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EPA-SAB-15-xxx

The Honorable Gina McCarthy
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
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 (which will determine whether or not to regulate the contaminant). 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 SAB concludes that the overlying principles used to evaluate contaminants are well described, but the documentation lacks specific information needed to follow the decision making process for listing 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 in applying the selection criteria; provide examples for both microbial and chemical contaminants that display the process of how contaminants were included or eliminated from the draft CCL 4; and 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.

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 submit candidate contaminants and supporting data. The SAB recommends that the EPA develop a strategy to 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 perform searches of the peer reviewed literature to identify new and emerging contaminants.

1
2 When evaluating candidate microbial contaminants that should be included on or excluded from the list,
3 the SAB recommends that several of the exclusion criteria in the EPA documents be reconsidered—for
4 example, the exclusion of anaerobic pathogens and pathogens that are not endemic to the United
5 States—because they may lead to the exclusion from the CCL of potentially significant microbial
6 hazards. Pathogens of emerging concern, including those associated with biofilms and drinking water
7 distribution systems, should be priorities for inclusion. In contrast, pathogens such as vegetative bacteria
8 that are, in effect, already addressed by existing regulations (such as the Surface Water Treatment Rule)
9 should be a lower priority for inclusion.

10
11 With respect to the chemical contaminants that should be included or excluded from the list, the SAB
12 notes that the list includes a number of contaminants carried forward from the CCL 3 but without
13 providing a sense of the relative priority or ranking of the listed chemicals. In light of the growing
14 number of contaminants on the CCL and the time required to move a contaminant through regulatory
15 determination and, where appropriate, promulgate a National Primary Drinking Water Regulation, the
16 SAB encourages the agency to develop more health advisories for contaminants where occurrence is
17 known to be sporadic but where the Health Reference Level/water concentration ratios are at a level of
18 concern. The EPA also should consider the frequency of occurrence of contaminants in the UCMR data
19 as a guide for removing or adding contaminants to the list and should consider the feasibility of listing
20 similar contaminants as a group rather than as individual chemicals. Finally, the agency should consider
21 adding more disinfection byproducts to the CCL, considering their potential human toxicity and
22 frequency of occurrence in public drinking water systems.

23
24 Thinking ahead to the next CCL, the SAB recommends that the agency implement a system that
25 integrates data collection and curation and uses a broader range of the best available data on drinking
26 water contaminants.

27
28 Thank you for the opportunity to provide advice on this important process. The SAB looks forward to
29 receiving your response.

30
31 Sincerely,

32
33
34
35 Dr. Peter S. Thorne
36 Chair
37 Science Advisory Board

35 Dr. Kimberly L. Jones
36 Chair
37 SAB Drinking Water Committee

38
39
40 Enclosure

NOTICE

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This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the agency. This report has not been reviewed for approval by the agency and, hence, the contents of this report do not represent the views and policies of the Environmental Protection Agency, or of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA website at <http://www.epa.gov/sab>.

Science Advisory Board (SAB) Draft Report (September 4, 2015) for Quality Review– Do Not Cite or Quote
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Acronyms and Abbreviations

1		
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3	CCL	Contaminant Candidate List
4	HRL	Health Reference Level
5	MCL	Maximum Contaminant Level
6	MCLG	Maximum Contaminant Level Goal
7	PCCL	Preliminary Contaminant Candidate List
8	SDWA	Safe Drinking Water Act
9	UCMR	Unregulated Contaminant Monitoring Rule
10	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 [xx] to conduct a quality review ...

The SAB concluded that the overlying principles used to evaluate candidate contaminants—from identifying the universe of chemicals through the final CCL 4—are well described. The transparency and clarity of the procedure has improved since CCL 3 was finalized. However, specific information needed to understand how the EPA made decisions at each step of the process was lacking. The SAB recommends a set of actions that 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 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 the treatment of CCL contaminants during the regulatory determination process.

The SAB is concerned that the agency is relying too heavily on nominations as the source for candidate contaminants and supporting data for the CCL process. 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) perform comprehensive searches of the peer

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

6
7 In responding to charge questions about pathogens that do not merit listing or that should be added to the
8 CCL 4, the SAB recommends general principles to be followed by the EPA in deciding what to include
9 or exclude from the list. These principles are motivated by two factors: (1) the overarching importance
10 of public health as the baseline for selection or exclusion of microorganisms in the CCL and (2) the role
11 of the CCL as a key initial step required for subsequent development of effective regulatory, monitoring,
12 and research decisions.

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

23
24 With respect to the chemical contaminants on the CCL 4, the SAB notes that the list includes a number
25 of contaminants carried forward from the CCL 3 but without providing a sense of the relative priority
26 (e.g., High, Medium, Low) of the listed chemicals. In light of the growing number of contaminants on
27 the CCL and the time required to move a contaminant through regulatory determination and, where
28 appropriate, promulgate a National Primary Drinking Water Regulation, the SAB encourages the agency
29 to develop more health advisories for contaminants for which occurrence is known to be sporadic but for
30 which the Health Reference Level / water concentration ratios are at a level of concern. The EPA also
31 should consider the frequency of occurrence of contaminants in the UCMR data as a guide for removing
32 contaminants from or adding contaminants to the list and should consider the feasibility of listing similar
33 contaminants as a group rather than as individual chemicals. The agency should consider adding more
34 disinfection byproducts to the CCL, considering their potential human toxicity and frequency of
35 occurrence in public drinking water systems.

36
37 For future CCLs, the SAB recommends that the EPA consider implementing a system that integrates
38 data collection and curation and uses a broader range of the best available data. A user interface that
39 curates data entered to the system from registered users would allow for broad-based population of the
40 knowledge base and would allow interested members of the public to evaluate the full dossier of data
41 available to the agency for each contaminant

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 [insert date] and [insert disposition].

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 compounds (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)

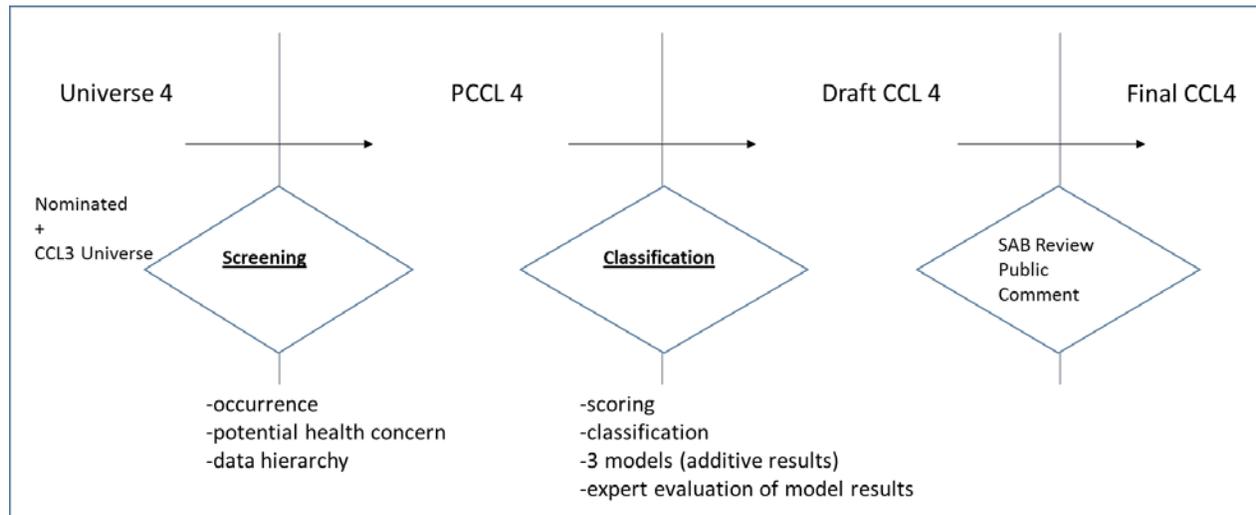


Figure 1. A schematic of the process used to develop the Contaminant Candidate List (CCL)

1 The SAB concluded that the overarching principles used to evaluate candidate contaminants—from
2 identifying the universe of chemicals through the final CCL 4 list—are well described. The transparency
3 and clarity of the procedure has improved since CCL 3 was finalized. However, the description of the
4 process still lacks sufficient detail to allow a reader to understand and follow the decisions made at each
5 step in the CCL’s development. In addition, the CCL 4 support documents should better describe what
6 the process is (and is not) intended to do. For example, the current process is not intended (and therefore
7 is not designed to) allow for definitive determination of each contaminant’s potential public health risk;
8 a much more rigorous review is conducted as part of the regulatory determination process. Limitations
9 in exposure/health data and quantifiable exposure/health indicators, as well as uncertainties in the role of
10 drinking water as a contributor to health risk for some potentially relevant contaminants, should be
11 discussed in the support documents.

12
13 It is not possible to fully evaluate the CCL 4 process without an understanding of how CCL
14 contaminants would subsequently be evaluated for a regulatory determination. Therefore, additional
15 detail in the CCL 4 support documents to describe the relationship of the CCL to the regulatory
16 determination process would help clarify expectations of the CCL segment.

17
18 Specific actions to be taken that would improve the clarity and transparency of the CCL 4 process
19 include:

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

30 These key points are discussed in more detail below.

31 **3.1.1. Consolidate Summary Information for all CCL 4 Contaminants**

32
33 **Recommendation: Develop a summary table (with appropriate use of hyperlinks) to show, for all**
34 **contaminants on the Preliminary CCL 4 (PCCL 4) (including those carried forward from the**
35 **CCL 3), why each was or was not listed on the draft CCL 4, and the scoring values for each**
36 **contaminant.**

37
38 The SAB found that the Contaminant Information Sheets (U.S. EPA 2015d) for each contaminant were
39 too cluttered with information, making it difficult for the reader to navigate through EPA’s decision on
40 whether to include a given contaminant on the draft CCL 4. While members may agree or disagree with
41 decisions made for individual contaminants, the SAB found that it was very challenging to review the
42 documents and make sense of how a nominated compound moved through the CCL 4 process or was
43 maintained from the previous CCL.

1 In the *Summary of Nominations for the Fourth Contaminant Candidate List* (U.S. EPA 2015a), a brief
2 review of the overall process, including the nomination process, is provided. This summary document is
3 clear from the standpoint of providing a list of what was nominated and then included/excluded on the
4 draft CCL 4. However, it is not transparent to the reader why many of the contaminants were included
5 while others were excluded. The summary document is missing the scoring values used to rate these
6 contaminants.

7
8 Some information is provided only in CCL 3 documentation, which was not updated for CCL 4. The
9 document *Summary of Nominations for the Fourth Contaminant Candidate List* (U.S. EPA 2015a)
10 provides a comprehensive overview of the nominated contaminants but not the contaminants retained
11 from the CCL 3. Appendix 1: Screening data for the Nominated Chemicals in the CCL 4 Universe from
12 *Screening Document for the Draft PCCL 4 Nominated Contaminants* (U.S. EPA 2015c) likewise
13 provides information on new contaminants but not those retained from CCL 3 (unless they were re-
14 nominated). It would be useful to provide information on the screening process and its results for all
15 potential contaminants, not just the new nominations. Such a comprehensive review would be useful for
16 evaluating the entire set of contaminants included in the draft CCL 4. It would also be helpful for this
17 document to provide a description of the weighting scheme used in the contaminant-scoring model
18 equation, perhaps with an application to an example contaminant.

19
20 In *Data Sources for the Contaminant Candidate List 4* (U.S. EPA 2015b), the EPA lists all reports or
21 databases used to characterize each contaminant. EPA provided the assessment factors (relevance,
22 completeness, redundancy, and retrievability) used to evaluate each source's suitability for analyzing the
23 CCL 4 contaminants. The document is clear. However, it is not transparent as to whether other data
24 sources were evaluated and excluded based on the failure to meet the requirements of the assessment
25 factors. Some of the sources did not meet the retrievability requirement but were still included as a
26 source. Was there a rubric used to assess these sources? Does inclusion mean that it had to meet at least
27 one or two of the assessment factors? The committee could not find the criteria that would cause a
28 source to be excluded in this document. Further, there is a wealth of knowledge in the literature on
29 contaminants on the CCL 3 and the CCL 4. The SAB DWC was informed by the EPA that the literature
30 was mined to include peer reviewed journal data in the EPA's data source for some contaminants. The
31 SAB recommends that this literature review and data mining process be a mandatory part of the data
32 search process for the CCL.

33
34 The SAB recommends that the EPA develop a single table that builds from the CCL 3 and includes all
35 draft CCL 4 contaminants. This table should include scoring values, a rating of each compound, EPA's
36 recommendation, and a brief note regarding the reasons (criteria employed) to include a compound on
37 the draft CCL 4. (It would also be helpful to have a similar table, or another portion of the same table,
38 listing nominated contaminants and other contaminants of significant interest to the general public and
39 the reasons they were excluded from the draft CCL 4.) A brief summary of the table contents and the
40 results of the CCL 4 process, with appropriate hyperlinks to more detailed information, would help the
41 reader put everything into perspective.

1 **3.1.2. Scoring Schemes and Selection Criteria: Chemical Contaminants**

2
3 **Recommendation: Present the results of the CCL 4 screening and classification process in a**
4 **manner that explicitly outlines the scoring schemes used in applying the selection criteria.**

5
6 The *Screening Document for the Draft PCCL 4 Nominated Contaminants* (U.S. EPA 2015c) provides an
7 explanation of how the EPA determines chemical contaminant potency (toxicity) and occurrence
8 (concentration, frequency). Exhibits 2 and 3 define the level of potency (in the form of toxicity
9 categories based on a quantitative or qualitative data element) while the level of occurrence is defined
10 from different data sources, with a preferred hierarchy when multiple data sources are available
11 (finished water>ambient water>total environmental releases>pesticide application rates>production
12 volume). The document also states that the EPA considered chemicals with descriptive data based on the
13 likelihood of occurrence in drinking water. This statement, however, is quite vague. Furthermore, in this
14 screening document, the SAB did not see how data variability (in terms of the number of data points and
15 the distribution of values for a given contaminant) was taken into account in determining both potency
16 and occurrence.

17
18 Once screening has been performed (i.e., determination for inclusion on the Preliminary CCI or PCCL),
19 chemical contaminants from the PCCL are selected for inclusion on the CCL using a classification
20 process summarized in the *Contaminant Information Sheets (CIS) for the Draft Fourth Preliminary*
21 *Contaminant Candidate List (PCCL 4) Nominated Contaminants* (U.S. EPA 2015d). This is
22 accomplished using additive results from three classification models—Artificial Neural Network
23 (ANN), Classification Tree with Linear Nodes (QUEST) and Linear Regression—and a scoring system
24 involving attribute scores (Potency, Severity, Magnitude, and Prevalence as metrics), health reference
25 level (HRL), and HRL/concentration ratio. The combined model results, expressed in four classification
26 decision categories (List, List?, Not List?, Not List) and the calculated HRL/concentration ratios then
27 were evaluated by an EPA team of experts. Tables are produced for each contaminant listing these
28 evaluation scores along with other health effects and occurrence-related data. In the attribute score, the
29 first two criteria are associated with toxicity and the latter two with occurrence. Each category is rated
30 on a 10-point scale.

31
32 The SAB recognizes that the classification models, calibrated with a training set, were applied in
33 evaluating whether a chemical should be listed on the CCL 4. The criteria used to evaluate and apply the
34 scores generated by these models should be summarized in the CCL 4 documents. Although detailed
35 information about the models is provided in the *Final Contaminant Candidate List 3 Chemicals:*
36 *Classification of the PCCL to CCL* (U.S. EPA 2009c), it is not clear whether the models were retrained
37 with new or updated information on contaminants carried over from the CCL 3 or on new contaminants
38 nominated during the CCL 4 process. More fundamentally, as described below, there was no
39 information on whether sensitivity analyses were performed to assess whether alternative approaches to
40 attribute scoring impacted model results. An explanation of the artificial neural network should be
41 provided along with a description of the process employed and how it was validated.

42
43 In addition to the attribute score modeling approach, a second approach utilized the HRL/concentration
44 ratio, i.e., the concentration in drinking water associated with a health-based risk level divided by an
45 anticipated or measured concentration in drinking water. When the ratio was <10, the compound was
46 included in the CCL. Again, the SAB recommends that the criteria to develop these numbers should be
47 specified and clarified. It appears from the documents that the second (ratio-based) approach is followed

1 and trumps the results from the scoring models. For contaminants that are close to this boundary and
2 have significant variability in the data, are they excluded or included? Is a combination of model
3 outcomes and HRL/concentration ratios used for those contaminants that have significant variability in
4 the HRL or concentration data? Again, the EPA should provide some explanation on how data
5 variability is treated and used in inclusion/exclusion decision points. An explicit description of how the
6 different data used for classification (the summary of the 3 models and the HRL/concentration ratio)
7 were used to make contaminant determinations, how these summary measures were prioritized, and how
8 (or if) data uncertainty was incorporated into this process would be helpful in the CCL 4 support
9 documents.

10
11 **Recommendation: Include a discussion of the effect of data variability and model sensitivity on the**
12 **results of the contaminant classification process.**

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

23 **3.1.3. Scoring Schemes and Selection Criteria: Pathogens**

24
25 **Recommendation: Clarify the scientific rationale for the approach used to prioritize pathogens for**
26 **inclusion in the CCL.**

27
28 The EPA document, *Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process* (U.S. EPA
29 2009d), describes the process upon which the CCL 4 was also based to move microorganisms to the
30 CCL. In deriving the draft CCL from the PCCL, a number of scoring systems were used for which the
31 scientific rationale was unclear. Clarification of the scientific rationale is needed. Some examples of the
32 lack of clarity in the process are described below.

33 ***Waterborne Disease Outbreaks***

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

- 1 • What is the rationale for assigning the same score (a 5) to a microorganism that has caused two
2 documented WBDOs in the U.S. surveillance between 1990 and 2004 as to a microorganism that
3 has caused dozens of such events over the same period?
- 4 • Why is no consideration given to the number of people who were affected by the WBDOs? Two
5 outbreaks involving four people would be assigned the same score as two outbreaks involving
6 one million people.
- 7 • A number of pathogens are clearly a public health problem in water but are addressed by existing
8 drinking water regulations, such as the Surface Water Treatment Rule. For example, health risks
9 associated with vegetative bacteria such as *E. coli*, *Campylobacter*, *Salmonella* and *Shigella* in
10 drinking water are reduced by measures implemented by water systems to reduce the occurrence
11 of unsafe levels of viruses, *Legionella*, and *Giardia lamblia*. Thus, such vegetative bacteria,
12 although important pathogens do not merit high prioritization on any CCL.

13 ***Occurrence***

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

18 ***Health Effects***

- 19 • The third component of the scoring process is the assignment of a health effects score for each
20 pathogen; scores range between 1 and 7. The rationale for the specific outcome categories and
21 associated scores is not provided. For example, why is the outcome, “Does the illness require
22 short term hospitalization (< week)?” given a score of 4 and the outcome, “Does the illness result
23 in long-term or permanent dysfunction or disability (i.e., sequelae)?” given a score of 5? Has a
24 sensitivity analysis been conducted to assess the effects of alternative scoring protocols on
25 pathogen prioritization?
- 26 • When determining the health effects score, separate scores are calculated for the “general”
27 population and “sensitive” populations. What is the rationale for giving each of these groups an
28 equivalent contribution to the health effects score? This is especially significant in view of
29 EPA’s statement that, “More importantly, nearly all pathogens have very high health effect
30 scores for the markedly immunosuppressed individuals; therefore there is little differentiation
31 between pathogens based on health effects for the immunosuppressed subpopulation” (p. 9, U.S.
32 EPA 2009d).

33 ***Composite Score***

- 34 • The document clearly describes how the final score for the pathogens is calculated. However, no
35 support for the following statement is provided, “Finally, EPA normalizes the Health Effects and
36 WBDO/Occurrence score because the Agency believes they are of equal importance” (p. 11,
37 U.S. EPA 2009d). What is the basis for this belief? Has an analysis been performed to assess the
38 impacts of normalizing these two scores?
- 39 • While the process for assigning scores is clearly described (although the rationale for the scoring
40 schemes is not adequately described, as discussed above), the process for determining which

1 pathogens on the PCCL were placed on the draft CCL is not clearly described. The document
2 states:

3 The 29 PCCL pathogens are ranked according to an equal weighting of their summed scores for
4 normalized health effects and the higher of the individual scores for WBDO and occurrence in
5 drinking water. EPA believes this ranking indicates the most important pathogens to consider for
6 the CCL 3. To determine which of the 29 PCCL pathogens should be the highest priority for
7 EPA’s drinking water program and included on the CCL 3, the Agency considered both scientific
8 and policy factors. The factors included the PCCL scores for WBDO, occurrence, and health
9 effects; comments and recommendations from the various expert panels; the specific intent of
10 SDWA; and the need to focus Agency resources on pathogens to provide the most effective
11 opportunities to advance public health protection. After consideration of these factors, EPA has
12 determined that the CCL 3 will include the 12 highest ranked pathogens. (p. 13, U.S. EPA 2009d)

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

15 • The EPA also made the following statement:

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

21 It is not clear how this assessment was made, as the “break point” between the top 12 pathogens
22 (0.5 units) and the next highest pathogen is equivalent to the “break point” between the top 6
23 pathogens and the seventh-highest pathogen. Even larger gaps (>1 unit) are seen between
24 pathogens farther down on the list.

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

28 **3.1.4. Illustrating the process with example contaminants**

29

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

32

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

1 did NOT make the list based on the scoring model, and (6) a chemical contaminant that did NOT make
2 the list based on the HRL/concentration model.

3 **3.1.5. Removing contaminants from prior CCLs**

4
5 **Recommendation: Clearly describe and improve the process for removing contaminants from**
6 **prior CCLs, where appropriate, when such lists serve in part as the basis for a new CCL.**

7
8 Clearly describing the “off-ramp” process for removing contaminants from the carry-over list (CCL 3 in
9 this case) would make the process more clear and transparent. The SAB found the removal process
10 difficult to identify. Aside from contaminants for which a regulatory determination (either positive or
11 negative) is made, the current process for updating and refining the CCL seems to rely primarily on
12 comments and data submitted by the public and expert review by the SAB. If that is indeed the case, a
13 more robust method that provides a clear process (and includes criteria) for removing contaminants from
14 the carry-over CCL should be explored. Such a process will help control the size of future CCLs and
15 focus efforts on the most appropriate contaminants.

16 **3.1.6. Summarizing contaminant review for regulatory determination**

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

22 **3.1.7. Conclusions**

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

30
31 Finally, the SAB notes that many of the above comments are similar to those made by the Board (U.S.
32 EPA Science Advisory Board 2009) when it reviewed the draft CCL 3. Examples from the 2009 SAB
33 report include:

34
35 The Committee concludes that the documentation, i.e., the FRN, is not transparent. Committee
36 members with decades of experience reviewing and analyzing EPA regulatory documents could
37 not follow specific contaminants through the process as presented in the FRN. The document is
38 not clear. Interpretation by several Committee members of the published CCL 3 processes
39 differed and were only clarified after discussion with EPA staff.

40
41 Committee members who tried to follow the decision-making process for one or more
42 contaminants could not do so.

43
44 It is unclear why changes to the CCL 4 process were not made to address these concerns. Are there
45 barriers in the CCL process that did not allow effective changes to be made? If barriers to the CCL

1 process exist, then these barriers should be addressed prior to the development of CCL5 so that the
2 process can undergo significant and meaningful improvements. A response by EPA to the SAB’s
3 specific recommendations would aid in SAB reviews of future CCLs.

4 **3.2. Additional Data Sources**

5 *Charge Question 2. Please identify any additional peer-reviewed information or data collected in*
6 *accordance with accepted methods which the agency should consider for CCL 4. Please see the Data*
7 *Sources support document and CCL 3 Universe support document for a list of data sources that EPA*
8 *used to evaluate contaminants for the Draft CCL 4.*
9

10 There are a number of potential limitations to the data used for the CCL process. These include: (1)
11 available exposure and/or health data may be old and not necessarily reflective of current conditions; (2)
12 quantifiable exposure and/or health indicators are not available for a large number of contaminants; (3)
13 the contribution of water to human exposure risk is uncertain for a number of potentially relevant
14 contaminants; and (4) the timing of the UCMR data collection does not align with the CCL process.
15 These data limitations conspire to give certain types of data more importance in the process (e.g.,
16 WBDO information, carcinogenicity risk) which may or may not be optimal for many contaminants.
17 Thus expanding and "modernizing" data sources used for the CCL process is an important undertaking.
18

19 As noted above, the SAB is concerned that the agency is relying too heavily on nominations as the
20 source for candidate contaminants and supporting data. The EPA should consider drafting a strategy to
21 proactively reach out to large utilities, relevant state agencies, and possibly other groups to obtain
22 occurrence information that may be useful in identifying potential candidates for the CCL. Among
23 others, this includes reaching out to the Water Reuse Association, the Water Research Foundation, the
24 American Water Works Association, and the Water Environment Research Foundation for occurrence
25 data, with an emphasis on contaminants related to direct and indirect potable water reuse.
26

27 The agency also should refer to any Unregulated Contaminant Monitoring Rule (UCMR) data that have
28 already been publically released. Currently this includes portions of the UCMR3. This recommendation
29 comes with the following caution: UCMR3 does not consider the quality of raw water (only finished
30 water).
31

32 For the CCL process, the EPA should include a method to examine data on temporal changes in
33 chemical production and use. This includes chemicals that are no longer in use or whose use has
34 decreased over time. This scan for changes in production and use should also be done to identify
35 contaminants for which data on occurrence are limited, but for which production and use data suggest
36 that occurrence may become a greater issue in the future. This process should include an evaluation of
37 the chemical properties as they relate to a chemical’s potential to become a water contaminant (e.g.,
38 vapor pressure, half-life).
39

40 Although the SAB understands the agency’s focus in the CCL process on data sources formatted for
41 automated retrieval, the EPA should consider performing searches of the peer reviewed literature to
42 identify new and emerging contaminants (e.g., recently developed pesticides and pharmaceuticals,
43 recently discovered disinfection by-products or leachates from plumbing materials) that may be
44 appropriate for the CCL. Contaminants selected for this review could be based on expert opinions,
45 including from scientists in EPA’s Office of Research and Development. It should be noted that this is

1 simply a refinement to the current process, and is not meant to replace the more quantitative processes
2 already in place.

3
4 The SAB recommends that EPA refer to the National Health and Nutrition Examination Survey’s
5 (NHANES) National Report on Human Exposure to Environmental Chemicals for potential data related
6 to occurrence. Most of these data will be urinary or blood levels of chemical contaminants, which do not
7 describe the route of exposure. Assuming there is not strong evidence that exposure is coming from
8 another (non-water) route, information on biologic levels could support the inclusion or prioritization of
9 a contaminant on the CCL. Again, this is recommended as a refinement to the current process, and is not
10 meant to replace the processes already in place.

11
12 If, given the time constraints associated with the CCL 4, it is not practical for the EPA to consult the
13 additional data sources recommended herein, or to implement other recommendations for expanded data
14 collection, the recommended sources and methods should be taken into consideration in developing
15 future CCLs.

16 **3.3. Contaminants That Do Not Merit Listing or That Should Be Added**

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

20
21 *Charge Question 4. Based on your expertise and experience, are there any contaminants which are*
22 *currently not on the Draft CCL 4 that should be listed? Please provide the basis for your conclusions*
23 *and any data or references.*

24 **3.3.1. Pathogens and Toxins**

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

31 **Recommendation: Reconsider screening criteria that may exclude potentially significant microbial** 32 **hazards.**

33 Some of the twelve exclusionary criteria for screening the Universe of possible pathogens to a PCCL
34 (described in the *Screening Document for the Draft PCCL 4 Nominated Contaminants*, U.S. EPA
35 2015c) may exclude important pathogens. In addition, excluding microorganisms based on meeting only
36 one criterion may lead to an incomplete CCL due to insufficient data for some pathogens. The SAB
37 recommends that the following screening criteria be reconsidered as they may lead to exclusion of
38 potentially significant microbial hazards:

- 39
40 • Excluding all anaerobes (criterion #1) risks excluding some relevant pathogens. For example,
41 vegetative anaerobes will not survive in water but some spore-forming microorganisms can
42 survive in water and, therefore, should be considered among potential CCL pathogens. For

1 example, *Clostridium difficile* is a spore-forming anaerobe that is a potential waterborne
2 pathogen, but it has been excluded from CCL consideration because it is an anaerobe.
3

- 4 • Exclusion of pathogens that are not endemic to North America (criterion #10) may be too
5 restrictive. Given the increasing globalization of commerce and resulting potential for
6 contaminants to be spread across the globe, non-endemic pathogens can be present in U.S.
7 waters.
8
- 9 • Exclusion of pathogens for which drinking water-related transmission has not been implicated
10 (criterion #8) or for which the natural habitat is in the environment but without evidence
11 associating the pathogen with drinking water-related disease (criterion #9) may be too restrictive.
12 For example, although *Pseudomonas aeruginosa* is most often considered a nosocomial (i.e.,
13 hospital-acquired) pathogen, they can adapt to and grow in a variety of environments, including
14 water. This microbe is associated with biofilm formation, and may thrive within distribution
15 systems, analogous to *Legionella*.

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

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

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

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

40 **3.3.2. Chemical Contaminants**

41 The SAB agrees with the overall conclusions in the previous SAB review of the CCL 3. As stated in the
42 SAB’s January 29, 2009, letter to Administrator Jackson, “With regard to providing any data that may
43 suggest that contaminants which are currently on (or not on) the draft CCL 3 list, and should not be

1 listed (or should be listed), the list is too large for the committee to complete a full review of these issues
2 in the time allotted.”

3
4 A complete answer to this question would require that the SAB review all of the scientific literature
5 pertaining to chemical occurrence in drinking water/drinking water sources between 2009 and 2015;
6 time constraints make such a review impossible. However, as noted in section 3.2, the SAB recommends
7 that the agency make greater use of the wealth of information in peer-reviewed and published literature
8 regarding the chemicals on the draft CCL 4. Further, the list as currently presented does not rank or
9 prioritize the chemicals. The SAB recommends that EPA adopt a prioritization strategy so that “legacy”
10 chemicals are still captured but high priority emerging chemicals are easily distinguished and
11 highlighted. A prioritized grouping (e.g., High, Medium and Low priority) of all the chemical
12 contaminants would bring greater transparency to the process and also help the public and researchers
13 focus their efforts to provide the most useful input for future decision-making.

14
15 The SAB recommends that the EPA consider the chemicals being monitored in finished drinking water
16 through the unregulated contaminant monitoring program (UCMR) as a guide for removing or adding
17 contaminants to the list. For instance, if the frequency of occurrence of a particular chemical is
18 consistently very low in finished drinking water, the agency may consider removing it unless it can be
19 demonstrated that there is a common thread to the occurrence data (e.g., geographic, or at utilities using
20 specific treatment technologies). The UCMR data should be reviewed and incorporated into agency
21 decision-making as soon as the data are publicly posted, rather than only after the entire UCMR dataset
22 is complete.

23
24 An example in which UCMR data can inform the CCL 4 is for estrogen hormones. For instance, for the
25 estrogen steroid hormones equilin and estrone, not one sample in the 7,169 evaluated in UCMR3 had a
26 positive detection at 4 and 2 ng/L, respectively. Estradiol, ethynylestradiol, and estriol all had sub-ng/L
27 method reporting levels, yet were only detected in 3, 3, and 1, respectively, out of 7,169 tests conducted.
28 Only one hit for estradiol appears to exceed the health reference level; however, this HRL is taken from
29 studies in rodents (Highman et al. 1980) in which dose response is not clear and the shorter term study
30 was used to calculate the cancer risk despite the availability of longer term exposure studies. Thus,
31 prudent use of UCMR data could potentially eliminate these estrogen hormones from the CCL, or tag
32 them as low priority for listing. Alternatively, chloropicrin was included in PCCL 3 but not in CCL 3,
33 and the rationale for this decision was not obvious. The SAB was not convinced that there was sufficient
34 evidence supporting the removal of chloropicrin and recommends that it remain on the CCL 4 so that
35 occurrence data on this chemical can continue to be collected.

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

43
44 The SAB recommends that EPA consider the feasibility of grouping contaminants. For instance, it might
45 be useful to consider halonitromethanes as a group rather than as individual chemicals.
46 In addition, the SAB recommends that EPA consider the addition of more disinfection byproducts,
47 especially iodinated haloacetic acids, other classes of nitrogenous DBPs, and other emerging

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1 disinfection byproducts considering their potential human toxicity and frequency of occurrence in public
2 drinking water systems. Example references for EPA to consider include: Chen et al. (2002); Monarca et
3 al. (2002); Richardson (2003); Plewa et al. (2004a, 2004b, 2008); Krasner et al. (2006); and Richardson
4 et al. (2007, 2008, 2014).

5
6
7

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. However, the process of developing CCLs would be improved in transparency and efficiency 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 rely on 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

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

3 **Summary of Other Recommendations**

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

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

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– This draft has not been reviewed or approved by the chartered SAB and does not represent EPA policy.

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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

1 used for CCL 3 to evaluate these contaminants. For more information on CCL 4, please visit:
2 <http://www2.epa.gov/ccl/draft-contaminant-candidate-list-4-ccl-4>.

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

11 **RELEVANT SUPPORT DOCUMENTS**

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

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

23 **CHARGE QUESTIONS**

- 24 1. Please provide comment on whether or not the Draft CCL 4 support documents (listed above) are
25 clear and transparent in presenting the approach used to list contaminants on the CCL 4. If not,
26 do you have any suggestions on how we could improve the clarity and transparency of the
27 support documents?
28
- 29 2. Please identify any additional peer-reviewed information or data collected in accordance with
30 accepted methods which the agency should consider for CCL 4. Please see the Data Sources
31 support document and CCL 3 Universe support document for a list of data sources that EPA used
32 to evaluate contaminants for the Draft CCL 4.
33
- 34 3. Based on your expertise and experience, are there any contaminants currently on the Draft CCL
35 4 that you think do not merit inclusion on the list? Please provide the basis for your conclusions
36 and any data or references.
37
- 38 4. Based on your expertise and experience, are there any contaminants which are currently not on
39 the Draft CCL 4 that should be listed? Please provide the basis for your conclusions and any
40 data or references.
41
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