

Science Advisory Board (SAB) Draft Report (6-30-2015) to Assist Meeting Deliberations – Do Not Cite or Quote – This draft is a work in progress, does not reflect consensus advice or recommendations, has not been reviewed or approved by the chartered SAB and does not represent EPA policy.

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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 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 process for evaluating contaminants is conceptually clear, but the documentation lacks specific details to enable a reader to thoroughly understand and follow the decision process for listing contaminants in the draft CCL. In order to improve transparency, the SAB recommends that EPA develop a summary table including the CCL 3 and CCL 4 lists 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 DCCL 4; and clearly describe and improve the process for removing contaminants from prior CCL lists.

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 the Unregulated Contaminants Monitoring Rule (UCMR 3), National Health and Nutrition Examination Survey (NHANES) and perform standard literature searches to identify new and emerging contaminants.

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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, the SAB recommends that the CCL
8 not include pathogens that are addressed with conventional drinking water treatment.

9
10 With respect to the chemical contaminants that should be included or excluded from the list, the SAB
11 notes that the list includes a number of contaminants carried forward from the CCL 3 but without
12 providing a sense of the relative priority or ranking of the listed chemicals. In light of the growing
13 number of contaminants on the CCL and the time required to move a contaminant through regulatory
14 determination and, where appropriate, promulgate a National Primary Drinking Water Regulation, the
15 SAB encourages the agency to develop more health advisories for contaminants where occurrence is
16 known to be sporadic but where the Health Reference Level/water concentration ratios are at a level of
17 concern. The EPA also should consider the frequency of occurrence of contaminants in the UCMR data
18 as a guide for removing or adding contaminants to the list and should consider the feasibility of listing
19 similar contaminants as a group rather than as individual chemicals. The agency should consider adding
20 more disinfection byproducts to the CCL, considering their toxicity and the fact that drinking water is
21 (in most cases) the sole source of exposure.

22
23 Thinking ahead to the next CCL, the SAB recommends that the agency implement a system that
24 integrates data collection and curation and uses a broader range of the best available data on drinking
25 water contaminants.

26
27 Thank you for the opportunity to provide advice on this important process. The SAB looks forward to
28 receiving your response.

29
30 Sincerely,

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35 Enclosure
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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>.

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45 *Did not participate in this review.

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**U.S. Environmental Protection Agency
Science Advisory Board**

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[to be added...]

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Acronyms and Abbreviations

1		
2		
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—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 [xx] to discuss its draft report, and the chartered SAB held a teleconference on [xx] to conduct a quality review ...

Overall, the SAB concluded that the overlying process for evaluating candidate contaminants—from the universe of chemicals through the final selection of the CCL 4 list—is conceptually clear. The transparency and clarity of the procedure has improved since CCL 3 was finalized. Yet when more detailed information is needed to understand how the EPA arrived at the draft CCL 4 list, the process and documents lacked specific details and therefore lacked clarity and transparency at the level needed to thoroughly understand and follow the decision making process. The SAB recommends four 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 CCL 3 lists 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 list; and
 - 4) Clearly describing and improving the process for removing contaminants from prior CCL lists.
- 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 the public, including states, to submit 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

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1 Monitoring Rule (UCMR 3) as it becomes available, (2) perform a standard literature search to identify
2 new and emerging contaminants, and (3) refer to the National Health and Nutrition Examination Survey
3 (NHANES) as an additional source of occurrence data. In addition, as part of the CCL process the EPA
4 should examine data on temporal changes in chemical production and use to identify contaminants for
5 which occurrence data are currently inadequate, but for which occurrence may become a greater issue in
6 the future.

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

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

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

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 that was 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—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, where 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 where 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 where 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 [insert date] to discuss the committee’s draft report and to reach consensus on recommendations and conclusions...

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)

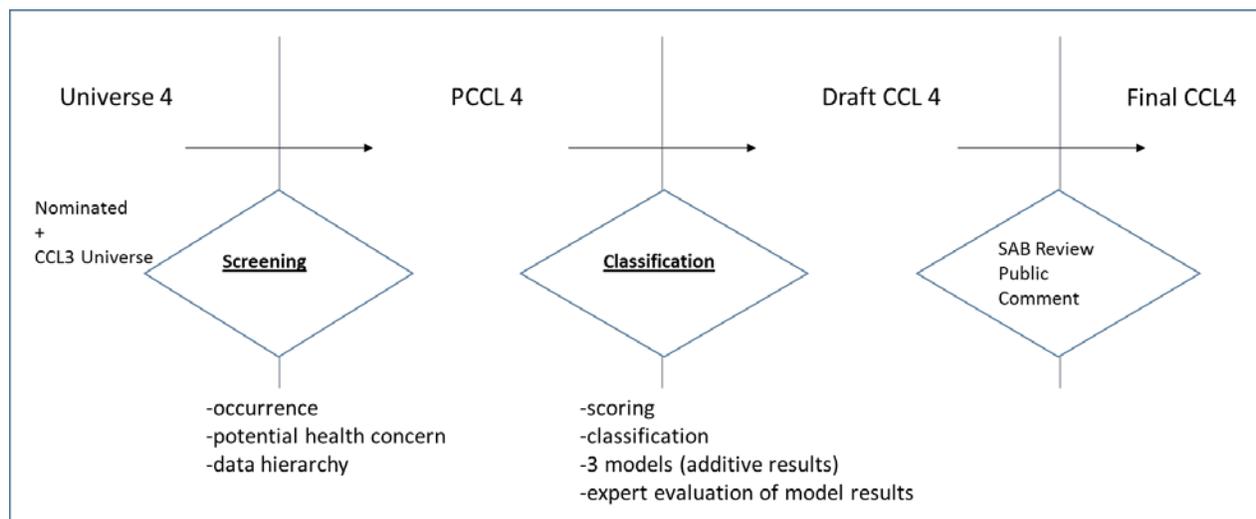


Figure 1. A schematic of the process used to develop the Contaminant Candidate List (CCL)

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1 Overall, the SAB concluded that the overlying process for evaluating candidate contaminants—from the
2 universe of chemicals through the final selection of the CCL 4 list—is conceptually clear, but not
3 transparent. The transparency and clarity of the procedure has improved since CCL 3 was finalized. Yet,
4 the description of the process still lacks sufficient detail to allow a reader easily to understand and
5 follow the decision making process for individual contaminants.

6
7 It is not possible to fully evaluate the CCL 4 process without an understanding of how CCL
8 contaminants would subsequently be evaluated for a regulatory determination. Therefore, additional
9 detail in the CCL 4 support documents to describe the relationship of the CCL to the regulatory
10 determination process would help clarify expectations of the CCL segment.

11
12 Specific actions to be taken that would improve the clarity and transparency of the CCL 4 process
13 include:

- 14 1) Summarizing information in one place (preferably a well-designed summary table), including co-
15 locating the CCL 4 and CCL 3 lists and making appropriate use of hyperlinks;
- 16 2) Presenting the results of the CCL 4 screening and classification process in a manner that
17 explicitly outlines the scoring schemes used in applying the selection criteria;
- 18 3) Providing examples for both microbial and chemical contaminants that display the process of
19 how contaminants were included on or eliminated from the draft CCL 4 list;
- 20 4) Clearly describing and improving the process for removing contaminants from prior CCL lists,
21 and
- 22 5) Including a summary of the treatment of CCL contaminants during the regulatory determination
23 process

24 These key points are discussed in more detail below.

25 **3.1.1. Consolidate Summary Information for all CCL 4 Contaminants**

26
27 **Recommendation: Develop a summary table (with appropriate use of hyperlinks) to show, for all**
28 **contaminants on the Preliminary CCL 4 (PCCL 4) (including those carried forward from CCL 3),**
29 **why each was or was not listed on the draft CCL 4, and the scoring values for each contaminant.**

30
31 The SAB found that the summary tables for each contaminant were too cluttered with information,
32 making it difficult for the reader to navigate through EPA’s decision on whether to include a given
33 contaminant on the draft CCL 4. While members may agree or disagree with decisions made for
34 individual contaminants, the SAB found that it was very challenging to review the documents and make
35 sense of how a nominated compound moved through the CCL 4 process or was maintained from the
36 previous CCL 3 list.

37
38 In the *Summary of Nominations for the Fourth Contaminant Candidate List* (U.S. EPA 2015a), a brief
39 review of the overall process, including the nomination process, is provided. This summary document is
40 clear from the standpoint of providing a list of what was nominated and then included/excluded on the
41 draft CCL 4 list. However, it is not transparent to the reader why many of the compounds were included
42 while others were excluded. The summary document is missing the scoring values used to rate these
43 compounds.

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

13
14 In *Data Sources for the Contaminate Candidate List 4* (U.S. EPA 2015b), the EPA lists all reports or
15 databases used to characterize each compound. EPA provided the assessment factors (relevance,
16 completeness, redundancy, and retrievability) used to evaluate each source’s suitability for analyzing the
17 CCL 4 compounds. The document is clear. However, it is not transparent as to whether other data
18 sources were evaluated and excluded based on the failure to meet the requirements of the assessment
19 factors. Some of the sources did not meet the retrievability requirement but were still included as a
20 source. Was there a rubric used to assess these sources? Does inclusion mean that it had to meet at least
21 one or two of the assessment factors? The committee could not find the criteria that would cause a
22 source to be excluded in this document. Further, there is a wealth of knowledge in the literature on
23 compounds on the CCL 3 and CCL 4 lists. The SAB DWC was informed by the EPA that the literature
24 was mined to include peer reviewed journal data in the EPA’s data source for some contaminants. The
25 SAB recommends that this literature review and data mining process be a mandatory part of the data
26 search process for the CCL.

27
28 The SAB recommends that EPA develop a single table that builds off the CCL 3 list and includes all
29 draft CCL 4 contaminants. This table should include scoring values, a rating of each compound, EPA’s
30 recommendation, and a brief note regarding the reasons (criteria employed) to include a compound on
31 the draft CCL 4 list. (It would also be helpful to have a similar table, or another portion of the same
32 table, listing nominated contaminants and other contaminants of significant interest to the general public
33 and the reasons they were excluded from the draft CCL 4.) A brief summary of the table contents and
34 the results of the CCL 4 process, with appropriate hyperlinks to more detailed information, would help
35 the reader put everything into perspective.

36 **3.1.2. Scoring Schemes and Selection Criteria: Chemical Contaminants**

37
38 **Recommendation: Present the results of the CCL 4 screening and classification process in a**
39 **manner that explicitly outlines the scoring schemes used in applying the selection criteria.**

40
41 The *Screening Document for the Draft PCCL 4 Nominated Contaminants* (U.S. EPA 2015c) provides an
42 explanation of how the EPA determines chemical contaminant potency (toxicity) and occurrence
43 (concentration, frequency). Exhibits 2 and 3 define the level of potency (in the form of toxicity
44 categories based on a quantitative or qualitative data element) while the level of occurrence is defined
45 from different data sources, with a preferred hierarchy when multiple data sources are available

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1 (finished water=ambient water>total environmental releases>pesticide application rates>production
2 volume). The document also states that the EPA considered chemicals with descriptive data based on the
3 likelihood of occurrence in drinking water. This statement, however, is quite vague. Furthermore, in this
4 screening document, the SAB did not see how data variability (in terms of the number of data points and
5 the distribution of values for a given contaminant) was taken into account in determining both potency
6 and occurrence.

7
8 Once screening has been performed (i.e., determination for inclusion on the Preliminary CCI or PCCL),
9 chemical contaminants from the PCCL are selected for inclusion on the CCL using a classification
10 process summarized in the *Contaminant Information Sheets (CIS) for the Draft Fourth Preliminary*
11 *Contaminant Candidate List (PCCL 4) Nominated Contaminants* (U.S. EPA 2015d). This is
12 accomplished using additive results from three classification models—Artificial Neural Network
13 (ANN), Classification Tree with Linear Nodes (QUEST) and Linear Regression—and a scoring system
14 involving attribute scores (Potency, Severity, Magnitude, and Prevalence as metrics), health reference
15 level (HRL), and HRL/concentration ratio. The combined model results, expressed in four classification
16 decision categories (List, List?, Not List?, Not List) and the calculated HRL/concentration ratios then
17 were evaluated by an EPA team of experts. Tables are produced for each contaminant listing these
18 evaluation scores along with other health effects and occurrence-related data. In the attribute score, the
19 first two criteria are associated with toxicity and the latter two with occurrence. Each category is rated
20 on a 10-point scale.

21
22 The SAB recognizes that the classification models, calibrated with a training set, were applied in
23 evaluating whether a chemical should be listed on the CCL 4. The criteria used to evaluate and apply the
24 scores generated by these models should be summarized in the CCL 4 documents. Although detailed
25 information about the models is provided in the *Final Contaminant Candidate List 3 Chemicals:*
26 *Classification of the PCCL to CCL* (U.S. EPA 2009c), it is not clear whether the models were retrained
27 with new or updated information on contaminants carried over from the CCL 3 list or on new
28 contaminants nominated during the CCL 4 process. Further it is not clear what cut-offs were used to
29 merit a rating of 10 for prevalence. An explanation of the neural network should be provided along with
30 a description of the process employed and how it was validated.

31
32 In addition to the attribute score modeling approach, a second approach utilized the HRL/concentration
33 ratio, i.e., the concentration in drinking water associated with a health-based risk level divided by an
34 anticipated or measured concentration in drinking water. When the ratio was <10, the compound was
35 included in the CCL. Again, the SAB recommends that the criteria to develop these numbers should be
36 summarized and clarified. It appears from the documents that the second (ratio-based) approach is
37 followed and trumps the results from the scoring models. For contaminants that are close to this
38 boundary and have significant variability in the data, are they excluded or included? Is a combination of
39 model outcomes and HRL/concentration ratios used for those contaminants that have significant
40 variability in the HRL or concentration data? Again, the EPA should provide some explanation on how
41 data variability is treated and used in inclusion/exclusion decision points.

1 **3.1.3. Scoring Schemes and Selection Criteria: Pathogens**

2
3 **Recommendation: Clarify the scientific rationale for the approach used to prioritize pathogens for**
4 **inclusion in the CCL.**

5
6 The EPA document, *Final Contaminant Candidate List 3 Microbes: PCCL to CCL Process* (U.S. EPA
7 2009d), describes the process used to move microorganisms to the CCL. This is the process upon which
8 the CCL 4 was also based. In deriving the draft CCL from the PCCL, a number of scoring systems were
9 used for which the scientific rationale was unclear. Clarification of the scientific rationale is needed.
10 Some examples of the lack of clarity in the process are described below.

11 ***Waterborne Disease Outbreaks***

- 12 • One part of the process of refining the PCCL to a draft CCL is to assign a score to each pathogen
13 based on its association with waterborne disease, using the Waterborne Disease Outbreak
14 (WBDO) Scoring Protocol. Using this protocol, it is clear how each pathogen is assigned a
15 score. It is not clear how the scoring protocol was developed. For example, what is the rationale
16 for giving a score of 4 to an organism that has “caused at least one documented WBDO in the
17 U.S. between 1990 and 2004” and a score of 3 to an organism that has “caused documented
18 WBDOs at any time in the U.S.”? How was it determined that these two situations warranted a
19 difference of one unit in a scoring system of five units? Was a sensitivity analysis conducted to
20 quantify the effects of the assignment of the numerical values to each of these conditions?
- 21 • What is the rationale for assigning a score of 5 to a microorganism that has caused two
22 documented WBDOs in the U.S. surveillance between 1990 and 2004 and score of 5 to a
23 microorganism that has caused dozens of documented WBDOs in the U.S. surveillance between
24 1990 and 2004?
- 25 • Why is no consideration given to the number of people who were affected by the WBDOs? Two
26 outbreaks involving four people would be assigned the same score as two outbreaks involving
27 one million people.

28 ***Occurrence***

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

33 ***Health Effects***

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

- 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 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 6 pathogens and the seventh-highest pathogen. Even larger gaps (>1 unit) are seen between pathogens farther down on the list.

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

4 **3.1.4. Illustrating the process with example contaminants**

5
6 **Recommendation: Provide examples for both microbial and chemical contaminants that display**
7 **the process of how contaminants were included on or eliminated from the draft CCL 4 list.**

8
9 The SAB concludes that a clearer understanding of the CCL selection process would be facilitated by a
10 limited number of examples tracking selected contaminants through the process from Universe to PCCL
11 to CCL. These examples should include both microbial and chemical contaminants, and contaminants
12 that made the list as well as contaminants excluded from the list using criteria employed by the EPA.
13 Since there are two toxicity/potency criteria used to decide whether to include a contaminant on the draft
14 CCL (i.e., the value from the scoring model and the HRL/concentration value), two sets of examples
15 should be provided for the chemical contaminants. Therefore a total of six examples should be included
16 (four chemical and two microbial).

17 **3.1.5. Removing contaminants from prior CCL lists**

18
19 **Recommendation: Clearly describe and improve the process for removing contaminants from**
20 **prior CCL lists.**

21
22 Clearly describing the “off-ramp” process for removing contaminants from the carry-over list (CCL 3 in
23 this case) would make the process more clear and transparent. The SAB found the “off-ramp” process
24 difficult to identify. Aside from contaminants for which a regulatory determination (either positive or
25 negative) is made, the current process for updating and refining the CCL seems to rely primarily on
26 comments and data submitted by the public and expert review by the SAB. If that is indeed the case, a
27 more robust method that provides a clear process (and includes criteria) for removing contaminants from
28 the carry-over CCL list should be explored. Such a process will help control the size of future CCL lists
29 and focus efforts on the most appropriate contaminants.

30 **3.1.6. Conclusions**

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

38
39 And finally, the SAB notes that many of the above comments are similar to those made by the Board
40 (U.S. EPA Science Advisory Board 2009) when it reviewed the draft CCL 3. Examples from the 2009
41 SAB report include:
42

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1 The Committee concludes that the documentation, i.e., the FRN, is not transparent. Committee
2 members with decades of experience reviewing and analyzing EPA regulatory documents could
3 not follow specific contaminants through the process as presented in the FRN. The document is
4 not clear. Interpretation by several Committee members of the published CCL 3 processes
5 differed and were only clarified after discussion with EPA staff.
6

7 At the April meeting, Committee members, each with decades of experience reviewing and
8 analyzing EPA regulatory documents, stated that they could not follow specific contaminants
9 through the process as presented in the FRN.

10
11 Committee members who tried to follow the decision-making process for one or more
12 contaminants could not do so.

13
14 It is unclear why changes to the CCL 4 process were not made to address these concerns. Are there
15 barriers in the CCL process that did not allow effective changes to be made? If barriers to the CCL
16 process exist, then these barriers should be addressed prior to the development of CCL5 so that the
17 process can undergo significant and meaningful improvements. A response by EPA to the SAB specific
18 recommendations would aid in SAB reviews of future CCLs.

19 **3.2. Additional Data Sources**

20 *Charge Question 2. Please identify any additional peer-reviewed information or data collected in*
21 *accordance with accepted methods which the agency should consider for CCL 4. Please see the Data*
22 *Sources support document and CCL 3 Universe support document for a list of data sources that EPA*
23 *used to evaluate contaminants for the Draft CCL 4.*
24

25 As noted above, the SAB is concerned that the agency is relying too heavily on the public, including
26 states, to submit candidate contaminants and supporting data. The EPA should consider drafting a
27 strategy to proactively reach out to large utilities, relevant state agencies, and possibly other groups to
28 obtain occurrence information that may be useful in identifying potential candidates for the CCL.
29 Among others, this includes reaching out to the Water Reuse Association, the Water Research
30 Foundation, the American Water Works Association, and the Water Environment Research Foundation
31 for occurrence data, with an emphasis on contaminants related to water reuse.
32

33 The agency also should refer to any Unregulated Contaminant Monitoring Rule (UCMR) data that have
34 already been publically released. Currently this includes portions of the UCMR3. This recommendation
35 comes with the following caution: UCMR3 does not consider the quality of raw water (only finished
36 water).
37

38 For the CCL process, the EPA should include a method to examine data on temporal changes in
39 chemical production and use. This includes chemicals that are no longer in use or whose use has
40 decreased over time. This scan for changes in production and use should also be done to identify
41 contaminants for which occurrence data is currently inadequate, but for which production and use data
42 suggests occurrence may become a greater issue in the future. This process should include an evaluation
43 of the chemical properties as they relate to a chemical's potential to become a water contaminant (e.g.,
44 vapor pressure, half-life).
45

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1 Although the SAB understands the agency’s focus in the CCL process on data sources formatted for
2 automated retrieval, the EPA should consider performing a standard literature search to identify new and
3 emerging contaminants (i.e., pesticides, pharmaceuticals) that may be appropriate for the CCL.
4 Contaminants selected for this review could be based on expert opinions, including from scientists in
5 EPA’s Office of Research and Development. It should be noted that this is simply a refinement to the
6 current process, and is not meant to replace the more quantitative processes already in place.

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

15 **3.3. Contaminants That Do Not Merit Listing or That Should Be Added**

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

19
20 *Charge Question 4. Based on your expertise and experience, are there any contaminants which are*
21 *currently not on the Draft CCL 4 that should be listed? Please provide the basis for your conclusions*
22 *and any data or references.*

23 **3.3.1. Pathogens and Toxins**

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

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

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

- 38
39 • Excluding all anaerobes (criterion #1) risks excluding some relevant pathogens. For example,
40 vegetative anaerobes will not survive in water but some spore-forming microorganisms can
41 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: Exclude from the CCL those pathogens that are addressed with conventional***
17 ***drinking water treatment.***

18 A number of pathogens are clearly a public health problem in water but are, by definition, addressed
19 with conventional drinking water treatment. For example, these treatments are effective at removing
20 vegetative bacteria such as *E. coli*, *Campylobacter*, *Salmonella* and *Shigella*. Thus, such vegetative
21 bacteria, although important pathogens, do not merit high prioritization on any CCL as they will be
22 addressed via conventional drinking water treatment.

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

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

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

34 Even though prioritization of contaminants occurs during the regulatory determination process, informed
35 prioritization (that addresses uncertainty) must occur at the CCL stage to optimize the utility of the
36 listing for subsequent research and monitoring, as well as for regulatory decision-making. For example,
37 research priorities should focus on contaminants likely to have the broadest public health impact. The
38 SAB recognizes that it is important to understand rare pathogens for which health impacts are
39 particularly deleterious. For example, *Naegleria fowleri* is a pathogen with rare occurrence but for which
40 exposure (generally via nasal entry from swimming/diving in contaminated water) can cause a fatal
41 central nervous system infection. Understanding this pathogen is important because of its devastating
42 toxicity even though, because of its rarity, its impact on overall population health is relatively limited.
43 However, a focus of research priorities on those pathogens most relevant to overall population health

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1 should be given a high priority. These can include pathogens with only modest health effects but
2 sufficient prevalence to have substantial public health impact by causing a large proportion of common
3 illnesses (e.g., diarrheal disease) in the population.

4 **3.3.2. Chemical Contaminants**

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

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

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

30
31 An example where UCMR data can inform the CCL 4 is for estrogen hormones. For instance, for the
32 estrogen steroid hormones equilin and estrone, not one sample in the 7,169 evaluated in UCMR3 had a
33 positive detection at 4 and 2 ng/L, respectively. Estradiol, ethynylestradiol, and estriol all had sub-ng/L
34 method reporting levels, yet were only detected in 3, 3, and 1, respectively, out of 7,169 tests conducted.
35 Only one hit for estradiol appears to exceed the health reference level; however, this HRL is taken from
36 studies in rodents where dose response is not clear and the shorter term study was used to calculate the
37 cancer risk despite the availability of longer term exposure studies. Thus, prudent use of UCMR data
38 could potentially eliminate these estrogen hormones from the CCL, or tag them as low priority for
39 listing.

40
41 In light of the growing number of contaminants on the CCL and the time required to move a
42 contaminant through regulatory determination and, where appropriate, promulgate a National Primary
43 Drinking Water Regulation, the SAB encourages the EPA to develop more health advisories for
44 contaminants identified on the CCL. Particularly, the EPA should consider formulating health advisories
45 for compounds whose occurrence is known to be sporadic but whose HRL/concentration ratios are at a

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1 level of concern. This approach would allow the process to protect against contaminants that have not
2 yet merited a positive regulatory determination, but may still cause health concerns.
3 The SAB recommends that EPA consider the feasibility of grouping contaminants. For instance, it might
4 be useful to consider halonitromethanes as a group rather than as individual chemicals.
5 In addition, the SAB recommends that EPA consider the addition of more disinfection byproducts,
6 especially iodinated haloacetic acids, other classes of nitrogenous DBPs, and other emerging
7 disinfection byproducts considering the toxicity and that drinking water is (in most cases) the sole
8 source of exposure. Example references for EPA to consider include: Chen et al. (2002); Monarca et al.
9 (2002); Richardson (2003); Plewa et al. (2004a, 2004b, 2008); Krasner et al. (2006); and Richardson et
10 al. (2007, 2008, 2014).

11
12 There are two chemical contaminants that the SAB recommends for reconsideration. The first is
13 nonylphenol. At the meeting, a public commenter noted that there was an editorial error in the data that
14 were used in the determination of whether nonylphenol should be included on the CCL. The SAB
15 recommends that the agency assess the primary source of the nonylphenol data to confirm or refute this
16 claim and update the assessment for this contaminant accordingly. Second, chloropicrin was included in
17 PCCL 3 but not in CCL 3, and the rationale for this decision was not obvious. The SAB was not
18 convinced that there was sufficient evidence supporting the removal of chloropicrin and recommends
19 that it remain on the CCL 4 list.

20
21

4. RECOMMENDATIONS FOR FUTURE CONTAMINANT CANDIDATE LISTS

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 and uses a broader range of the best available data. 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, 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. 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 apparent 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, in order to better avoid redundancy.

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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

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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

24 **CHARGE QUESTIONS**

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