UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

January 11, 2016

EPA-SAB-16-002

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Subject: Review of the EPA's Draft Fourth Contaminant Candidate List (CCL 4)

Dear Administrator McCarthy:

EPA's Office of Ground Water and Drinking Water requested that the Science Advisory Board (SAB) provide advice on EPA's Draft Fourth Drinking Water Contaminant Candidate List (CCL 4). Contaminants on the CCL 4 can be chosen by the agency to undergo a regulatory determination. The CCL 4 also influences the research agenda and other rules such as the Unregulated Contaminant Monitoring Rule.

The EPA charge to the SAB requested advice on the clarity and transparency of the CCL 4 support documents in presenting the approach used to list contaminants on the CCL 4, additional data sources that the agency should consider, and contaminants that the SAB recommends to be added or deleted from the draft contaminant list. The SAB Drinking Water Committee met to receive a briefing on the process used to develop the CCL 4, hear public comments and develop recommendations for the agency, through the chartered SAB, in response to the EPA charge questions. The enclosed report provides recommendations to enhance the clarity and utility of the CCL 4 and key recommendations are highlighted below.

The SAB concludes that the general protocol used to evaluate contaminants is well described, but the documentation lacks specific information needed to follow the decision making process for listing individual contaminants on the draft CCL. In order to improve transparency, the SAB recommends that the EPA develop a summary table including the CCL 3 and CCL 4 with appropriate use of hyperlinks; present the results of the CCL 4 screening and classification process in a manner that explicitly outlines the scoring schemes used and their scientific rationale in applying the selection criteria; provide examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL 4; and clearly describe and improve the process for removing contaminants from prior CCLs, where appropriate. The agency also should evaluate and describe the effect of data variability and model sensitivity on the results of the contaminant classification process.

Regarding peer-reviewed information and data utilized in the CCL 4 process, the SAB is concerned that the agency relies too heavily on the public to nominate candidate contaminants and to provide new data for previously listed contaminants. The SAB recommends that the EPA develop a strategy to proactively

reach out to large utilities, relevant state agencies and other groups to obtain occurrence information. The agency also should utilize available data from the Unregulated Contaminants Monitoring Rule (UCMR 3), National Health and Nutrition Examination Survey (NHANES) biomonitoring data for human exposure, and consider performing searches of the peer reviewed literature to identify new and emerging contaminants.

When evaluating candidate microbial contaminants that should be included on or excluded from the list, the SAB recommends that several of the exclusion criteria in the EPA documents be reconsidered because they may lead to the exclusion from the CCL of potentially significant microbial hazards. Pathogens of emerging concern, including those associated with biofilms and drinking water distribution systems, should be priorities for inclusion. In contrast, pathogens such as vegetative bacteria that are, in effect, already addressed by existing regulations (such as the Surface Water Treatment Rule) should be a lower priority for inclusion.

With respect to the chemical contaminants that should be included on or excluded from the list, the SAB notes that the list includes a number of contaminants carried forward from the CCL 3 but without providing a sense of the relative priority or ranking of the listed chemicals. In light of the growing number of contaminants on the CCL and the time required to move a contaminant through the regulatory process, the SAB encourages the agency to develop more health advisories for contaminants where occurrence is known to be sporadic but where the Health Reference Level/water concentration ratios are at a level of concern. The EPA also should consider the frequency of occurrence of contaminants in the UCMR data as a guide for removing or adding contaminants to the list and should consider the feasibility of listing similar contaminants as a group rather than as individual chemicals. Finally, the agency should consider adding more disinfection byproducts to the CCL, considering their potential human toxicity and frequency of occurrence in public drinking water systems.

Thinking ahead to the next CCL, the SAB recommends that the agency implement a system that integrates data collection and curation into a more modern data infrastructure and uses a broader range of the best available data on drinking water contaminants. If the agency implements such a system, a mid-course review by the SAB of the new data collection and curation effort is suggested.

Finally, the SAB notes that many of the concerns in the enclosed report were expressed in the SAB review of the CCL 3. If there are barriers in the CCL process that are preventing effective changes from being made, these barriers should be addressed prior to development of the CCL 5. A response by the EPA to the SAB's specific recommendations would aid in SAB reviews of future CCLs.

Thank you for the opportunity to provide advice on this important process. The SAB looks forward to receiving your response.

Sincerely,

/S/

Dr. Peter S. Thorne
Chair
Science Advisory Board

/S/

Dr. Kimberly L. Jones
Chair
SAB Drinking Water Committee

Enclosure

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Acronyms and Abbreviations

CCL	Contaminant Candidate List
DBP	Disinfection Byproducts
FRN	Federal Register Notice
HRL	Health Reference Level
MCL	Maximum Contaminant Level
MCLG	Maximum Contaminant Level Goal
PCCL	Preliminary Contaminant Candidate List
SDWA	Safe Drinking Water Act
UCMR	Unregulated Contaminant Monitoring Rule
WBDO	Waterborne Disease Outbreak

1. EXECUTIVE SUMMARY

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the EPA every five years to identify a list of unregulated contaminants (i.e., the Contaminant Candidate List or CCL) that occur or are anticipated to occur in public drinking water systems and may require regulation. Contaminants considered for listing include both chemical and microbial contaminants. The SDWA also specifies that the agency is to consult with the scientific community, including the Science Advisory Board, and provide notice and opportunity for public comment prior to publishing a final CCL. The CCL serves a dual purpose of identifying priorities for potential future regulation and to inform future research and monitoring needs.

The EPA Office of Water requested the SAB to review the draft Fourth CCL (CCL 4), which was released for public review and comment on February 4, 2015. The draft CCL 4 includes 100 chemicals or chemical groups and 12 microbial contaminants. The EPA charge to the SAB requested advice on the clarity and transparency of the CCL 4 support documents in presenting the approach used to list contaminants on the CCL 4, additional data sources that the agency should consider, and contaminants that the SAB recommends be added or deleted from the draft contaminant list. The SAB Drinking Water Committee met April 29-30, 2015, to receive a briefing on the process used to develop the CCL 4 and to hear public comments and deliberate on responses to the EPA charge questions. The committee held a public teleconference on August 3, 2015, to discuss its draft report, and the chartered SAB held a teleconference on September 24, 2015, to conduct a quality review and approve the report with clarifying edits.

The SAB concluded that the general protocol used to evaluate candidate contaminants—from identifying the universe of chemicals through the final CCL 4—is well described. The transparency and clarity of the procedure has improved since the CCL 3 was finalized. However, specific information needed to understand how the EPA made decisions for individual contaminants at each step of the process was lacking. The SAB recommends a set of actions that the EPA could take to improve the clarity and transparency of the listing process:

1) Summarizing information in one place (preferably a well-designed summary table), including co-locating the CCL 4 and the CCL 3 and making appropriate use of hyperlinks;
2) Presenting the results of the CCL 4 screening and classification process in a manner that explicitly outlines the scoring schemes used (and their scientific rationale) in applying the selection criteria;
3) Providing examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL 4;
4) Clearly describing and improving the process for removing contaminants from prior CCLs, where appropriate, when such lists serve as the basis for a new CCL; and
5) Including a summary of how CCL contaminants are further evaluated during the regulatory determination process to help clarify expectations for the CCL process.

The SAB is concerned that the agency is relying too heavily on public nominations as the source for new candidate contaminants and for new data on previously listed contaminants. Thus, the SAB recommends that the EPA develop a strategy to proactively reach out to large utilities, relevant state agencies, and other groups to obtain occurrence information that may be useful in identifying potential candidates for the CCL. In addition, the agency should (1) make use of data collected under the Unregulated

Contaminants Monitoring Rule (UCMR 3) as it becomes available, (2) consider performing searches of the peer reviewed literature to identify new and emerging contaminants, and (3) refer to the National Health and Nutrition Examination Survey (NHANES) as an additional source of human exposure data. In addition, as part of the CCL process the EPA should examine data on temporal changes in chemical production and use to identify contaminants for which data on occurrence are limited, but for which occurrence may become a greater concern in the future.

In responding to charge questions about pathogens that do not merit listing or that should be added to the CCL 4, the SAB recommends general principles to be followed by the EPA in deciding what to include on or exclude from the list. These principles are motivated by two factors: (1) the overarching importance of public health as the baseline for selection or exclusion of microorganisms in the CCL and (2) the role of the CCL as a key initial step required for subsequent development of effective regulatory, monitoring, and research decisions.

- The SAB recommends that several of the exclusion criteria described in the EPA documents be reconsidered—for example, the exclusion of anaerobic pathogens and pathogens that are not endemic to the United States—because they may lead to the exclusion from the CCL of potentially significant microbial hazards.
- The SAB also recommends that pathogens of emerging concern, including those associated with biofilms and drinking water distribution systems, be priorities for inclusion.
- In contrast, the SAB recommends that pathogens such as vegetative bacteria that are, in effect, already addressed by existing regulations should be a lower priority for inclusion.
- Research and monitoring priorities (e.g., decisions under the UCMR) should focus on contaminants likely to have the broadest public health impact.

With respect to the chemical contaminants on the CCL 4, the SAB notes that the list includes a number of contaminants carried forward from the CCL 3 but without providing a sense of the relative priority (e.g., High, Medium, Low) of the listed chemicals. In light of the growing number of contaminants on the CCL and the time required to move a contaminant through regulatory determination and, where appropriate, promulgate a National Primary Drinking Water Regulation, the SAB encourages the agency to develop more health advisories for contaminants for which occurrence is known to be sporadic but for which the Health Reference Level / water concentration ratios are at a level of concern. The EPA also should consider the frequency of occurrence of contaminants in the UCMR data as a guide for removing contaminants from or adding contaminants to the list and should consider the feasibility of listing similar contaminants as a group rather than as individual chemicals. The agency should consider adding more disinfection byproducts to the CCL, considering their potential human toxicity and frequency of occurrence in public drinking water systems.

For future CCLs, the SAB recommends that the EPA consider implementing a system that integrates data collection and curation and uses a broader range of the best available data. A user interface that curates data entered to the system from registered users would allow for broad-based population of the knowledge base and would allow interested members of the public to evaluate the full dossier of data available to the agency for each contaminant. Modernizing data sources and data infrastructure is critical to an effective CCL development process and this modernization should be a priority as it will greatly improve efficiency and transparency. If the agency implements such a system, a mid-course review by the SAB of the new data collection and curation effort is suggested rather than waiting until the draft CCL 5 is released.

2. INTRODUCTION

2.1. Background

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the EPA every five years to identify a list of unregulated contaminants (i.e., the Contaminant Candidate List or CCL) that occur or are anticipated to occur in public drinking water systems and may require regulation. Contaminants considered for listing include both chemical and microbial contaminants. The SDWA also specifies that the agency is to consult with the scientific community, including the Science Advisory Board, and provide notice and opportunity for public comment prior to publishing a final CCL. The CCL serves a dual purpose of identifying priorities for potential future regulation and to inform future research and monitoring needs.

A subsequent step in the drinking water protection program is the regulatory determination, in which the agency selects a minimum of five contaminants from the CCL to undergo a more detailed analysis of data on occurrence and health effects to determine whether or not to regulate. Contaminants that are candidates for regulation are those that may have an adverse health effect, occur in public water systems at levels of public health concern, and for which there is a meaningful opportunity for health risk reduction. The SDWA also requires the agency every five years to identify up to 30 unregulated contaminants to be monitored by public drinking water systems (the Unregulated Contaminant Monitoring Rule or UCMR) as a means of collecting data on their occurrence in drinking water; these data support the identification of contaminants to be listed on the CCL as well as regulatory determinations. And, finally, for those contaminants for which a decision is made to regulate, the agency develops a health-based Maximum Contaminant Level Goal (MCLG) and a National Primary Drinking Water Standard that includes a legally enforceable Maximum Contaminant Level (MCL) or a required treatment technique for a contaminant.

2.2. Charge to the SAB

On February 4, 2015, the EPA released its draft Fourth Contaminant Candidate List (CCL 4) for public comment and review by the SAB. The draft CCL 4 includes 100 chemicals or chemical groups and 12 microbial contaminants. In the EPA charge, the SAB was asked to comment on the clarity and transparency of the CCL 4 support documents in presenting the approach used to list contaminants on the CCL 4, additional data sources that the agency should consider, and contaminants that the SAB recommends be added or deleted from the draft contaminant list. The full charge is attached as Appendix A.

The SAB Drinking Water Committee (DWC) met on April 29-30, 2015, to hear briefings from the EPA on the draft CCL 4 (including the process used to evaluate contaminants nominated by the states, the water utility sector and other members of the public) and to develop advice for the EPA in response to the charge questions. A public teleconference meeting was held on August 3, 2015, to discuss the committee's draft report and to reach consensus on recommendations and conclusions. The committee's report was reviewed by the chartered SAB on September 24, 2015, and approved with clarifying edits.

3. RESPONSE TO THE CHARGE QUESTIONS

3.1. Clarity of the CCL 4 Support Documents

Charge Question 1. Please provide comment on whether or not the Draft CCL 4 support documents are clear and transparent in presenting the approach used to list contaminants on the CCL 4. If not, do you have any suggestions on how we could improve the clarity and transparency of the support documents?

The EPA used a multi-step process (Figure 1) to develop the draft CCL 4; the process includes three key elements:

- Identification of a broad universe of potential biological and chemical contaminants (CCL Universe);
- Application of screening criteria based on potential occurrence and human health relevance (preliminary CCL or PCCL); and
- Selection of priority contaminants based on more detailed occurrence and health effect data as well as expert judgment, public comment, and external advisory committees (draft and final CCL).

The following documents were provided to support the selection of the contaminants (100 chemicals or chemical groups and 12 microbial contaminants) on the draft CCL 4:

- Summary of Nominations for the Fourth Contaminant Candidate List (U.S.EPA 2015a)
- Data Sources for the Contaminant Candidate List 4 (U.S. EPA 2015b)
- Screening Document for the Draft PCCL 4 Nominated Contaminants (U.S. EPA 2015c)
- Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants (U.S. EPA 2015d)
- Final Contaminant Candidate List 3 Chemicals: Identifying the Universe (U.S. EPA 2009a)
- Final Contaminant Candidate List 3 Microbes: Identifying the Universe (U.S. EPA 2009b)

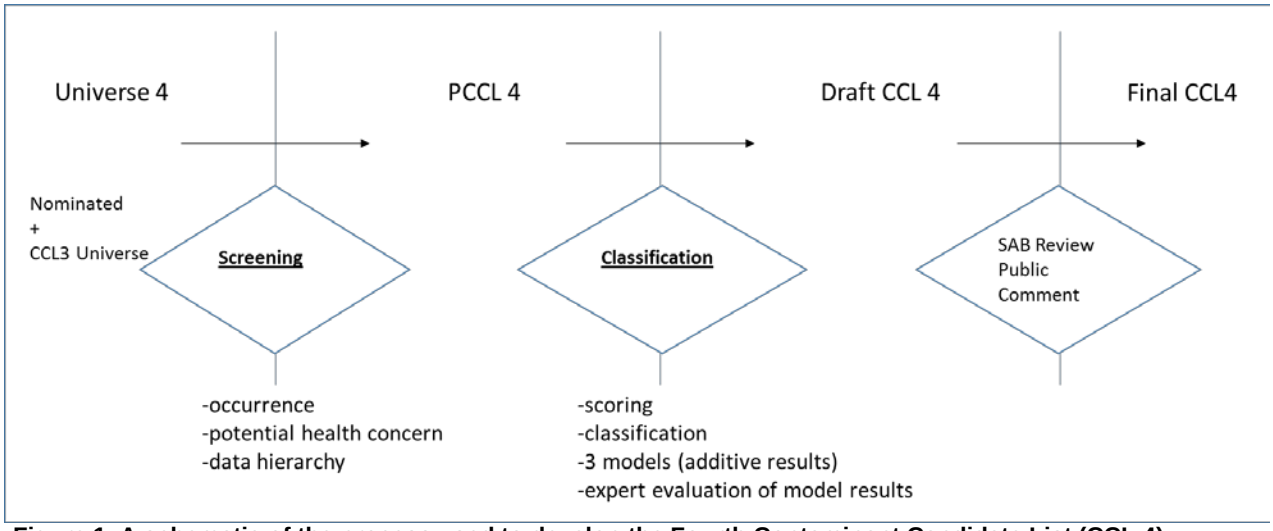

Figure 1. A schematic of the process used to develop the Fourth Contaminant Candidate List (CCL 4)

The SAB concluded that the general protocol used to evaluate candidate contaminants—from identifying the universe of chemicals through the final CCL 4—is well described. The transparency and

clarity of the procedure has improved since the CCL 3 was finalized. However, the description of the process still lacks sufficient detail to allow a reader to understand and follow the decisions made for individual contaminants at each step in the CCL's development. In addition, the CCL 4 support documents should better describe what the process is (and is not) intended to do. For example, the current process is not intended (and therefore is not designed) to allow for definitive determination of each contaminant's potential public health risk; a much more rigorous review is conducted as part of the regulatory determination process. Limitations in exposure/health data and quantifiable exposure/health indicators, as well as uncertainties in the role of drinking water as a contributor to health risk for some potentially relevant contaminants, should be discussed in the support documents.

It is not possible to fully evaluate the CCL 4 process without an understanding of how CCL contaminants would subsequently be evaluated for a regulatory determination. Therefore, additional detail in the CCL 4 support documents to describe the relationship of the CCL to the regulatory determination process would help clarify expectations of the CCL segment.

Specific actions to be taken that would improve the clarity and transparency of the CCL 4 process include:

1) Summarizing information in one place (preferably a well-designed summary table), including co-locating the CCL 4 and the CCL 3 and making appropriate use of hyperlinks;
2) Presenting the results of the CCL 4 screening and classification process in a manner that explicitly outlines the scoring schemes used (and their scientific basis) in applying the selection criteria;
3) Providing examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL 4;
4) Clearly describing and improving the process for removing contaminants from prior CCLs, where appropriate, when such lists serve in part as the basis for a new CCL; and
5) Including a summary of how CCL contaminants are further evaluated during the regulatory determination process to help clarify expectations for the CCL process.

These key points are discussed in more detail below.

3.1.1. Consolidate Summary Information for all CCL 4 Contaminants

Recommendation: Develop a summary table (with appropriate use of hyperlinks) to show, for all contaminants on the Preliminary CCL 4 (PCCL 4) (including those carried forward from the CCL 3), why each was or was not listed on the draft CCL 4, and the scoring values for each contaminant.

The SAB found that the Contaminant Information Sheets (U.S. EPA 2015d) for each contaminant were too cluttered with information, making it difficult for the reader to navigate through EPA's decision on whether to include a given contaminant on the draft CCL 4. While members may agree or disagree with decisions made for individual contaminants, the SAB found that it was very challenging to review the documents and make sense of how a nominated compound moved through the CCL 4 process or was maintained from the CCL 3.

In the *Summary of Nominations for the Fourth Contaminant Candidate List* (U.S. EPA 2015a), a brief review of the overall process, including the nomination process, is provided. This summary document is

clear from the standpoint of providing a list of what was nominated and then included/excluded on the draft CCL 4. However, it is not transparent to the reader why many of the contaminants were included while others were excluded. The summary document is missing the scoring values used to rate these contaminants.

Some information is provided only in CCL 3 documentation, which was not updated for CCL 4. The document *Summary of Nominations for the Fourth Contaminant Candidate List* (U.S. EPA 2015a) provides a comprehensive overview of the nominated contaminants but not the contaminants retained from the CCL 3. Appendix 1: Screening data for the Nominated Chemicals in the CCL 4 Universe from *Screening Document for the Draft PCCL 4 Nominated Contaminants* (U.S. EPA 2015c) likewise provides information on new contaminants but not those retained from CCL 3 (unless they were re-nominated). It would be useful to provide information on the screening process and its results for all potential contaminants, not just the new nominations. Such a comprehensive review would be useful for evaluating the entire set of contaminants included in the draft CCL 4. It would also be helpful for this document to provide a description of the weighting scheme used in the contaminant-scoring model equation, perhaps with an application to an example contaminant.

In *Data Sources for the Contaminant Candidate List 4* (U.S. EPA 2015b), the EPA lists all reports or databases used to characterize each contaminant. EPA provided the assessment factors (relevance, completeness, redundancy, and retrievability) used to evaluate each source's suitability for analyzing the CCL 4 contaminants. The document is clear. However, it is not transparent as to whether other data sources were evaluated and excluded based on the failure to meet the requirements of the assessment factors. Some of the sources did not meet the retrievability requirement but were still included as a source. Was there a rubric used to assess these sources? Does inclusion mean that it had to meet at least one or two of the assessment factors? The committee could not find the criteria that would cause a source to be excluded in this document. Further, there is a wealth of knowledge in the literature on contaminants on the CCL 3 and the CCL 4. The SAB DWC was informed by the EPA that the literature was mined to include peer reviewed journal data in the EPA's data source for some contaminants. The SAB recommends that this literature review and data mining process be a mandatory part of the data search process for the CCL.

The SAB recommends that the EPA develop a single table that builds from the CCL 3 and includes all draft CCL 4 contaminants. This table should include scoring values, a rating of each compound, EPA's recommendation, and a brief note regarding the reasons (criteria employed) to include a compound on the draft CCL 4. (It would also be helpful to have a similar table, or another portion of the same table, listing nominated contaminants and other contaminants of significant interest to the general public and the reasons they were excluded from the draft CCL 4.) A brief summary of the table contents and the results of the CCL 4 process, with appropriate hyperlinks to more detailed information, would help the reader put everything into perspective.

3.1.2. Scoring Schemes and Selection Criteria: Chemical Contaminants

Recommendation: **Present the results of the CCL 4 screening and classification process in a manner that explicitly outlines the scoring schemes (and their scientific rationale) used in applying the selection criteria**.

The *Screening Document for the Draft PCCL 4 Nominated Contaminants* (U.S. EPA 2015c) provides an explanation of how the EPA determines chemical contaminant potency (toxicity) and occurrence

(concentration, frequency). Exhibits 2 and 3 define the level of potency (in the form of toxicity categories based on a quantitative or qualitative data element) while the level of occurrence is defined from different data sources, with a preferred hierarchy when multiple data sources are available (finished water=ambient water>total environmental releases>pesticide application rates>production volume). The document also states that the EPA considered chemicals with descriptive data based on the likelihood of occurrence in drinking water. This statement, however, is quite vague. Furthermore, in this screening document, the SAB did not see how data variability (in terms of the number of data points and the distribution of values for a given contaminant) was taken into account in determining both potency and occurrence.

Once screening has been performed (i.e., determination for inclusion on the Preliminary CCl or PCCL), chemical contaminants from the PCCL are selected for inclusion on the CCL using a classification process summarized in the *Contaminant Information Sheets (CIS) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants* (U.S. EPA 2015d). This is accomplished using additive results from three classification models—Artificial Neural Network (ANN), Classification Tree with Linear Nodes (QUEST) and Linear Regression—and a scoring system involving attribute scores (Potency, Severity, Magnitude, and Prevalence as metrics), health reference level (HRL), and HRL/concentration ratio. The combined model results, expressed in four classification decision categories (List, List?, Not List?, Not List) and the calculated HRL/concentration ratios then were evaluated by an EPA team of experts. Tables are produced for each contaminant listing these evaluation scores along with other health effects and occurrence-related data. In the attribute score, the first two criteria are associated with toxicity and the latter two with occurrence. Each category is rated on a 10-point scale.

The SAB recognizes that the classification models, calibrated with a training set, were applied in evaluating whether a chemical should be listed on the CCL 4. The criteria used to evaluate and apply the scores generated by these models should be summarized in the CCL 4 documents. Although detailed information about the models is provided in the *Final Contaminant Candidate List 3 Chemicals: Classification of the PCCL to CCL* (U.S. EPA 2009c), it is not clear whether the models were retrained with new or updated information on contaminants carried over from the CCL 3 or on new contaminants nominated during the CCL 4 process. More fundamentally, as described below, there was no information on whether sensitivity analyses were performed to assess whether alternative approaches to attribute scoring impacted model results. An explanation of the artificial neural network should be provided along with a description of the process employed and how it was validated.

In addition to the attribute score modeling approach, a second approach utilized the HRL/concentration ratio, i.e., the concentration in drinking water associated with a health-based risk level divided by an anticipated or measured concentration in drinking water. When the ratio was <10, the compound was included in the CCL. Again, the SAB recommends that the criteria to develop these numbers should be specified and clarified. It appears from the documents that the second (ratio-based) approach is followed and trumps the results from the scoring models. For contaminants that are close to this boundary and have significant variability in the data, are they excluded or included? Is a combination of model outcomes and HRL/concentration ratios used for those contaminants that have significant variability in the HRL or concentration data? Again, the EPA should provide some explanation on how data variability is treated and used in inclusion/exclusion decision points. An explicit description of how the different data used for classification (the summary of the three models and the HRL/concentration ratio) were used to make contaminant determinations, how these summary measures were prioritized, and how

(or if) data uncertainty was incorporated into this process would be helpful in the CCL 4 support documents.

Recommendation: Include a discussion of the effect of data variability and model sensitivity on the results of the contaminant classification process.

As noted above, there are four attributes that the models used for classification of chemical contaminants: potency, severity, magnitude and prevalence. The quality and nature of the data used to assign scores to the attributes varied widely across chemical contaminants and it was not clear how or if the agency accounted for this data variability. Further, the basis for assignment of attribute scores was often unclear. For example, it was not clear what cut-offs were used to merit a rating of 10 for prevalence. The four attribute scores formed the basis for model classifications; thus it is possible that different attribute scoring criteria might have changed some contaminant classifications or rankings. However, there was no discussion of how sensitive model results were to the attribute scoring schemes. Similar concerns were raised regarding the sensitivity of pathogen listing choices to the scoring and weighting assumptions (see Section 3.1.3).

3.1.3. Scoring Schemes and Selection Criteria: Pathogens

Recommendation: Clarify the scientific rationale for the approach used to prioritize pathogens for inclusion in the CCL.

The EPA document, *Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process* (U.S. EPA 2009d), describes the process upon which the CCL 4 was also based to move microorganisms to the CCL. In deriving the draft CCL from the PCCL, a number of scoring systems were used for which the scientific rationale was unclear. Clarification of the scientific rationale is needed. Some examples of the lack of clarity in the process are described below.

Waterborne Disease Outbreaks

- One part of the process of refining the PCCL to a draft CCL is to assign a score to each pathogen based on its association with waterborne disease, using the Waterborne Disease Outbreak (WBDO) Scoring Protocol. Using this protocol, it is clear how each pathogen is assigned a score. It is not clear how the scoring protocol was developed. For example, what is the rationale for giving a score of 4 to an organism that has "caused at least one documented WBDO in the U.S. between 1990 and 2004" and a score of 3 to an organism that has "caused documented WBDOs at any time in the U.S."? How was it determined that these two situations warranted a difference of one unit in a scoring system of five units? Was a sensitivity analysis conducted to quantify the effects of the assignment of the numerical values to each of these conditions?

- What is the rationale for assigning the same score (a 5) to a microorganism that has caused two documented WBDOs in the U.S. surveillance between 1990 and 2004 as to a microorganism that has caused dozens of such events over the same period?

- Why is no consideration given to the number of people who were affected by the WBDOs? Two outbreaks involving four people would be assigned the same score as two outbreaks involving one million people.

- A number of pathogens are clearly a public health problem in water but are addressed by existing drinking water regulations, such as the Surface Water Treatment Rule. For example, health risks

associated with vegetative bacteria such as *E. coli, Campylobacter, Salmonella* and *Shigella* in drinking water are reduced by measures implemented by water systems to reduce the occurrence of unsafe levels of viruses, *Legionella*, and *Giardia lamblia*. Thus, such vegetative bacteria, although important pathogens, do not merit high prioritization on any CCL.

Occurrence

- A second component of the process is to assign the pathogens a score based on occurrence in water; the scores range between 1 and 3. Again, what is the rationale for the specific numbers chosen for each condition? Has a sensitivity analysis been conducted to assess the effects of alternative scoring protocols on pathogen prioritization?

Health Effects

- The third component of the scoring process is the assignment of a health effects score for each pathogen; scores range between 1 and 7. The rationale for the specific outcome categories and associated scores is not provided. For example, why is the outcome, "Does the illness require short term hospitalization (< week)?" given a score of 4 and the outcome, "Does the illness result in long-term or permanent dysfunction or disability (i.e., sequelae)?" given a score of 5? Has a sensitivity analysis been conducted to assess the effects of alternative scoring protocols on pathogen prioritization?

- When determining the health effects score, separate scores are calculated for the "general" population and "sensitive" populations. What is the rationale for giving each of these groups an equivalent contribution to the health effects score? This is especially significant in view of the EPA's statement that, "More importantly, nearly all pathogens have very high health effect scores for the markedly immunosuppressed individuals; therefore there is little differentiation between pathogens based on health effects for the immunosuppressed subpopulation" (p. 9, U.S. EPA 2009d).

Composite Score

- The document clearly describes how the final score for the pathogens is calculated. However, no support for the following statement is provided: "Finally, EPA normalizes the Health Effects and WBDO/Occurrence score because the Agency believes they are of equal importance" (p. 11, U.S. EPA 2009d). What is the basis for this belief? Has an analysis been performed to assess the impacts of normalizing these two scores?

- While the process for assigning scores is clearly described (although the rationale for the scoring schemes is not adequately described, as discussed above), the process for determining which pathogens on the PCCL were placed on the draft CCL is not clearly described. The document states:

> The 29 PCCL pathogens are ranked according to an equal weighting of their summed scores for normalized health effects and the higher of the individual scores for WBDO and occurrence in drinking water. EPA believes this ranking indicates the most important pathogens to consider for the CCL 3. To determine which of the 29 PCCL pathogens should be the highest priority for EPA's drinking water program and included on the CCL 3, the Agency considered both scientific and policy factors. The factors included the PCCL scores for WBDO, occurrence, and health effects; comments and recommendations from the various expert panels; the specific intent of SDWA; and the need to focus Agency resources on pathogens to provide the most effective

> opportunities to advance public health protection. After consideration of these factors, EPA has determined that the CCL 3 will include the 12 highest ranked pathogens. (p. 13, U.S. EPA 2009d)

Based on this statement, it is not clear how strongly the scientific data, compared to the other factors, impacted the final decision.

- The EPA also made the following statement:

> Additionally, there are a few "natural" break points in the ranked scores for the 29 pathogens, with the top 12 forming the highest ranked group of pathogens. EPA believes that the overall rankings strongly reflect the best available scientific data and high quality expert input employed in the CCL selection process, and therefore should be important factors in helping to identify the top priority pathogens for the draft CCL 3. (p. 13, U.S. EPA 2009d)

It is not clear how this assessment was made, as the "break point" between the top 12 pathogens (0.5 units) and the next highest pathogen is equivalent to the "break point" between the top six pathogens and the seventh-highest pathogen. Even larger gaps (>1 unit) are seen between pathogens farther down on the list.

These decisions have a tremendous impact on the CCL but may or may not result in an optimal listing selection. A more robust and better justified process is needed—the sensitivity of listing choices to the scoring and weighting assumptions needs to be explicitly described.

3.1.4. Illustrating the Process with Example Contaminants

Recommendation: Provide examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL 4.

The SAB concludes that a clearer understanding of the CCL selection process would be facilitated by a limited number of examples tracking selected contaminants through the process from Universe to PCCL to CCL. These examples should include both microbial and chemical contaminants, and contaminants that made the list as well as contaminants excluded from the list using criteria employed by the EPA. Since there are two toxicity/potency criteria used to decide whether to include a chemical contaminant on the draft CCL (i.e., the value from the scoring model and the HRL/concentration value), two sets of examples should be provided for the chemical contaminants. Therefore a total of six examples should be included: (1) a microbial contaminant that made the list, (2) a microbial contaminant that did NOT make the list, (3) a chemical contaminant that made the list based on the scoring model, (4) a chemical contaminant that made the list based on the HRL/concentration value, (5) a chemical contaminant that did NOT make the list based on the scoring model, and (6) a chemical contaminant that did NOT make the list based on the HRL/concentration model.

3.1.5. Removing Contaminants from Prior CCLs

Recommendation: **Clearly describe and improve the process for removing contaminants from prior CCLs, where appropriate, when such lists serve in part as the basis for a new CCL.**

Clearly describing the "off-ramp" process for removing contaminants from the carry-over list (CCL 3 in this case) would make the process more clear and transparent. The SAB found the removal process difficult to identify. Aside from contaminants for which a regulatory determination (either positive or

negative) is made, the current process for updating and refining the CCL seems to rely primarily on comments and data submitted by the public and expert review by the SAB. If that is indeed the case, a more robust method that provides a clear process (and includes criteria) for removing contaminants from the carry-over CCL should be explored. Such a process will help control the size of future CCLs and focus efforts on the most appropriate contaminants.

3.1.6. Summarizing Contaminant Review for Regulatory Determination

After the completion of the CCL, a more rigorous review of contaminant occurrence and health effects data, and availability of analytical methods for monitoring is undertaken as part of the regulatory determination process. The CCL support documents should more clearly explain the nature and extent of the contaminant evaluation that occurs in these subsequent steps to provide critical context for the CCL; i.e., to allow readers to understand what can or should be accomplished with the CCL process.

3.1.7. Conclusions

Overall, the screening document and tables are difficult to follow. There is no clear and transparent way to determine why a specific contaminant is included on or excluded from the CCL 4 by reading the summary tables, which do not include scoring metrics. The models used to generate scoring metrics should be more clearly described, and it is also not clear whether the scoring metrics were revised with new information on the nominated contaminants and on contaminants carried over from the CCL 3. This is important because these metrics lead to a ranking for each contaminant and, eventually, to a decision to include or not include a contaminant on the CCL 4.

Finally, the SAB notes that many of the above comments are similar to those made by the SAB (U.S. EPA Science Advisory Board 2009) when it reviewed the draft CCL 3. Examples from the 2009 SAB report include:

> The Committee concludes that the documentation, i.e., the FRN, is not transparent. Committee members with decades of experience reviewing and analyzing EPA regulatory documents could not follow specific contaminants through the process as presented in the FRN. The document is not clear. Interpretation by several Committee members of the published CCL 3 processes differed and were only clarified after discussion with EPA staff.
>
> Committee members who tried to follow the decision-making process for one or more contaminants could not do so.

It is unclear why changes to the CCL 4 process were not made to address these concerns. Are there barriers in the CCL process that did not allow effective changes to be made? If barriers to the CCL process exist, then these barriers should be addressed prior to the development of CCL5 so that the process can undergo significant and meaningful improvements. A response by the EPA to the SAB's specific recommendations would aid in SAB reviews of future CCLs.

3.2. Additional Data Sources

Charge Question 2. Please identify any additional peer-reviewed information or data collected in accordance with accepted methods which the agency should consider for CCL 4. Please see the Data Sources support document and CCL 3 Universe support document for a list of data sources that EPA used to evaluate contaminants for the Draft CCL 4.

There are a number of potential limitations to the data used for the CCL process. These include: (1) available exposure and/or health data may be old and not necessarily reflective of current conditions; (2) quantifiable exposure and/or health indicators are not available for a large number of contaminants; (3) the contribution of water to human exposure risk is uncertain for a number of potentially relevant contaminants; and (4) the timing of the UCMR data collection does not align with the CCL process. These data limitations conspire to give certain types of data more importance in the process (e.g., WBDO information, carcinogenicity risk) which may or may not be optimal for many contaminants. Thus expanding and "modernizing" data sources used for the CCL process is an important undertaking.

The SAB is concerned that the agency is relying too heavily on the public to nominate new candidate contaminants and to provide new data for previously listed contaminants. (At the April 2015 DWC meeting, the EPA presenters indicated that the agency did not update data for contaminants that were carried forward from the CCL 3, focusing instead on newly nominated contaminants.) The EPA should consider drafting a strategy to proactively reach out to large utilities, relevant state agencies, and possibly other groups to obtain occurrence information that may be useful in identifying potential candidates for the CCL. Among others, this includes reaching out to the Water Reuse Association, the Water Research Foundation, the American Water Works Association, and the Water Environment Research Foundation for occurrence data, with an emphasis on contaminants related to direct and indirect potable water reuse.

The agency also should refer to any Unregulated Contaminant Monitoring Rule (UCMR) data that have already been publicly released. Currently this includes portions of the UCMR 3. In evaluating UCMR data, it is important to recognize that the data reflect the quality of finished water rather than raw water. This is in contrast to many of the other data which are specific to (or at least include) raw water. For example, UCMR data are inherently a good resource to evaluate the potential occurrence of disinfection byproducts. In contrast, UCMR data likely would not be a good resource to evaluate if a groundwater contaminant is problematic for small water systems that utilize groundwater because many such systems do not treat their water and or just add disinfection and, therefore, contaminants usually removed by treatment might occur in these systems.

For the CCL process, the EPA should include a method to examine data on temporal changes in chemical production and use. This includes chemicals that are no longer in use or whose use has decreased over time. This scan for changes in production and use also should be done to identify contaminants for which data on occurrence are limited, but for which production and use data suggest that occurrence may become a greater issue in the future. This process should include an evaluation of the chemical properties as they relate to a chemical's potential to become a water contaminant (e.g., vapor pressure, half-life).

Although the SAB understands the agency's focus in the CCL process on data sources formatted for automated retrieval, the EPA should consider performing searches of the peer reviewed literature to identify new and emerging contaminants (e.g., recently developed pesticides and pharmaceuticals, recently discovered disinfection byproducts or leachates from plumbing materials) that may be

appropriate for the CCL. Contaminants selected for this review could be based on expert opinions, including from scientists in EPA's Office of Research and Development. It should be noted that this is simply a refinement to the current process, and is not meant to replace the more quantitative processes already in place.

The SAB recommends that the EPA refer to the National Health and Nutrition Examination Survey's (NHANES) National Report on Human Exposure to Environmental Chemicals for potential data related to occurrence. Most of these data will be urinary or blood levels of chemical contaminants, which do not describe the route of exposure. Assuming there is not strong evidence that exposure is coming from another (non-ingestion) route, information on biologic levels could support the inclusion or prioritization of a contaminant on the CCL. Again, this is recommended as a refinement to the current process, and is not meant to replace the processes already in place.

If, given the time constraints associated with the CCL 4, it is not practical for the EPA to consult the additional data sources recommended herein, or to implement other recommendations for expanded data collection, the recommended sources and methods should be taken into consideration in developing future CCLs.

3.3. Contaminants That Do Not Merit Listing or That Should Be Added

Charge Question 3. Based on your expertise and experience, are there any contaminants currently on the Draft CCL 4 that you think do not merit inclusion on the list? Please provide the basis for your conclusions and any data or references.

Charge Question 4. Based on your expertise and experience, are there any contaminants which are currently not on the Draft CCL 4 that should be listed? Please provide the basis for your conclusions and any data or references.

3.3.1. Pathogens and Toxins

In responding to Charge Questions 3 and 4 with respect to pathogens, the SAB takes the approach of recommending general principles to be followed by the agency in deciding what to include in or exclude from CCL 4. These principles are motivated by two factors: (1) the overarching importance of public health as the baseline for selection or exclusion of microorganisms in the CCL and (2) the role of the CCL as a key initial step required for subsequent development of effective regulatory, monitoring, and research decisions. Specific pathogens are noted as exemplars of contaminants that would be included or excluded by application of the principles.

Recommendation: Reconsider screening criteria that may exclude potentially significant microbial hazards.

Some of the 12 exclusionary criteria for screening the Universe of possible pathogens to a PCCL (described in the *Screening Document for the Draft PCCL 4 Nominated Contaminants*, U.S. EPA 2015c) may exclude important pathogens. In addition, excluding microorganisms based on meeting only one criterion may lead to an incomplete CCL due to insufficient data for some pathogens. The SAB recommends that the following screening criteria be reconsidered as they may lead to exclusion of potentially significant microbial hazards:

- Excluding all anaerobes (criterion #1) may exclude some relevant pathogens. For example, vegetative anaerobes will not survive in water but some spore-forming microorganisms can

survive in water and, therefore, should be considered among potential CCL pathogens. For example, *Clostridium difficile* is a spore-forming anaerobe that is a potential waterborne pathogen, but it has been excluded from CCL consideration because it is an anaerobe.

- Exclusion of pathogens that are not endemic to North America (criterion #10) may be too restrictive. Given the increasing globalization of commerce and resulting potential for contaminants to be spread across the globe, non-endemic pathogens can be present in U.S. waters.

- Exclusion of pathogens for which drinking water-related transmission has not been implicated (criterion #8) or that are naturally occurring in the environment but without evidence associating the pathogen with drinking water-related disease (criterion #9) may be too restrictive. For example, although *Pseudomonas aeruginosa* is most often considered a nosocomial (i.e., hospital-acquired) pathogen, they can adapt to and grow in a variety of environments, including water. This microbe is associated with biofilm formation, and may thrive within distribution systems, analogous to *Legionella*.

Recommendation: Include on the CCL pathogens of emerging concern (such as those found in biofilms and water distribution systems) for which there are not well-established and effective treatments.

Decisions for inclusion on the CCL should incorporate pathogens of emerging concern for which we do not have well-established and effective treatments. These include microorganisms such as *Legionella* and bacteria in the *Mycobacterium avium* complex (MAC) that can be found in biofilms and water distribution systems, which are under EPA jurisdiction.

Recommendation: Research and monitoring priorities should focus on contaminants likely to have the broadest public health impact, including both pathogens that cause widespread effects and those that are rare but fatal.

Even though prioritization of contaminants occurs during the regulatory determination process, informed prioritization (that addresses uncertainty) must occur at the CCL stage to optimize the utility of the listing for subsequent research and monitoring, as well as for regulatory decision-making. For example, research priorities should focus on contaminants likely to have the broadest public health impact. The SAB recognizes that it is important to understand rare pathogens for which health impacts are particularly deleterious. For example, *Naegleria fowleri* is a pathogen with rare occurrence but for which exposure (generally via nasal entry from swimming/diving in contaminated water) can cause a fatal central nervous system infection. Understanding this pathogen is important because of its devastating toxicity even though, because of its rarity, its impact on overall population health is relatively limited. However, a focus of research priorities on those pathogens most relevant to overall population health should be given a high priority. These can include pathogens, such as noroviruses, with only modest health effects but sufficient prevalence to have substantial public health impact by causing a large proportion of common illnesses (e.g., diarrheal disease) in the population.

3.3.2. Chemical Contaminants

The SAB agrees with the overall conclusions in the previous SAB review of the CCL 3. As stated in the SAB's January 29, 2009, letter to Administrator Jackson, "With regard to providing any data that may suggest that contaminants which are currently on (or not on) the draft CCL 3 list, and should not be listed (or should be listed), the list is too large for the committee to complete a full review of these issues in the time allotted."

A complete answer to this charge question would require that the SAB review all of the scientific literature pertaining to chemical occurrence in drinking water/drinking water sources between 2009 and 2015; time constraints make such a review impossible. However, as noted in section 3.2, the SAB recommends that the agency make greater use of the wealth of information in peer-reviewed and published literature regarding the chemicals on the draft CCL 4. Rather than commenting on each contaminant on the draft CCL 4, the SAB comments on guiding principles for listing chemicals on the CCL, with specific chemicals noted as exemplars of contaminants that would be included or excluded by application of the principles. Charge questions for future CCL reviews might better be focused on obtaining input on the prioritization methodology and processes in place to add or remove contaminants from the list.

At each of its public meetings for this advisory activity, the DWC heard and considered public comments regarding specific contaminants on the draft CCL 4. Similar public comments were provided to the chartered SAB at its meeting to review the DWC draft report. Public commenters urged the agency to consider physical-chemical properties of candidate contaminants, including their reactivity in water, as well as the most relevant toxicity information. Commenters suggested that the half-life of some listed contaminants (e.g., ethylene oxide, ethylene glycol, toluene diisocyanate) was too short to pose a health risk. Other commenters noted that the contaminant list was too long to guide priorities for addressing drinking water concerns and that the most recent data were not used for some contaminants. After considerable discussion, the DWC concluded that it lacked the time and resources to independently evaluate each contaminant on the CCL 4 and would not attempt to endorse or refute the commenters' concerns about specific contaminants. The SAB agrees with the public commenters that physical-chemical properties of contaminants should be considered, but notes that contaminants with a half-life in drinking water sources of days to weeks may still pose a public health concern. Regarding the number of contaminants to include on the CCL, the SAB discussed this question in response to public comments but concluded that there is no *a priori* "correct" size for the list since including too many contaminants would dilute the effectiveness of the CCL for setting priorities but too short a list might not encourage data collection on some relevant contaminants.

Recommendation: The EPA should adopt a prioritization strategy so that "legacy" chemicals are still captured but high priority emerging chemicals are easily distinguished and highlighted.

The draft CCL 4 currently does not rank or prioritize the chemicals. A prioritized grouping (e.g., High, Medium and Low priority) of all the chemical contaminants would bring greater transparency to the process and also help the public and researchers focus their efforts to provide the most useful input for future decision-making.

Recommendation: The EPA should consider the chemicals being monitored in finished drinking water through the unregulated contaminant monitoring program (UCMR) as a guide for removing or adding contaminants to the list.

For instance, if the frequency of occurrence of a particular chemical is consistently very low in finished drinking water, the agency may consider removing it unless it can be demonstrated that there is a common thread to the occurrence data (e.g., geographic, or at utilities using specific treatment technologies). The UCMR data should be reviewed and incorporated into agency decision-making as soon as the data are publicly posted, rather than only after the entire UCMR dataset is complete.

Estrogen hormones provide an example for how UCMR data can inform the CCL 4. For instance, for the estrogen steroid hormones equilin and estrone, not one sample in the 7,169 evaluated in UCMR3 had a positive detection at 4 and 2 ng/L, respectively. Estradiol, ethinylestradiol, and estriol all had sub-ng/L method reporting levels, yet were only detected in 3, 3, and 1, respectively, out of 7,169 tests conducted. Only one hit for estradiol appears to exceed the health reference level; however, this HRL is taken from studies in rodents (Highman et al. 1980) in which dose response is not clear and the shorter term study was used to calculate the cancer risk despite the availability of longer term exposure studies. Thus, prudent use of UCMR data could potentially eliminate these estrogen hormones from the CCL, or tag them as low priority for listing.

Recommendation: The SAB encourages the EPA to develop more health advisories for Health Advisories for contaminants on the CCL.

In light of the growing number of contaminants on the CCL and the time required to move a contaminant through regulatory determination and, where appropriate, promulgate a National Primary Drinking Water Regulation, the SAB encourages the EPA to develop more health advisories for contaminants identified on the CCL. Particularly, the EPA should consider formulating health advisories for compounds whose occurrence is known to be sporadic but whose HRL/concentration ratios are at a level of concern. This approach would allow the process to protect against contaminants that have not yet merited a positive regulatory determination, but may still cause health concerns.

Recommendation: The EPA should evaluate additional disinfection byproducts (DBPs) for inclusion and should consider the feasibility of grouping contaminants for listing on the CCL.

For instance, it might be useful to consider halonitromethanes as a group rather than as individual chemicals. In addition, the SAB recommends that the EPA evaluate additional DBPs for inclusion, especially iodinated haloacetic acids, other classes of nitrogenous DBPs, and other emerging DBPs considering their potential human toxicity and frequency of occurrence in public drinking water systems. Chloropicrin was included in PCCL 3 but not in CCL 3, and the rationale for this decision was not obvious. In light of the *in vitro* genotoxicity and cytotoxicity of halonitromethanes, it would be prudent to keep chloropicrin on the CCL so that occurrence data on this chemical can continue to be collected.

Example references on DBPs for the EPA to consider include: Chen et al. (2002); Monarca et al. (2002); Richardson (2003); Plewa et al. (2004a, 2004b, 2008); Krasner et al. (2006); and Richardson et al. (2007, 2008, 2014).

4. RECOMMENDATIONS FOR FUTURE CONTAMINANT CANDIDATE LISTS

Recommendation: The EPA should expand its efforts to identify relevant data to guide the development of future CCLs and build a knowledge base that brings together contaminant data, weighting schemes, and documentation and evaluation of the methods used to develop the CCL.

The SAB understands that the development of the third iteration of the CCL (CCL 3) was based on a rigorous scientific process with input from the National Academy of Sciences (NAS)/National Research Council (NRC) Panels as well as the EPA's National Drinking Water Advisory Council (NDWAC) and the SAB. This level of outside review is helpful in ensuring that the CCL process is based on the best science. However, the transparency and efficiency of the process of developing CCLs would be further improved by putting in place a system that integrates data collection and curation (including data management and maintenance) and uses a broader range of the best available data. Optimizing this system to improve upon currently used data resources is important (see Section 3.2 for a summary of current data limitations). For instance, the EPA should make use of occurrence data from the UCMR even if the final data set is not complete. If the EPA has issued interim reports on the UCMR publically, then those data should be incorporated into the CCL dossiers. A knowledge base of contaminants that includes occurrence and hazard data, methods used to develop these data, and contaminant characterization should be developed. This knowledge base would serve as the basis for following the universe of contaminants considered in the CCL process. Through real-time application of the expert system used to weight criteria for CCL determinations (e.g., the artificial neural network), users would be able to view a continuously updated dossier list.

A user interface that curates data entered to the system from registered users would allow for broad-based population of the knowledge base. Data curation addresses management of data through its lifecycle from data discovery, entry, retrieval, quality verification, and interpretation over time. At a minimum, the options for uploading references to peer-reviewed publications relevant to each contaminant should be included. The data base might also be used to determine grouping of materials that allow for read-across of candidate contaminants.

The SAB also recommends that the EPA utilize data from *in vitro* screening of chemicals, particularly those processed through the NIH Toxicology in the 21st Century Program (Tox21) and EPA's ToxCast program.

Current bio-informatics technology has dramatically expanded the universe of microbes that can be characterized, and our capacity to identify microbes is likely to continue to grow. Development of information systems technology that can manage this wealth of data will be important to the effective selection of pathogens for listing on future CCLs.

The SAB also recommends that the modeling used in the CCL process become more transparent and the algorithm used be better explained. Suggestions from the previous SAB review (of the CCL 3) (U.S. EPA Science Advisory Board 2009) are similar to the questions raised in the current review, and the SAB suggests that the EPA provide responses for how they addressed previous comments from the SAB to better avoid redundancy.

The knowledge based proposed would automate many of the activities involved in the generation of a CCL at each generation, including improved data discovery and expanded data availability, broader

solicitation of information from the scientific community and stakeholders, and data interpretation such as that done using the expert system used to generate the current CCL.

Modernizing data sources and data infrastructure is critical to an effective CCL development process and this modernization should be a priority as it will greatly improve efficiency and transparency. If the agency implements such a system, a mid-course review by the SAB of the new data collection and curation effort is suggested rather than waiting until the draft CCL 5 is released.

Summary of Other Recommendations

Throughout the report, the SAB recommends enhancements to the data collection and analysis that support the CCL. Many of the recommendations can be implemented, at least partially, for the CCL 4. Others will require additional time and resources and likely will be implemented for future CCLs. A summary of key recommendations includes the following:

- Develop a proactive outreach strategy to seek occurrence data from a broad range of sources;
- Reconsider the timings of the UCMR and CCL so that the UCMR can serve as a data source for the CCL;
- Summarize information in one place (preferably a well-designed summary table), including co-locating the current and immediately preceding CCLs and making appropriate use of hyperlinks;
- Present the results of the CCL screening and classification process in a manner that explicitly outlines the scoring schemes used (and their scientific rationale) in applying the selection criteria;
- Provide examples for both microbial and chemical contaminants that display the process of how contaminants were included on or eliminated from the draft CCL;
- Clearly describe and improve the process for removing contaminants from prior CCLs, where appropriate, when such lists serve as the basis for a new CCL; and
- Include a summary of how CCL contaminants are further evaluated during the regulatory determination process.

REFERENCES

Chen, P.H., S.D. Richardson, S.W. Krasner, G. Majetich and G.L. Glish. 2002. Hydrogen Abstraction and Decomposition of Bromopicrin and Other Trihalogenated Disinfection Byproducts by GC/MS. *Environ. Sci. Technol*. 36: 3362-3371.

Highman, B., D.L. Greenman, M.J. Norvell, J. Farmer and T.E. Shellenberger. 1980. Neoplastic and Preneoplastic Lesions Induced in Female C3H Mice by Diets Containing Diethylstilbestrol or 17β-Estradiol. *J. Envir. Pathol. Toxicol*. 4: 81-95.

Krasner, S.W. et al. 2006. Occurrence of a new generation of disinfection byproducts. *Environ. Sci. Technol*. 40: 7175-7185, doi:10.1021/es060353j.

Monarca, S. et al. 2002. Mutagenicity and disinfection by-products in surface drinking water disinfected with peracetic acid. *Environ. Toxicol. Chem*. 21: 309-318.

Plewa, M. J. et al. 2004. Chemical and biological characterization of newly discovered iodoacid drinking water disinfection byproducts. *Environ. Sci. Technol*. 38: 4713-4722.

Plewa, M.J., E.D. Wagner, P.R. Jazwierska, D. Susan, P.H. Chen and A.B. McKague. 2004. Halonitromethane Drinking Water Disinfection Byproducts: Chemical Characterization and Mammalian Cell Cytotoxicity and Genotoxicity. *Environ. Sci. Technol.* 38: 62-68.

Plewa, M.J. et al. 2008. Occurrence, synthesis, and mammalian cell cytotoxicity and genotoxicity of haloacetamides: An emerging class of nitrogenous drinking water disinfection byproducts. *Environ. Sci. Technol*. 42: 955-961, doi:10.1021/es071754h.

Richardson, S.D. 2003. Disinfection by-products and other emerging contaminants in drinking water. *Trac-Trends Anal. Chem*. 22: 666-684.

Richardson, S.D. and T.A. Ternes. 2014. Water Analysis: Emerging Contaminants and Current Issues. *Anal. Chem*. 86: 2813-2848, doi:10.1021/ac500508t.

Richardson, S.D., M.J. Plewa, E.D. Wagner, R. Schoeny amd D.M. DeMarini. 2007. Occurrence, genotoxicity, and carcinogenicity of regulated and emerging disinfection by-products in drinking water: a review and roadmap for research. *Reviews in Mutation Research* 636: 178-242.

Richardson, S.D. et al. 2008. Occurrence and mammalian cell toxicity of iodinated disinfection byproducts in drinking water. *Environ. Sci. Technol*. 42: 8330–8338, doi: 10.1021/es801169k.

U.S. EPA (U.S. Environmental Protection Agency). 2009a. Final Contaminant Candidate List 3 Chemicals: Identifying the Universe. Office of Water (4607M). EPA 815-R-09-006. August 2009.

U.S. EPA (U.S. Environmental Protection Agency). 2009b. Final Candidate Contaminant List 3 Microbes: Identifying the Universe. Office of Water (4607M). EPA 815-R-09-004. August 2009.

U.S. EPA (U.S. Environmental Protection Agency). 2009c. Final Contaminant Candidate List 3 Chemicals: Classification of the PCCL to CCL. Office of Water (4607M). EPA 815-R-09-008. August 2009.

U.S. EPA (U.S. Environmental Protection Agency). 2009d. Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process. Office of Water (4607M). EPA 815-R-09-009. August 2009.

U.S. EPA (U.S. Environmental Protection Agency). 2015a. Summary of Nominations for the Fourth Contaminant Candidate List. Office of Water (4607M) EPA 815-R-15-001 January 2015.

U.S. EPA (U.S. Environmental Protection Agency). 2015b. Data Sources for the Contaminant Candidate List 4. Office of Water (4607M) EPA 815-R-15-004 January 2015.

U.S. EPA (U.S. Environmental Protection Agency). 2015c. Screening Document for the Draft PCCL 4 Nominated Contaminants. Office of Water (4607M), EPA 815-R-15-002, January 2015.

U.S. EPA (U.S. Environmental Protection Agency). 2015d. Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants. Office of Water (4607M) EPA 815-R-15-003 January 2015.

U.S. EPA (U.S. Environmental Protection Agency) Science Advisory Board. 2009. SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3). EPA-SAB-09-011. January 29, 2009.

APPENDIX A: CHARGE TO THE SAB

Review of the Draft Contaminant Candidate List (CCL4) for Unregulated Contaminants in Drinking Water

BACKGROUND

The Safe Drinking Water Act (SDWA) requires EPA to publish a list of currently unregulated contaminants (called the Contaminant Candidate List or CCL) that are known or anticipated to occur in public water systems and which may require future regulation. The SDWA requires the agency to publish the CCL every five years. The CCL is one tool EPA uses to identify priority contaminants for future regulatory decision making and research needs. The CCL does not impose any requirements on any regulated entity. After publication of the CCL, SDWA requires the agency to determine whether or not to regulate at least five contaminants from the most current CCL, in a separate process called Regulatory Determination.

The agency published the previous CCL (the Final CCL 3) on October 8, 2009 (74 FR 51850 (USEPA, 2009e)). The CCL 3 contained 104 chemicals or chemical groups and 12 microbial contaminants. In developing CCL 3, EPA improved and built upon the process that was used for CCL 1 and CCL 2.

The CCL 3 process was developed based on recommendations from the National Academies of Sciences' National Research Council and the National Drinking Water Advisory Council. EPA used a multi-step process to select contaminants for the CCL 3, which included the following key steps:

- Identification of a broad universe of potential drinking water contaminants (the CCL 3 Universe);
- Screening the CCL 3 Universe to develop a preliminary CCL (PCCL), using criteria based on the potential to occur in public water systems and the potential for public health concern;
- Evaluation of the PCCL contaminants based on a more detailed evaluation of occurrence and health effects data, using a scoring and classification system; and
- Incorporating public input and expert review in the CCL 3 process.

EPA also considered new information on contaminants identified by surveillance efforts, which included collaboration with internal EPA offices and other federal agencies and the review of scientific publications and data. The agency provided the public with the opportunity to nominate contaminants to be considered for the Draft CCL 3 and sought public comment on the Draft CCL 3 before the list was finalized. The EPA SAB and its Drinking Water Committee reviewed the Draft CCL 3 and provided an advisory to the Administrator on January 29, 2009. SAB's recommendations on the CCL 3 process and EPA's response are summarized in the Final CCL 3 Federal Register Notice (74 FR 51850, USEPA 2009). More information on the CCL 3 can be found online at: http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3.

In May 2012, EPA sought public input by requesting nominations of contaminants to be considered for inclusion on the CCL 4. The agency evaluated the nominated contaminants and contaminants with previous negative regulatory determinations. The agency reviewed the data provided by the public and collected additional data for the nominated contaminants and contaminants with previous negative regulatory determinations. EPA used the same process for screening and scoring contaminants that was used for CCL 3 to evaluate these contaminants. For more information on CCL 4, please visit: http://www2.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4.

The Draft CCL 4 was published on February 4, 2015, and includes 100 chemicals or chemical groups and 12 microbes. The list includes, among others, chemicals used in commerce, pesticides, biological toxins, disinfection byproducts, pharmaceuticals and waterborne pathogens. The agency conducted an abbreviated evaluation and selection process for CCL 4. This abbreviated CCL 4 process included a three-pronged approach: (1) carrying forward CCL 3 contaminants (except those with regulatory determinations), (2) seeking and evaluating nominations from the public for additional contaminants to consider, and (3) evaluating any new data for those contaminants with previous negative regulatory determinations from CCL 1 or CCL 2 for potential inclusion on the CCL 4.

RELEVANT SUPPORT DOCUMENTS

The Draft CCL 4 Federal Register Notice, Fact Sheet, and Technical support documents (listed below) are available for more detailed information and can be found online at: http://www2.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4. For a list of CCL 3 technical support documents, see http://www2.epa.gov/ccl/contaminant-candidate-list-3-ccl-3#tech_support_docs

1. Summary of Nominations for the Fourth Contaminant Candidate List
2. Data Sources for the Contaminant Candidate List 4
3. Screening Document for the Draft PCCL 4 Nominated Contaminants
4. Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants
5. Final Contaminant Candidate List 3 Chemicals: Identifying the Universe
6. Final Contaminant Candidate List 3 Microbes: Identifying the Universe

CHARGE QUESTIONS

1. Please provide comment on whether or not the Draft CCL 4 support documents (listed above) are clear and transparent in presenting the approach used to list contaminants on the CCL 4. If not, do you have any suggestions on how we could improve the clarity and transparency of the support documents?

2. Please identify any additional peer-reviewed information or data collected in accordance with accepted methods which the agency should consider for CCL 4. Please see the Data Sources support document and CCL 3 Universe support document for a list of data sources that EPA used to evaluate contaminants for the Draft CCL 4.

3. Based on your expertise and experience, are there any contaminants currently on the Draft CCL 4 that you think do not merit inclusion on the list? Please provide the basis for your conclusions and any data or references.

4. Based on your expertise and experience, are there any contaminants which are currently not on the Draft CCL 4 that should be listed? Please provide the basis for your conclusions and any data or references.