

SAB Comments on Drinking Water Contaminant Candidate List 3 Draft Panel Report

1. Dr. Dr. LD McMullen:

I had the opportunity to be part of the process in developing the first CCL as part of the National Drinking Water Advisory Council. We also helped in developing some of the ideas for the development of the second CCL.

I have read the document and have found it to be well organized and easy to follow. I believe it answers the charge questions that were presented to the committee.

On page 9 first paragraph, I think an example might helpful such as an addition or removal. This could be helpful to the agency and make sure that the point is not missed. This is done very well in the second paragraph on page 9.

The direction of the last paragraph on page 9 I agree with. However, I got a little lost in the process proposed. There are several different types of data needed for regulation. It seemed that the message was not to put anything on the list until all or most of the data was available. I don't think that was the intent of the CCL. We may want to talk about that.

On page 10 second paragraph, I think I agree with the intent of the paragraph. However, it could be made a little more clear, by stating it was pathogens in the water that have been exposed to antibiotics in the water, or maybe I don't understand the point correctly.

On page 15 last paragraph and on to the top of page 16, I agree with the idea if we are sure that the science is there to support the idea. I did not follow the discussion of substitute a non-regulated compound for a regulated one. An example might be of help.

On page 16 first fall paragraph, I agree with the statement that in some areas wastewater discharges can make up a significant portion of a water treatment plant raw water source. However, there are many areas of the country where that is not the case such as the Midwest and Great Lakes area. We may want to qualify the paragraph a little more. Also, do we know that the NPDES monitoring results have emerging contaminants? I don't think it is common for municipal discharges.

2. Meryl Karol:

a) Are the original charge questions to the SAB Panel adequately addressed in the draft report?

Yes

b) Is the draft report clear and logical?

The draft report is logical and, in general, clear. However, the following lines would benefit from some careful editing:

p. 2 lines 23-31

p. 8 lines 40-43

p.12 lines 17-18

c) *Are the conclusions drawn, and/or the recommendations made supported by information in the body of the report?*

Yes

d) *Errors/omissions*

p. 2 line 20 change as follows:in the determination ~~in~~ of whether....

p. 11 line 7 The flowchart was not included

3. Dr. James Sanders:

Are the charge questions adequately addressed?

Yes, the Committee addressed the charge questions adequately. While this draft report is brief, each of the questions is discussed, and the comments herein should help to improve the process for listing contaminants in the future.

Is the report clear and logical?

For the most part, the report is clear. There are some typographical errors, and some wording that is not clear to me. For example:

p. 11, line 13. Does the committee mean “impart” instead of import?

p. 11, line 24. What are training chemicals?

p. 14, line 12. Broader, not boarder.

Are the conclusions supported?

The Committee has provided appropriate comments and recommendations. Their efforts should improve the process in the future.

4. Dr. Thomas Wallsten:

I have read the three draft reviews. It appeared to me that all three adequately addressed the charge questions, were logically laid out, and provided supporting information for their conclusions and recommendations. I have three comments on the reports:

- a) The review of the White Paper on "Aquatic Life Criteria for Contaminants of Concern" mentioned the use of expert panels to provide professional judgment during criteria development (Section 4.1.6). I concur that such panels can be very useful. My question is whether EPA has, or has not considered, guidelines for how such panels should operate to assure careful, unbiased judgmental extrapolations from available data to end points of concern?

- b) The same white paper urges that attention be paid to the possible effects of mixtures of contaminants, not just contaminants acting alone. This point would seem to apply to the "SAB Advisory on EPA's Third Drinking Contaminant Candidate List," yet I did not see it mentioned there (although I may have missed it).
- c) Finally, only the review of "Toxicological Review of Acrylamide" included a list of abbreviations. While some acronyms are common (e.g., LOEL, NOEL, DNA), others may be unique to specific fields or topics (e.g., CEC, ROPC, WBDO). It would be helpful for all reports to have a list of acronyms.

5. Dr. Terry Daniel:

The original charge questions to the SAB Panel are adequately addressed in the draft report, the report is clear and logical, and the conclusions and recommendations are supported by the information in the body of the report.

Some suggestions for extensions to some sections for the CCL3 review are presented below.

The Federal Register Notice implies that the lists of candidate contaminants are intended for both technical audiences (e.g., scientists and water utilities managers) as well as concerned citizens. An alphabetically arranged list with little or no information about the relevant characteristics (viz. criteria for drinking water safety) seems less than optimal for either audience. The SAB Committee noted in several places that it was difficult for readers to determine the reasons for inclusion of a chemical/pathogen on the list or to get any sense of the urgency, severity or priority for regulation of one candidate over others. The Committee suggested that organizing the list even roughly on the basis of priority for consideration for regulation would be helpful. In particular it was suggested that the listing should first identify contaminants that are well researched and are known to have both significant occurrence and health risks. A second category for contaminants where adequate data is currently lacking could be divided to distinguish those for which occurrence data, health risk data or both is insufficient. This second group identifies contaminants for which there is a need for monitoring and for targeted research to close the indicated data gaps. Finally there are many nominated contaminants about which relatively little is known, so that this category calls for a broader and longer term program of research.

In addition to priority-based classifications, the Committee recommends that contaminants be grouped according to mode of action, occurrence, health effects and/or other relevant factors. Any meaningful grouping and prioritization would be an improvement over an alphabetically arranged list of 93 chemicals and 11 pathogens. However, the noted difficulty for readers seeking to determine why a given contaminant is on the list would need to be extended to include questions about why it has been assigned to a given priority class and why it is included in one or

another grouping. One approach to addressing such questions is to include relevant information about each contaminant directly in the listing. That is, the list could be presented as a matrix, where priorities and groupings are explicitly designated, along with summary indicators of critical criteria, such as potency/concentration ratio, occurrence, mode of action, health effects, source, model scores, expert panel conclusions, etc. The committee also suggested that citations of government documents and other sources relevant to the evaluation of each candidate contaminant be more readily accessible for readers. Including all of the desired information in a printed listing would be unwieldy, so there would have to be constraints on the size of the suggested matrix. Of course, an electronic version of the matrix would be less restricted in this regard, as the reader could follow hyperlinks (in the matrix) to find additional information relevant to their questions about a particular contaminant.

6. Dr. Rogene Henderson:

I found it difficult to follow the advisory without having seen the write-up of the process on which advice was being given. However, I thought the report addressed the charge questions in a logical and rational manner and I think the report would be clear to someone familiar with the process by which the CCL3 was developed. The tone seemed appropriate; it was helpful and not derogatory.

7. Dr. David Allen:

- Page 5: There appears to be a header missing after "Other SAB Members"
- Page 11 Lines 7 and 8: The language led me to expect to see a flowchart, which was not included
- Page 17, line 2: grammatical error

8. Dr. Duncan Patten:

General Comment. In all three cases, the SAB review committees have offered excellent review and advice to EPA. The reviews are comprehensive and in sufficient detail to allow EPA staff to reconsider their positions on topics of concern and to rewrite or rework the materials presented in the white papers.

In order to fully assess the responses of the SAB review committee, one would have to be more expert in the particular field of science than I am. Thus my comments are more general, but specific in some cases.

An aside comment on Cumulative Effects and Synergism relevant to two of the reviews.

One question that comes to my mind as I read the reviews, and thus responses to EPA questions, especially those for "Aquatic Life Water Quality" and "Drinking Water Contaminant Candidate List" deals with the concepts of "cumulative effects" and "synergism" in effects of contaminants. Why aren't these concepts considered more critically in testing or selecting contaminants of concern? Only in the Aquatic Life Water Quality review is the concept of synergism (page 11) even considered, and apparently only in passing. Are not the synergistic interactions as well as cumulative

effects among and within contaminants of importance in selection and testing of toxic effects?

Comments specific to Contaminant Candidate List (CCL3):

The response of the SAB committee was quite thorough but some of its statements in response to EPA questions need more detail.

When the committee mentions that it acknowledges that the process should be “an adaptive process” (page 8, line 18) is the committee clear, or does it understand what this means? It should ask for goals and outputs to be identified in this process that will help the improvement of the report.

In the development of “models” for the SAB report, the committee should address how good the model development was (page 8, line 26).

Bottom of page 8 the committee emphasizes “transparency”. Is articulating the decisions by experts primarily the improvement needed to gain more transparency?

Top of page 9. Committee members could not follow the decision making process for some contaminants. It is uncertain whether putting the information on the web site and developing hyperlinks will solve this. Better guidelines of how the process proceeds might be in order.

After page 9, line 37 there should be some statement that emphasizes longevity of pesticides in ecosystems which would be a criterion for cancelling or keeping a pesticide.

Part 2 on clarification regarding steps... that will make it more transparent is probably one of, if not the, most critical commentaries in the review. Clarity is one thing, but transparency of process and expert inputs for example, may be most important to acceptability of the CCL3 report.

Decisions Regarding Data Sets...(paragraph lines 6-14, page 13) Emphasis on large populous states seems imbalanced. The committee should recommend some emphasis on geographic distribution (not necessarily within state boundaries but perhaps watersheds).

Page 13 (line 33)... should point out clearly how literature has appropriate data on outbreaks, etc.

Page 15, line 22. Good statement on consideration of “risk assessment”.

Page 18, lines 13-14. Does the committee believe “these chemicals may be of lower priority..” because the assessment approach was wrong. Needs to be clear.

9. Dr. Bernd Kahn:

I have read the three draft Reviews and consider them to be well written.

10. Dr. Timothy Buckley:

This report seems more problematic in that it is not organized around the charge questions. It may very well be that the charge questions have been addressed, but it is very difficult to tell the way this report is currently organized. I also have a few editorial suggestions that can be taken or left.

Letter, Page 2. Lines state that “The Committee expressed some concern that the lack of clarity could impede the ability of others to understand the basis for decisions about the CCL, an enunciated criterion for transparency made during the reviews by the National Research Council and NDWAC.” **I would break this up into two sentences and replace “enunciated” with “stated.”**

Letter Page 2, Line 31 **replace “better” in “to generate a better list” with “more scientifically credible”.**

Letter Page 2, Line 43, “make regulatory determination on” **Can you just say “regulate” here or “develop regulations.”**

Report Body, Page 8, Line 14: **Consider replacing “data-driven” with “evidence-based.”** Same Page, Line 44: **“stated” instead of “enunciated.”**

11. Dr. Jerald Schnoor:

I have read the 18 page report from the Drinking Water Committee (EPEC) of the SAB reviewing the EPA’s Draft Third Drinking Water Contaminant Candidate List (CCL 3) Report, and I find it to be a good report. It speaks to the charges provided by EPA and answers the questions posed. (I did not read the original Federal Register Notice and support documents for the draft CCL 3.) My comments on the DWC report are summarized below.

If EPA is going to use internal (or external) expert panels in the future to generate or scrutinize CCL lists (which is currently the conventional wisdom in the U.S. and Europe and with which I agree) then we will be challenged to provide better communication about the deliberation and results of the panel. The discussion on the top of page 9 in this regard is highly relevant and important to getting the process right.

I especially liked the recommendation that the Drinking Water Committee made to be involved during the document development process and not just at the end (Page 17, lines 12-14), and the entire discussion on page 17 (see point #4, lines 18-46).

My overall impression is that the report is surprisingly positive considering the overall conclusions that it is still not an adequately transparent process and that the DWC Committee still does not understand why certain pathogens and chemicals

appear on the list and why others do not. This illustrates the problem and confusion for the public when some chemicals are scrutinized in some countries and not in others, why some states have set MCLs and others have nothing, and why some experts express dismay and concern over potential exposures and others do not. Somehow we need to get to a point of agreement by simplifying the process, increasing its transparency and reproducibility, and improving our risk communication to the public and water utilities.

12. Dr. Steve Roberts:

The panel report is very well written and provides thoughtful comments and recommendations that should be valuable to the Agency. Each of the charge questions was addressed clearly in the report, with supporting rationale and examples. This is an excellent report – I have no suggested changes.

13. Dr. David Dzombak:

(a) Are the original charge questions to the SAB Panel adequately addressed in the draft report?

The SAB Drinking Water Committee has addressed all of the charge questions, but at different levels of depth, and not in a systematic manner. The Committee has provided extended, very useful commentary on the process used to develop the CCL3 list, which relates mostly to Charge Question 1, but has addressed Charge Questions 2, 3, and 4 directly only in a brief manner at the end of the report. I recommend that the report be more direct and transparent about addressing the charge questions by organizing it around the charge questions. I don't think this will require a great deal of revision, but it will do much to clarify the responses of the committee to the charge questions.

(b) Is the draft report clear and logical?

The report is logically organized but focuses almost entirely on the process used to develop the CCL3 list. This discussion pertains to Charge Question 1, which asks if “the Federal Register Notice and support documents are clear, transparent, and adequate to provide an understanding of the overall processes and selection of contaminants for the draft CCL3.” Charge Questions 2, 3, and 4, which ask whether the listed contaminants have the highest potential to occur in public water systems and cause adverse human health effects, and for recommendations about contaminants that should be removed or added to the list, are answered directly only in brief statements in Section 4, near the end of the report. I recommend that the report be reorganized to have individual sections of the report for each of the charge questions, and that direct responses to Charge Questions 2, 3, and 4 be given in the sections corresponding to each of those questions.

The organization of the letter to the Administrator would also benefit by a sequential and direct addressing of all of the charge questions. The emphasis of the importance of improving the process for determining the CCL list is fine, but Committee responses to Charge Questions 2, 3, and 4 should be more clearly stated. In the letter, the opening sentence of the paragraph on the bottom of page 2 (lines 39-41) is not

well stated. The corresponding language in the report body (page 11, last paragraph) is clear and discusses prioritization among contaminants, but the “prioritizing between” statement in the letter refers to two approaches and is confusing.

(c) Are the conclusions drawn, and/or recommendations made, supported by the information in the body of the draft SAB report?

The conclusions drawn by the Committee for Charge Question 1 are well supported in the report. The limited conclusions related to Charge Questions 2, 3, and 4, however, are discussed only briefly and warrant some additional discussion. Separate sections for each of the charge questions would make apparent where more support discussion is needed.

14.