on this.

It is very helpful when the report makes specific recommendations, and these should be presented in the form of bullets so that they are easy to identify (such as in the Executive Summary on page 9). It may be helpful to have a summary list of recommendations at the end of each section of the report (e.g. section 5.3 on pages 39-40). Other places where bulleted lists of recommendations could be useful are:

- Pg. 26 – there is a discussion about several omissions that the DWC recommends that the MRA protocol address in the chapter on exposure.

- Pg. 32 – 34: the DWC raises a number of important issues that should be included in the Health Effects chapter of the protocol. It would be helpful to have a summary of the recommendations for this chapter

Minor editing is needed in the following areas:

- Pg. 27, lines 26-29
- Pg. 28, lines 12-14: It is important to use more precise terminology in these sentences. I suggest revising as follows: “The estimates of human infective dose used in developing the dose-response relationship have uncertainty associated with the dose. Freshly-harvested oocysts were used as the inoculum in the human challenge studies and are often used in disinfection studies, yet the age of oocysts in an environmental sample can vary widely, ...”
- Pg. 28, line 26
- Pg. 29, line 4: should specify analytical methods for detecting microorganisms in water
- Pg. 32, lines 1-4: This paragraph seems disconnected from the previous text. Is the DWC referring to the need for further animal studies for certain pathogens?
- Pg. 35, lines 4-12: It seems more logical to move this paragraph on susceptible subpopulations to the following section 4.4.

4. Are conclusions and recommendations supported by the body of report:

The conclusions and recommendations in the report seem to be logical extensions of the body of the report. It would be helpful to make sure that they are easier to find by adding a summary to the end of each section that highlights the main conclusions and recommendations.

Comments from Dr. Eileen Murphy

Drinking Water Committee's Review of EPA's Microbial Risk Assessment Protocol
 March 24, 2010
 Eileen Murphy Comments

Charge 1: whether the original charge questions to SAB Standing or Ad Hoc Committee was adequately addressed:

The charge questions were addressed adequately with one exception. Charge 4 was broken down into five sections. The first two followed the charge directly ("4.1 Scientifically accepted dose-response models" and "4.2. Animal dose-Response Models") The next three are not part of the charge at all – "4.3. Human Health Outcomes, 4.4. Susceptible Populations and 4.5. Quality of Life." While the points raised in these three sections were valid, they were not related to the actual fourth charge question, which was specifically about models.

The response to Charge 4.1 did not cover "models...which should be included as tools for determining human dose-responses from waterborne exposures via oral, inhalation, and dermal routes...". The MRA itself does not go into these topics, and the DWC did not cover it in this section.

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

No overt technical errors appeared in the report.

Charge 3: whether the Committee's report is clear and logical:

The report clear and logical and easy to follow. The report being reviewed by the DWC was very long, representing a challenge for addressing the charges in a logical way. By presenting the charges by chapter, they kept the flow clear and logical.

Charge 4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report:

Yes. Examples were provided in most instances.

Other:

P. 21, lines 5-8: the recommendation to eliminate "wordiness" is vague. Maintain the suggestion that the draft undergo a robust technical edit.

Recommendation is unclear: p. 22, lines 11-14: not sure how the committee is suggesting that the document be divided – specifically, the "advanced and detailed discussions for inclusion in a second" document and several white papers. Not sure what the purpose of the white papers would be or if they would be useful to stakeholders for MRA.

Comments from other SAB members

Comments from Dr. Rogene Henderson

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

The report was quite clear in stating each charge question and addressing it with specific comments.

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

I am not an expert in this field but I did not note any technical errors or omissions.

3. Whether the Committee's report is clear and logical.

The report appeared logical to me.

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

The recommendations were supported by the body of the report. The letter reflects the major points made in addressing each charge question as described in the Executive Summary.

Comments from Dr. Bernd Kahn

The review is well done; here are some suggested corrections:

p.2, 1.32: Insert comma after 'events'.

p.2, 1.34: Delete 'and' and replace with period. Begin next sentence with 'Finally,'.

p.2, 1.5: Insert comma after 'Again'.

p.7: Insert acronyms and explanation for 'HACCP' and 'ILSI'.

p.10, 1.6: Replace 'though' with 'through'.

p.10, 1.12: Replace 'its role' with 'their roles'.

p.10, 1.18: Replace 'occur with' by 'result from'.

p.12, 1.20: Delete 'as a separate chapter' (said earlier in sentence); also p.18, 1.20.

p.18, 1.9: Insert 'were' after 'changes'.

p.18, 1.16: Delete 'However' (this sentence repeats the previous one).

p.19, 1.13: Insert 'the' before 'problem'.

p.19, 1.17: Previously, the Committee recommended eliminating 'Protocol' from the title; here it seems to offer an alternative,

p.24, 1.25 and 27: Delete these parentheses.

p.27, 1.13: Delete the two commas.

p.27, 1.27: One or more words seem to be missing before 'is found'.

Bernd Kahn March 2010

Comments from Dr. Judith Meyer

1. Whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

Yes, they have been addressed clearly.

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

In general the report is quite thorough. I have only one concern, which is with the recommendation that additional statistical review (e.g., p. 12, lines 3-4, but also in other places) is needed. I would have thought that this review committee would have been augmented with this additional expertise. I read the statement as saying that the committee didn't have the expertise to evaluate the statistical section. Perhaps that is not what was meant. Are you calling for statistical review or a rewriting of the statistical section by an expert? I would have thought review is what this committee has done. Clarification is needed.

3. Whether the Committee's report is clear and logical;

Yes, the document is clearly written and easy to follow.

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

Yes, although (p. 12) some further justification for the recommendation to move around all the appendices is needed. Is it because having that information in an appendix makes it seem less significant than it is?

Editorial comments

1. Letter, p. 2, line 9: I don't think "concision" is a word – conciseness. Also on p. 9, line 18.

2. Interagency microbial risk group is mentioned in letter, but I don't think I saw it elsewhere in the document. I have no idea what agencies are involved. And it is strange that it is in the letter but nowhere else (unless I missed it).

3. p. 14, lines 11-12: does this imply that the previously mentioned MRAs were quantitative?

4. p. 30, line 24: data ARE available, not is

5. p. 31, line 15: Although I have no idea what a gnotobiotic piglet model is, I think the references to the various studies that have been done with it need some specific citations to the literature so this suggestion can be more useful to the reader. There are several other references to useful studies in the same paragraph; yet there are no citations for any of them. Citations are needed!

6. p. 36, lines 10-11: is the cost benefit analysis part of the risk management? If so, that should be clarified.

7. p. 39, line 2: need to BE clearly...

Comments from Dr. Duncan Patten

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

The original charge questions are well covered by the report, although in many cases they were not questions but rather "requests" (see comments below).

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

There appear to be no technical errors or omissions, although this is not an area of my expertise and others can better answer this.

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

There is some inconsistency in how the committee responds to the charge questions. In some places they as in Charge question 1, the committee responds to separate restated components of the question and in others, such as Charge question 3 they respond without restating the question. Consistency would help....

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

As far as I can tell, yes.... the recommendation for developing a new document with actual protocol steps and using this one as background is fully justified and appropriate.

Other comments: There should be some consistency between what is requested as stated in letter to administrator, and what the charge questions request, although as pointed out below, some of not questions but requests. The committee uses a general set of requests in the letter and Executive Summary that do not wholly cover the charges.

I've brought this issue up in other requests for review and do so here. When SAB is requested to review a document and the EPA office requesting it uses charge questions, they should use questions rather than requests. For example, in Charge Question 3, the Charge Question "requests" the review committee to suggest what additional material should be in the report rather than asking for critique of what is in the report and then addressing omissions if necessary. These types of Charge "Questions" appear to be an admission of the authors of the original report that they have not fully done their homework and are asking the review committee to help them rewrite the report. Suggestions for how to rewrite and what to include in a revision should result from a review of a fully complete and documented draft which may have need of improvement.

Comments from Dr. Amanda Rodewald

Overall I thought that the Drinking Water Committee did an excellent job in addressing the charge questions and preparing a clear and concise report.

4. are the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;

Yes, the committee provided detailed responses to all charge questions. I make two observations that the committee may want to consider.

First, in Section 1.4 (page 19, lines 9-10), the reports states that “*The strength of the document, explaining the principles of MRA, may also be its weakness **if the document is intended to be a protocol***” [bold emphasis in original document]. I noticed, however, that the first charge question described that the intent of the Protocol was to “*provide a comprehensive and robust suite of approaches, tools, methods, and procedures...*” – a description that seems more far-reaching than a straightforward and streamlined protocol. Given this, it might be appropriate to explain the principles of MRA. My guess is that the committee’s response reflects the more detailed information they received at the meeting regarding the purpose of the Protocol.

Second, the response to Charge Question 2 seemed comparatively thin, but this likely is a consequence of the inclusion of some recommendations in section 1.

5. are there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee’s report;

No, the report looks great. I only have one minor suggestion. On page 2, line 32, the phrase “for example” seems misplaced.

6. is the Committee’s report is clear and logical;

Yes, the Committee clearly and concisely responded to the charge questions. My only comment here is that the paragraph on page 22, lines 21-26, could be more explicitly linked to the charge question and to the previous paragraphs.

7. are the conclusions drawn or recommendations provided are supported by the body of the Committee’s report.

Yes.

Comments from Dr. Stephen Roberts

Comments on the SAB review of EPA's Microbial Risk Assessment Protocol
Steve Roberts

1. The Executive Summary should concisely and faithfully capture the salient points of the panel report. It does not accomplish this well, in my opinion. In the Executive Summary, panel recommendations are presented as bullets, whereas in the main body of the report they are bulleted in some places and simply appear in the narrative in others. The organization of presentation of topics is different as well, compounding the difficulty in comparing the Executive Summary with the main body of the report.

For example, the response to charge question 1 is covered on page 9 of the Executive Summary and pages 15-20 of the main report. The Executive Summary has four bulleted recommendations in response to this charge question, while the main report has seven (pages 16, 17, 18, and 20). Among these, only three are the essentially the same. The response to charge question 2 resulted in one bulleted recommendation in the Executive Summary – “The Committee recommends formatting all the diagrams in the chapter to the standard logic-diagram format.” (page 10). The response to this charge question in the main report also has one bulleted recommendation, which is different: “The title of the document should be changed to eliminate the suggestion that this is a detailed, step-by-step process.” (page 22). This recommendation does appear in some fashion in the Executive Summary, but it is included in the response to charge question 1. Recommendations in response to charge questions 3 and 4 are presented entirely in narrative form in the main report and are captured with varying degrees of success in bullets in the Executive Summary. The principal recommendations in response to charge question 5 are presented in narrative form in the main report and bullets in the Executive Summary. Additional recommendations (primarily editorial) are presented in bulleted form in the main report and are absent from the Executive Summary. All of this is potentially confusing. I recommend re-evaluation of the Executive Summary and the format of the main report. Conclusions and recommendations should be presented in a way that can be more readily understood by the reader, and the Executive Summary should more clearly reflect the content of the main report.

2. It is apparent that the panel is unhappy with Appendix G in particular, but the problem(s) are not clearly articulated in the report, in my opinion. Comments in various places in the report suggest that Appendix G is:

- A. Poorly written, as suggested by the recommendation that it be reviewed by a “technical editor” (page 9).
- B. Inaccurate, as suggested by the recommendation that it requires “statistical expert technical review” (page 9) by “an engaged, broadly-knowledgeable expert in statistical methods” (page 11) with regard to “accuracy in its description of the extant literature and methods” (page 18).
- C. Incomplete, as implied by the statement “It is apparent that individuals ensured that their favorite methodological approaches were included ...”
- D. Inappropriate for this document, as suggested by the recommendation that it be “included in a second more advanced MRA document and/or separate white papers.” (page 12).

Perhaps the Appendix suffers from all of these, but I think that the report would be more helpful if the deficiencies are more clearly described with examples.

3. Overall, the report seems responsive in answering the charge questions. The response to charge question 2 may have been less than what the Agency was seeking, however. This charge question asks for suggestions to enhance or expand guidance to allow users to prepare and conduct risk assessments for a broad range of types of risk management questions, and several types of EPA uses of MRA are identified (pages 20 and 21). Presumably the intent of identifying these uses was to prompt the panel whether additional or expanded guidance is needed so that risk assessments to support each of these uses can be conducted. That question wasn't answered. The response instead is very general (change the title of the document; clarify when stakeholders should become involved; change diagrams; incorporate novel pathogens and routes; page 22) and I suspect may not be the kind of information that was sought.

Editorial suggestions:

1. pg 10, line 3: replace "which" with "that"
2. pg 10, lines 13-14, "the greatest variability to risk assessment is in defining the exposure." Suggest re-phrasing to something like "the greatest source of variability in risk is from exposure."
3. pg 10, line 23: Shouldn't "risk management" really be "risk assessment"? I'm not sure how indicator organisms would be used in risk management.
4. pg 11, line 8: Suggest deleting "engaged".
5. pg 11, lines 8-10, "It is apparent that individuals ensured that their favorite methodological approaches were included in the analysis in Appendix G ...": This looks like unnecessary speculation to me. If the statistical methods presented are incomplete, simply say that and ideally provide examples of important methods left out of the discussion.
6. pg 12, lines 19-20 [also pg 18, lines 19-20]: "separate chapter" appears twice; one should be removed
7. pg 19, line 13: Should read "formulate the problem"

Comments from Dr. James Sanders

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

Yes, the DWC addressed each question.

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

To the extent that I have looked, no.

3. Was the Committee's report is clear and logical?

For the most part, yes. However, I do have one overall comment.

There seems to be a disconnect between the DWC's desire and recommendation that the EPA should get this report out quickly, and the many recommendations for what appear to be extensive changes, even suggestions that whole sections be moved around or used to develop several stand-alone white papers. The recommended revisions don't appear to be ones which will be quickly done, unless the OW has been working in the background on such revisions. Also, the DWC states that the report is well written, but often refers to its verbosity. To me, the two are incompatible, aren't they?

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

Yes, the DWC has discussed its recommendations carefully, and provide examples of possible changes and direction.