



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

[Date]

EPA-SAB-09-00

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3)

Dear Administrator Johnson,

EPA's Office of Ground Water and Drinking Water requested that the Science Advisory Board (SAB) Drinking Water Committee (hereafter, the DWC or Committee) provide advice on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3). Contaminants on the CCL 3 can be chosen by the Agency to undergo a regulatory determination (which will determine whether or not to regulate the contaminant). The CCL 3 also influences the research agenda and other rules such as the Unregulated Contaminant Monitoring Rule.

The Agency asked whether the Federal Register Notice (FRN) and support documents are clear, transparent, and adequate to provide an understanding of the overall processes and selection of contaminants for the draft CCL 3. The Committee concludes that the documentation of the processes lacks transparency. The CCL 3 uses a more data-driven process than previous CCLs, as well as some models and algorithms, to whittle the universe of contaminants (Universe) to a Preliminary CCL (PCCL) and the CCL. However, EPA also used experts' professional judgments to revise the process and to modify the contaminants on the list. These modifications were not readily apparent in the current documentation. An understanding of the decision-making process is an important criterion for transparency, according to the reviews by the National Research Council and National Drinking Water Advisory Council. The Committee recommends that EPA develop a CCL 3 process flow chart for chemicals and for pathogens that includes links to other documents (data and models) used, as well as delineates where expert judgment was used. Developing one or more flowcharts will: (1) increase transparency; (2) allow a stakeholder to track the progress of a contaminant through the system; (3) highlight decisions that might suggest improvements for future CCL processes; and (4) clarify why contaminants that were included on previous CCL lists were excluded from the draft CCL 3.

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2 The Committee was asked whether the draft CCL 3 list includes contaminants that have
3 the highest potential to occur in public water systems and cause adverse human health effects.
4 This question goes to the heart of prioritization and decision-making in the selection process
5 from the Universe to the PCCL to the CCL 3. The Committee's major conclusions are:
6

- 7 • For chemicals, the list is too large to achieve the stated objectives of the CCL process or
8 to review by the DWC in the time allocated. To fulfill the Agency's objectives of
9 choosing chemicals that have the greatest opportunity for improving the safety of
10 drinking water and protecting public health, the Committee recommends additional
11 prioritization of the current list. A shorter list will clarify which chemicals have a
12 reasonable probability of being selected for regulatory determination.
13
- 14 • For pathogens, the waterborne disease outbreak data base was used to address both
15 occurrence and health effects. This data base does not adequately address whether there
16 is a substantial likelihood that the pathogen will occur in public water systems with a
17 frequency and at levels of public health concern. The Committee recommends that
18 occurrence be based on endemic disease data and published literature on occurrence.
19

20 The Committee was asked to provide any data that suggest: (1) contaminants that are
21 currently on the draft CCL 3 list **should not** be listed; and (2) contaminants that are **not** currently
22 on the draft CCL 3 list **should** be listed. The Committee concludes that the draft CCL 3 includes
23 contaminants that should not be listed and excludes contaminants that should be included.
24 Rather than attempting to examine each of the 104 contaminants on the draft CCL 3, the
25 Committee offers suggestions that could be used to identify chemicals and pathogens that should
26 have a lower priority for regulatory determinations. Similarly, the Committee provides sources
27 of additional, publicly available data that are expected to raise the priority of contaminants of
28 greater public health concern.
29

30 Thank you for the opportunity to provide advice on this important process. The SAB
31 Drinking Water Committee looks forward to receiving your response regarding this advisory.
32
33

34 Sincerely,
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38

39 Dr. Deborah L. Swackhamer, Chair
40 Science Advisory Board

Dr. Joan B. Rose, Chair
Drinking Water Committee

NOTICE

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3 This report has been written as part of the activities of the EPA Science Advisory Board (SAB),
4 a public advisory group providing extramural scientific information and advice to the
5 Administrator and other officials of the Environmental Protection Agency. The SAB is
6 structured to provide balanced, expert assessment of scientific matters related to problems facing
7 the Agency. This report has not been reviewed for approval by the Agency and, hence, the
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**U.S. Environmental Protection Agency
Science Advisory Board
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Draft Report Prepared by the Drinking Water Committee for Quality Review and Approval by the Chartered Science Advisory Board (SAB). This document does not represent EPA policy.

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Executive Summary

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4 EPA's Office of Ground Water and Drinking Water requested that the Science Advisory
5 Board (SAB) Drinking Water Committee (hereafter, the Committee or DWC) provide advice on
6 EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3) and the process used to
7 derive it. This list is the source of contaminants that are considered for a regulatory
8 determination. In addition, the CCL 3 interfaces with the Agency's research agenda.
9

10 In regard to whether the Federal Register Notice (FRN, EPA 2008) and support
11 documents are clear, transparent, and adequate to provide an understanding of the overall
12 processes and selection of contaminants for the draft CCL 3, **the Committee concludes that the**
13 **documentation, i.e., the FRN, is not transparent. Committee members with decades of**
14 **experience reviewing and analyzing EPA regulatory documents could not follow specific**
15 **contaminants through the process as presented in the FRN. The document is not clear.**
16 **Interpretation by several Committee members of the published CCL 3 processes differed**
17 **and were only clarified after discussion with EPA staff.** The lack of clarity in the process led
18 to frustration, and Committee members who tried to follow the decision-making process for one
19 or more contaminants could not do so. The Committee recommends that both the FRN and the
20 EPA web sites contain citations for all documents used in the process, and that the web site post
21 the documents and/or hyperlinks directly to each document, as well as the location of the
22 regulatory docket.
23

24 The Committee recommends that EPA develop CCL 3 process flow charts for chemicals
25 and pathogens. These flow charts should include links to other documents (data and models)
26 used, as well as delineate where expert judgment was used to go from the universe of
27 contaminants (Universe) to the Preliminary CCL (PCCL) to the CCL 3. Developing flowcharts
28 that a stakeholder can use to track the progress of a contaminant through the system (with the
29 appropriate references and URLs for each step) would not only make the process more
30 transparent, but they might also highlight decisions that might suggest improvements for future
31 CCL processes. The Committee also recommends that EPA document and justify why certain
32 contaminants that were included on previous CCL lists were excluded from the draft CCL 3.
33 This will improve readers' understanding of the evolution of the process as well as its
34 transparency.
35

36 In regard to whether the draft CCL 3 list represents those contaminants that have the
37 highest potential to occur in public water systems and cause adverse human health effects, **the**
38 **CCL 3 does not clearly achieve the stated objectives of the CCL process for prioritization.**
39 If the goal is to consider at least five contaminants per five-year review cycle for regulatory
40 determinations, a process that yields 104 contaminants has not whittled the Universe sufficiently
41 to be efficient or effective. Such a large list can not clearly communicate which contaminants
42 might – or might not – be considered for regulatory determination. The Committee has several
43 specific recommendations. For chemicals, explanations should be attached to each bullet
44 (Section III.A.4; page 9644 of the FRN), as it moves from the PCCL to the CCL, so that the
45 decision rules are more clearly explicated for the high, medium, and low uncertainty bins. It is
46 further recommended by the Committee that EPA should “re-train” the model, this time using

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1 only chemicals that would fall into the medium certainty bin. Certainty and data should drive the
2 prioritization of the contaminants, where there is sufficient information to make a regulatory
3 determination. For pathogens, the cutoff for moving from the PCCL to the CCL 3 was arbitrary
4 and not determined based on priority. The Committee recommends that occurrence based on
5 endemic disease data and published literature on occurrence be used to modify the
6 priorities/rankings of the pathogen PCCL.

7
8 With regard to providing any data that may suggest that contaminants which are currently
9 on (or not on) the draft CCL 3 list, and should not be listed (or should be listed), the list is too
10 large for the committee to complete a full review of these issues in the time allotted. There are
11 **104 contaminants on the draft CCL 3, and members of the Committee could not effectively**
12 **review each contaminant on the draft CCL 3, or the numerous potential contaminants that**
13 **are not on the draft CCL 3.** Rather, the Committee chose to present some critical examples of
14 contaminants that their expertise and experience suggested should not have a sufficiently high
15 priority to be on the draft CCL 3 and suggest reasons why the current process might have
16 excluded others.

- 17
- 18 • For chemical contaminants, the Committee recommends that EPA should evaluate
19 whether pesticides that have been or are about to be cancelled completely should be on
20 the list for additional SDWA regulation. This determination could be made after some
21 assessment of use, occurrence (transport and fate), and particularly persistence, which
22 will help to determine if the agent as used previously would have any ongoing
23 contamination issues. This will assist in the determination of whether the contaminant
24 should be considered for a regulatory determination or not. In some cases, these types of
25 pesticides may not require additional regulation and should be excluded from the CCL
26 process. The Committee recognizes that at least some evaluation of cancelled pesticides
27 would be necessary.
 - 28
 - 29 • The Committee also recommends that N-nitrosodimethylamine (NDMA), methyl tertiary
30 butyl ether (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high
31 priority for consideration by the Agency, because there is a higher degree of certainty
32 about their toxicity, occurrence, and treatability.
 - 33
 - 34 • For pathogenic contaminants, the Committee noted that two globally important
35 waterborne pathogens, *Adenovirus* and *Mycobacteria*, were excluded from the draft CCL
36 3. These pathogens should be on the list. Other pathogens, *Vibrio cholera* and
37 *Entamoeba*, were included and should be excluded from the list. Rare outbreaks, and the
38 outbreak data base in general, were used in determining the ranking and placement on the
39 CCL 3. The Committee recommends that endemic disease data sets, numbers of
40 outbreaks, geographical distribution of outbreaks and outbreak venues, as well as the
41 peer-reviewed literature (which would better inform occurrence in U.S. waters), be used
42 for the pathogens. Both the use of more of the publicly available data, as well as more
43 comprehensive use of the databases already used to develop the CCL process, would
44 improve the ranking.
- 45

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- 1 • The CCL 3 process also does not evaluate some of the less direct, potential hazards of
2 contaminants. For example, exposure to antibiotics may lead to antibiotic resistant
3 pathogens. The CCL 3 process does not identify this impact as a threat to human health.
4

5 The CCL is used for several diverse purposes, and the CCL process may need to be
6 modified to reflect these uses. At a minimum, a further prioritization of the CCL should be
7 undertaken for each of these purposes. For example, the CCL 3 list should be used to distinguish
8 between those contaminants with nearly a sufficiency of information for regulatory
9 determination and those with greater uncertainty, i.e., with the need for collection of additional
10 data before a contaminant would move off the CCL 3 toward a regulatory determination.
11

12 The Committee’s report begins with background information on the CCL 3 process with
13 web addresses where additional information can be found. The Agency’s charge questions are
14 then presented, first *in toto* and then separated with the Committee’s response to each question.
15 The final section contains references cited by the Committee.

1 **Background and Introduction**
2

3 EPA’s Office of Ground Water and Drinking Water requested that the Science Advisory
4 Board (SAB) Drinking Water Committee provide advice on EPA’s Draft Third Drinking Water
5 Contaminant Candidate List (CCL 3) and the process used to derive it. The CCL 3 is a list which
6 contains potentially harmful drinking water contaminants that may require regulations in the
7 future that are currently not regulated. The process for the CCL 3 is outlined in the Federal
8 Register Notice (FRN; EPA, 2008 available at: [http://www.epa.gov/fedrgstr/EPA-](http://www.epa.gov/fedrgstr/EPA-WATER/2008/February/Day-21/w3114.pdf)
9 [WATER/2008/February/Day-21/w3114.pdf](http://www.epa.gov/fedrgstr/EPA-WATER/2008/February/Day-21/w3114.pdf)). This document states:

10
11 “Section 1412(b) (1) of SDWA, as amended in 1996, requires EPA to publish the
12 Contaminant Candidate List every five years. SDWA specifies that the list must include
13 contaminants that are not subject to any proposed or promulgated NPDWRs, are known
14 or anticipated to occur in public water systems (PWSs), and may require regulation under
15 SDWA.

16
17 “The 1996 SDWA Amendments also specify three criteria to determine whether a
18 contaminant may require regulation:

- 19
- 20 • The contaminant may have an adverse effect on the health of persons;
 - 21
 - 22 • The contaminant is known to occur or there is a substantial likelihood that the
23 contaminant will occur in public water systems with a frequency and at levels of
24 public health concern; and
 - 25
 - 26 • In the sole judgment of the Administrator, regulation of such contaminant
27 presents a meaningful opportunity for health risk reduction for persons served by
28 public water systems.”
29

30 EPA’s web page titled, “Drinking Water Contaminant Candidate List and Regulatory
31 Determinations,” (available at: <http://www.epa.gov/safewater/ccl/ccl3.html#overview>) states:

32
33 “In developing the draft CCL 3, we implemented a different process from that used for
34 CCL 1 and CCL 2. This new process builds on evaluations used for previous CCLs and
35 was based on substantial expert input and recommendations from the National Academy
36 of Science’s National Research Council (NRC) and the National Drinking Water
37 Advisory Council (NDWAC).

38
39 “We used a multi-step CCL process to identify contaminants for inclusion on the draft
40 CCL 3. The key steps include:

- 41
- 42 • Identifying a broad universe of potential drinking water contaminants (called the
43 CCL 3 Universe). We initially considered approximately 7,500 potential chemical
44 and microbial contaminants.
45

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- 1 • Applying screening criteria to the universe we identified 560 of those
2 contaminants that should be further evaluated (the preliminary CCL or PCCL)
3 based on a contaminant’s potential to occur in public water systems and the
4 potential for public health concern.
5
- 6 • We then selected 104 contaminants from the PCCL to include on the CCL based
7 on more detailed evaluation of occurrence and health effects and expert judgment
8 applied in a transparent reproducible manner.
9
- 10 • We incorporated information from the public, expert input, and expert review in
11 the CCL process.”

12
13 Information regarding the CCL processes and lists can be accessed through the CCL web page
14 at: <http://www.epa.gov/safewater/ccl/index.html>.
15

1 **Review of the Draft CCL 3: EPA’s Charge Questions to and the Meetings of the Drinking**
2 **Water Committee of the Science Advisory Board**

3
4 The new process developed in response to the recommendations of the NRC and
5 NDWAC, as well as the specific chemicals and microbial pathogens on the draft CCL 3 list,
6 were subject to review. The charge questions posed to the DWC by EPA follow.

- 7
8 1. Please comment on whether the Federal Register Notice and support documents are clear,
9 transparent, and adequate to provide an understanding of the overall processes and
10 selection of contaminants for the draft CCL 3.
11
12 2. Please comment on whether the draft CCL 3 list represents those contaminants that have
13 the highest potential to occur in public water systems and cause adverse human health
14 effects.
15
16 3. Please provide any data that may suggest that contaminants which are currently on the
17 draft CCL 3 list should not be listed.
18
19 4. Please provide any data that may suggest that contaminants which are currently not on
20 the draft CCL 3 list should be listed.

21
22 The DWC of EPA’s SAB met in a public session on April 23 – 24, 2008 in Washington,
23 DC, to review the draft CCL 3. The Committee held a subsequent teleconference call on August
24 13, 2008 to discuss its draft advisory report.

1 **Charge Question 1**
2

3 **Please comment on whether the Federal Register Notice and support documents are**
4 **clear, transparent, and adequate to provide an understanding of the overall processes and**
5 **selection of contaminants for the draft CCL 3.**
6

7 **Committee Response**
8

9 **The FRN (EPA, 2008) that describes the process is not transparent and is not**
10 **adequate to provide an overall understanding of the selection of contaminants for the draft**
11 **CCL 3. At the April meeting, Committee members, each with decades of experience**
12 **reviewing and analyzing EPA regulatory documents, stated that they could not follow**
13 **specific contaminants through the process as presented in the FRN.**
14

15 The Committee affirms that the process used to produce the CCL 3 represents a major
16 improvement from the processes used to generate CCL 1 and CCL 2. The processes used to
17 generate the first two lists relied heavily upon expert opinion, best professional judgment, and
18 stakeholder nominations. Potential health risks contributed to the first part of the assessment,
19 followed secondarily by whether the contaminant occurred in drinking water. The CCL 3
20 process outlined in the FRN uses a more data-driven, systematic approach, focusing on assessing
21 information (including surrogate information) to identify contaminants based on: the potential or
22 known occurrence in drinking water; and their potential or known ability to cause adverse effects
23 in people. As recommended by the NRC and NDWAC, the CCL 3 process attempted to address
24 the Universe and developed a PCCL. Expert panels were used along the way as part of the
25 review and to modify the process. During the assessment, 6000 chemical contaminants and 1400
26 pathogens were identified. **The Committee views the current process as a first iteration of a**
27 **data-derived CCL**, and acknowledges that, as recommended by the NDWAC, the process
28 should be adaptive to improve and further develop with additional experience and data. The
29 Committee's comments on the limitations of the current process should be viewed in this
30 context.
31

32 Numerous challenges must be overcome when whittling the initial Universe down to a
33 CCL. EPA has documented its decision-making process, described its attempts to identify biases
34 in that process, and obtained expert feedback on the process. In general, the approach is
35 scientifically justified and, particularly for the chemical list, is a labor-intensive process that
36 includes the development of mathematical models to create the chemical list. The current
37 models are useful in sorting through the chemical and pathogen contaminants, but as discussed
38 further in this report, are expected to improve during additional iterations of the process.
39

40 The Committee found that use of an only data-supported process, i.e., without
41 professional judgment, for the CCL 3 (as described in the FRN) generated a list of contaminants
42 that is suboptimal. Based on the changes made by EPA's panel of internal experts, the
43 Committee infers that EPA's scientists also agreed that expert judgment was necessary at several
44 points in the process for developing the CCL 3. Therefore, EPA requested the opinions of
45 internal experts for professional assessment of chemicals or pathogens to revise the process, and
46 thus the contaminants, on the draft CCL 3. The Committee was not concerned that, in

1 developing the process, a review was needed and mid-course corrections were undertaken.
2 Rather, **the Committee found that these modifications (or suggestions) by Agency staff that**
3 **were accepted or rejected were not readily apparent as the Committee reviewed the**
4 **documentation in the FRN. In addition, the justifications for the decisions in which expert**
5 **opinion was accepted or rejected were not articulated.** The Committee found that this lack of
6 full transparency would impede the ability of other people to repeat the CCL 3 process and
7 obtain the same results as EPA – either with the current contaminants or with additional
8 contaminants that might be of interest. **In particular, the Committee could not discern at**
9 **which steps the data drove the primary outcome and at which steps the experts were used**
10 **to address key decisions in the process.** Such reproducibility of process was a stated criterion
11 for transparency made by the NRC and NDWAC. Additionally, some of the information about
12 individual contaminants and decisions made about them were only available in the regulatory
13 docket. Committee members either did not know that the docket might contain such information
14 or had difficulty locating the docket and/or the information desired.
15

16 The Committee recommends that both the FRN and the EPA web sites contain citations
17 for all of the documents used in this process, and that the web site post the documents and/or
18 hyperlinks directly to each document, as well as the location of the regulatory docket.
19 Additionally, use of hypertext in an online matrix of the contaminants might allow interested
20 parties to readily access the appropriate section of the documents where the information
21 influenced the related decisions in the process. Such a hypertext matrix could also be used to
22 provide readers with a summary of indicators or critical criteria, such as potency-to-
23 concentration ratios, occurrence data, mode-of-action decisions, health effects of concern, model
24 scores, expert panel conclusions, etc.
25

26 **The document is not clear. At the April meeting, Committee members asked for**
27 **clarification of the process for selecting the draft CCL. After additional information was**
28 **presented by representatives of EPA's Office of Water, several Committee members stated**
29 **that they had interpreted the text or tables differently, based on their independent reading**
30 **of the FRN. These statements apply both to the process used to select the chemicals and to**
31 **the process used to select the pathogens.**
32

33 The lack of clarity in the process led to frustration, as Committee members attempted to
34 determine why specific contaminants on the PCCL were retained or removed from the group of
35 contaminants that would become the draft CCL 3. **Committee members who tried to follow**
36 **the decision-making process for one or more contaminants could not do so.** The process for
37 selecting the chemicals was quite clear and logically presented until after the three models were
38 run and the resulting lists were created. At that point, the presentation became very murky.
39 Committee members expressed the difficulty in determining what supporting data were used for
40 each of the chemicals that did get onto the list. For example, it is not shown what level of
41 certainty “bin” each came from, what the data were in the exposure and health effects category,
42 and what the modeled list-not list determinations were. A table presenting these results is
43 recommended. In addition, it would be helpful to show similar results for at least a subset of the
44 chemicals that remained on the PCCL, to help inform the reader as to why these were not
45 selected. The Committee specifically raised numerous questions about the bullet points in
46 section 4 on p. 9644 of the FRN. It was not clear from the text that the 36 chemicals in the high

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1 certainty bin, for example, were included irrespective of the model results, whereas the 24
2 pesticides chosen from the medium certainty bin included only those with an “L” or an “L-L?”
3 ranking. This information needs to be clarified. In addition, there needs to be a clearly written
4 justification for diverging from the results of the model at the end of the process.
5

6 The Committee recommends that explanations be attached to each bullet (Section
7 III.A.4., page 9644 of the FRN) for the chemical list as it moves from the PCCL to the CCL so
8 that the decision rules are more clearly explicated for the high, medium, and low uncertainty
9 bins. Since the “training” of the model used chemicals from all certainty bins, the Committee
10 also recommends that EPA “re-train” the model, using only chemicals that would fall into the
11 medium certainty bin, i.e., the bin of chemicals for which the model was ultimately used. Clear
12 identification of certainty of the data should then drive the prioritization of the contaminants in
13 those cases where there is sufficient information to make a regulatory determination.
14

15 **The Committee recommends that EPA develop one or more flow charts that a**
16 **stakeholder can use to track the progress of a contaminant through the system, with the**
17 **appropriate references and URLs for each step.** Such flow charts would not only make the
18 process more transparent, but they might also highlight decisions that suggest improvements for
19 future CCL processes. Also, parameters chosen for the models or specification decisions, should
20 be provided (in more detail than is provided in Appendix E of the FRN). The CCL 3 process
21 flow charts should include links to other documents (data and models) used, as well as delineate
22 where expert judgment was used to go from the Universe to the PCCL to the CCL 3. The
23 Committee also recommends that EPA document and justify why certain contaminants that were
24 included on previous CCL lists were excluded from the draft CCL 3. This will improve readers’
25 understanding of the evolution of the CCL process, as well as its transparency.
26

27 Other recommendations for the chemical selection process include:
28

- 29 • To further improve the clarity of the process, approaches that were discarded should be
30 moved to the end of the document, perhaps in an appendix.
- 31
- 32 • The training set used for the initial calibration of the model for chemicals should be
33 readily available in the documentation via links to the web site.
- 34
- 35 • Additional deficiencies should be corrected in the details of the presentation of the
36 process. Details are lacking, for example, as to how fate parameters like the
37 octanol/water partition coefficients were used in the evaluation.
- 38
- 39 • All parameters should include the appropriate units, e.g., on LD₅₀ and related parameters
40 in Exhibit 9.
- 41

42 The process for selection of pathogen contaminants, as outlined in the FRN, was overall
43 judged a relatively transparent one. However, derivation of the relative numerical rankings was
44 not clear. An analytical protocol was employed; however, it did not discretely quantify potency,
45 for example, in terms of dose-response relationship as it had for the chemicals proposed for CCL

1 3 inclusion. The sources of information and data that were used in candidate selection are clear,
2 and the effort to be inclusive in receiving information from non-government organizations
3 (NGOs), the public, professional organizations, and municipalities is apparent. The development
4 of the Universe and the PCCL were data driven.
5

6 As with the process used to select chemicals, FRN lacked transparency with regard to the
7 selection of pathogens. Details about how information was used to assign a numerical rating to
8 the pathogens, for example, were not clear. Although outbreak data were critical to the selection
9 process, the role of these data, used to rank both the exposure and the health risks, was not
10 readily apparent. The cut-off for the PCCL to the CCL 3 for pathogens was arbitrary and not
11 determined based on a specific understanding of the data or uncertainty of the data. Thus,
12 support for this cut-off was not adequate. **The Committee recommends that occurrence based**
13 **on endemic disease data, and published literature on occurrence be used to modify the**
14 **priorities and rankings of the pathogens on the PCCL as they move to the CCL.**

1 **Charge Question 2**
2

3 **Please comment on whether the draft CCL 3 list represents those contaminants that**
4 **have the highest potential to occur in public water systems and cause adverse human**
5 **health effects.**
6

7 **Committee Response**
8

9 **The CCL 3 does not clearly achieve the stated objectives of the CCL process. If the**
10 **goal is to consider at least five contaminants per five-year review cycle for regulatory**
11 **determinations, a process that yields 104 contaminants has not whittled the Universe**
12 **sufficiently to be efficient or effective. Such a large list can not clearly communicate to the**
13 **DWC, other specific interested parties, and/or the general public which contaminants**
14 **might – or might not – be considered for a meaningful regulatory determination.**
15

16 Obtaining the list of contaminants for the draft CCL 3 involved development of a new
17 contaminant-selection process. The process of selecting the CCL 3 involved three major steps:
18 (1) identifying the Universe of contaminants that might be of concern; (2) using data on
19 occurrence and potential to cause adverse effects to obtain a PCCL; and (3) using data,
20 processes, and opinions from EPA’s internal experts to refine the selection into a draft CCL.
21 This goes to the heart of the question on prioritization and decision making in the selection
22 process from the Universe to the PCCL to the CCL. The uncertainty analysis for health effects –
23 and particularly for occurrence – should be articulated to address this issue. Selection of the
24 databases with specific attributes can determine whether parameters are estimated directly or
25 when surrogates must be used. Lack of readily available data can constrain the decision options
26 within the process. In particular, data selection should include identifying and obtaining data
27 that are necessary for the optimal operation of the CCL process. This applies both to data that
28 are appropriate for understanding the occurrence of contaminants and to data on the potential
29 health effects of those contaminants. Key areas to improve the process that should be explored
30 and addressed in the future include: sensitivity analysis of models and data; data uncertainty;
31 and data quality.
32

33 The Committee recommends consideration of emerging issues and on-going research
34 when selecting chemicals. There are also some clear categories of contaminants that need
35 special attention in selecting the CCL including pharmaceuticals, personal care products,
36 endocrine disruptors, antibiotics, and algal toxins. Such contaminants may warrant changes in
37 the CCL selection processes. General exposure to even low levels of antibiotics in drinking
38 water, for example, may lead to antibiotic-resistant pathogens either in a person drinking the
39 water or the general environment. The current CCL process for chemicals would not identify
40 this as an adverse effect. In addition, opportunistic pathogens (e.g., *Serratia* and *Pseudomonas*)
41 should be addressed, as waterborne disease from these pathogens in hospital settings has been
42 documented. The Committee recommends that EPA explore approaches that would bring in
43 these atypical health-related data and occurrence data into the CCL process.
44

1 Models and Selection Processes

2
3 Chemical Contaminants

4
5 The discussion in the FRN regarding the methodology for moving chemicals from the
6 PCCL to the CCL is organized in a chronological manner. This presentation imparts
7 significance to a complex and somewhat cumbersome initial methodology that was ultimately
8 subsumed within a new methodological framework proposed by EPA’s internal expert panels.
9 This complex, initial approach was not used to determine which chemicals moved from the
10 PCCL to the CCL. The actual approach began by dividing the chemical PCCL into three groups
11 (high, medium, and low uncertainty) depending on the type of data available to characterize the
12 contaminant. For each of these groups, a new decision rule was developed to determine whether
13 or not the contaminant should move forward to the CCL. While these decision rules are
14 indicated in the bullets in Section III.A.4. (page 9644 of the FRN), the explanations attached to
15 each bullet need to be expanded so that the decision rules are more clearly explicated. The initial
16 classification model was “trained” using chemicals of all types. Since this model was only used
17 for chemicals in the “medium certainty” bin, EPA should “re-train” the model, using only
18 chemicals that would fall into this bin.
19

20 The Committee noted that the draft CCL 3 gives equal weight to all chemicals, although
21 some chemicals are likely to be ready for regulatory determination, while others will require a
22 significant amount of additional research before a regulatory determination can be made. Thus,
23 the Committee recommends further prioritization within the CCL 3. Additional data and
24 processes should be used to priority rank the CCL 3 chemicals, by a method that will
25 differentiate between chemicals that have sufficient, existing information for a data-based
26 regulatory decision and those that do not. Priority-ranking chemicals may also require
27 reformulating or retraining the algorithms, since the dependent variable of the algorithm must
28 now indicate whether a contaminant should be studied for regulatory determination, and with
29 what urgency the contaminant should be studied.
30

31 Pathogen Contaminants

32
33 The process for moving pathogens from the PCCL to CCL does not sufficiently address
34 priority of occurrence or of health impacts. In particular, it is somewhat ambiguous as to how
35 the ultimate pathogen scores for this process were developed. For pathogens, it appears that the
36 internal EPA experts adjusted the scoring system. **This adjustment by expert judgment
37 should be presented more prominently, and the decision rules explained in more detail.**
38 The Committee concludes decisions regarding the selection of data sets, and the level of
39 resolution of the information within those data sets, was partially responsible for the suboptimal
40 results. The relative weighting of Center for Disease Control and Prevention (CDC) Waterborne
41 Disease Outbreaks (WBDO) “Occurrence” and “Health Effect Scoring”, as well as data
42 normalization, is described, but not necessarily adequate, for addressing the most important
43 pathogens. The Committee recommends that the limitations of WBDO data sets be articulated
44 clearly. Such limitations, for example, include underestimation of waterborne disease via a
45 passive surveillance and the percentages of outbreaks where no etiological agent is identified.
46 Exhibit 15 of the FRN shows evidence of WBDO using the CDC surveillance database. Over

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1 the more than three-decade period in question, the scoring system does not differentiate between
2 pathogens that have caused many outbreaks and those that caused only two outbreaks.
3 Furthermore, scoring of the WBDO data does not appear to take into account the geographic
4 dispersion of the outbreaks. Also lacking are data on specific, identified pathogens for the
5 majority of studied outbreaks. Furthermore, a rudimentary sensitivity analysis of the pathogen-
6 weighting criteria would have demonstrated that the results are not robust to small changes in the
7 scoring. For example, a change of only "1" unit in WBDO score would move some organisms
8 on or off the list. Also, the use of "Occurrence" data does not appear to be a quantitatively
9 robust term, i.e., the 1-to-3 ranking scale may have less utility than initially expected. An
10 occurrence term of 3 appears only to mean that it has been found in U.S. drinking water, but not
11 that it is found with any type of frequency or geographic distribution in U.S. drinking waters. In
12 fact, a score of 3 may mean that it was only found once in drinking water. Outbreak data were
13 not independent of occurrence, as an outbreak would by itself imply that the organism had been
14 found in drinking water and influence that score. This interrelationship gave the WBDO a
15 greater weight in the ranking. If the pathogen were only detected once, the exposure potential,
16 and therefore the risk, may be quite low.

17
18 Decisions Regarding Data Sets

19
20 In several places EPA appears to use data that may not be optimal for its stated intent of
21 offering equal protection to water consumers. For example, on page 9640 of the FRN,
22 prevalence is defined as "...the percent of public water systems or monitoring sites across the
23 nation with detections, number of states with releases..." Neither of these measures takes into
24 account the number of people who are potentially exposed to contaminants through these
25 drinking water systems. A contaminant that is found in two or three small states could receive
26 greater weighting than one found in a large, populous state. Similarly, geographic distribution
27 (not necessarily within state boundaries but perhaps watersheds) might be an additional
28 consideration for exposure. The reasons for and implications of such decisions should be
29 discussed.

30
31 The Committee recommends the use of more of the publicly available data and the more
32 comprehensive use of the databases already used to develop the CCL 3. In particular,
33 information in the peer-reviewed, published literature could be effectively used at certain
34 junctures of the process, especially when the list of chemicals or pathogens considered for a
35 particular decision is sufficiently small to reduce the burden of a literature search and analysis.
36 Similarly, the increasing use of wastewater affected sources of drinking water suggests that
37 databases containing information on contaminants in wastewater effluents would inform the
38 CCL process.

39
40 Chemical Contaminants

41
42 EPA used a hierarchical approach for data sources to indicate health effects. For full
43 transparency, the order in this hierarchy of references should be clearly presented. Furthermore,
44 for food-use pesticides, it would seem more appropriate to use the population-adjusted dose
45 (PAD), i.e., the dose that incorporates the additional uncertainty factor for children under the
46 Food Quality Protection Act (FQPA), rather than the reference dose (RfD) in the calculation of a

1 health reference level (HRL). Therefore, the Committee recommends that the Agency
2 recalculate the health-concentration ratios for those pesticides on the PCCL that have PADs
3 smaller than their respective RfDs. It is possible that additional substances may qualify for
4 inclusion on the draft CCL 3 because their revised ratio could now be 10 or less.

5
6 Pathogen Contaminants
7

8 The data used (or more specifically, the data not used) and the resulting pathogens
9 selected, were not necessarily the optimal set to consider for a regulatory determination. For
10 example, a choice was made by EPA to rely primarily on national data sources and use only data
11 sources with entries (in this case, for recorded outbreaks) for all of the organisms. This led to
12 heavy reliance on CDC databases and lack of use of the peer-reviewed, published scientific
13 literature. This process does not necessarily represent the "best available science." While there
14 was general agreement that a pathogen's presence in the WBDO should bring special attention to
15 that microbial pathogen, the WBDO grading system does not appear to provide sufficient
16 resolution regarding details to be useful as a scoring algorithm without modifiers. **Thus, the full
17 breadth or ranges of available data were not used.**
18

19 The WBDO has several limitations that are not addressed in the FRN. This data base
20 does not distinguish between an organism that has caused outbreaks in the Marshall Islands
21 (*Cholera*) and an organism that has caused several outbreaks in the continental U.S. (norovirus
22 and *Campylobacter*). The potential problems caused by highly endemic diseases that are never
23 detected as outbreaks (and therefore not in the WBDO) are not fully explained by the Agency in
24 the FRN.
25

26 A supplementary table containing the published, waterborne-attributed, case reports for
27 each of the organisms would be useful. There is also a lack of data and discussion about the
28 prevalence of organisms in sewage and wastewater. As a result, organisms such as *Naegleria* or
29 *Vibrio* may receive a pathogen PCCL score higher than expected because of this weighting for
30 "Occurrence," which is tied to whether there has been an outbreak. An environmental
31 frequency or distribution score for pathogens, rather than or in addition to its "Occurrence"
32 score, is needed. The ranking and the cut-off level that separated the PCCL from the CCL
33 seemed arbitrary and should be better described (Exhibit 18).
34

35 The potential effect of the information that was not used is less clear. As EPA is aware,
36 the CDC is the premier organization in reporting disease statistics and occurrence for organisms
37 typically associated with waterborne disease. EPA has partnered well with CDC, including
38 evaluating the likelihood of disease outbreaks, as the consequences of global environmental
39 change become manifest. CDC also partners with many other organizations and associations in
40 disease surveillance. Perhaps most notable are state public health offices, responsible for first
41 response in reporting disease associated with water and food-borne exposure. EPA should
42 explore methods for accessing such data. CDC accesses a broader base of data, which may or
43 may not be immediately available to the EPA, as data indicators for PCCL consideration. Some
44 of these sources include United States Geological Service (USGS) well-monitoring programs,
45 and the National Environmental Health Association (NEHA). NEHA also has many partner
46 organizations such as the Council for State and Territorial Epidemiologists (CSTE). Other

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1 organizations such as the Bureau of Environmental Epidemiology (Florida) or the New York
2 City Department of Environmental Protection, Waterborne Disease Risk Assessment Program,
3 may prove useful, as other data or sentinel sources of information on outbreaks.

4
5 At the international level the United Nations Food and Agricultural Organization (UN-
6 FAO) and World Health Organization (WHO) monitor and report relevant outbreak and disease
7 incidence. Significantly, the European counterpart to the CDC, the European Center for Disease
8 Prevention and Control (ECDC), continues to develop its waterborne disease and monitoring
9 program and makes data relatively available through its Enter-net databases for waterborne
10 disease organisms. It is likely the EPA is aware of all these sources, but it may wish to
11 investigate whether these and other information channels could facilitate more robust and
12 quantitative tools in assessment of PCCL consideration and CCL listing.

13
14 Peer-reviewed research articles in journals and periodicals received less attention as data
15 sources than disease monitoring or surveillance data from other agencies, state, or municipal
16 sources. Given the relatively limited number of microbial pathogens proposed for inclusion on
17 the CCL, reviews of the scientific literature are desirable in addition to the sources that were
18 used to develop this draft CCL 3. Exceptions to the process whereby journal articles were used
19 for bacteria included publications on *Arcobacter* and *Mycobacterium avium* complex (MAC). It
20 is likely that other organisms would change position with regard to CCL listing, if outside data
21 and professional judgment were used. The literature may also be more current with respect to
22 sensitivity, selectivity, and specificity than the information derived from some more standard
23 methods.

24
25 There was discussion in the FRN about not using susceptibility to water treatment to
26 guide the selection list. This may be appropriate for the PCCL as well as the CCL. However, as
27 with the chemicals, further prioritization is recommended for the CCL 3 with regard to
28 sufficiency of the data for regulatory determination as compared with investment in generating
29 more data (on methods, occurrence, and health effects). For example, if the Agency
30 demonstrates that the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) or
31 the Ground Water Rule (GWR) already address risk management for specific pathogens, this fact
32 could be articulated and influence selection for the CCL. Neither public health nor water
33 science benefits from having a number of pathogens on a CCL that can readily be removed once
34 they are “controlled”, without formally establishing an MCL or treatment technique. The large
35 numbers of *Legionella* cases, and the fact that no current regulatory approach can be documented
36 to reduce this risk, for example, suggest that this type of pathogen be given a higher priority on
37 the CCL.

38
39 Use Of The CCL For Regulatory Decisions

40
41 The CCL 3, as currently defined, serves two distinct purposes. The first is to identify
42 unregulated contaminants that might have sufficiently high occurrence and produce adverse
43 effects of concern, so that resources might be directed to obtaining more information. Toward
44 this end, either data on occurrence or data on adverse effects could lead to development of
45 sufficiency to move to a regulatory determination. In contrast, the second goal is to select those
46 contaminants that should be considered for imminent regulatory determination. In general, such

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1 action would require the existence of, rather than the generation of, information on both
2 occurrence and adversity. Priority setting within the draft CCL 3 should use such criteria.
3 Absent this prioritization, the CCL 3 will not achieve its stated goal.
4

5 The number of contaminants on each CCL keeps increasing. However, regulatory
6 determinations are only made for 5 to 10 contaminants every five years. The continued increase
7 in contaminants on the list may give the public a sense that water quality is declining with time.
8 EPA should consider how to address this issue of risk perception in its documents on the CCL
9 process.

1 **Charge Question 3**
2

3 **Please provide any data that may suggest that contaminants which are currently on**
4 **the draft CCL 3 list should not be listed.**
5

6 **Committee Response**
7

8 **With 104 contaminants on the draft CCL 3, members of the DWC could not**
9 **effectively review each contaminant. For example, one member provided short summaries**
10 **of a subset of the chemical contaminants (appended to the minutes of the meeting), and the**
11 **list was 15 pages long (available on web site). Instead, the DWC chose to present some**
12 **critical examples of contaminants that their expertise and experience suggested should not**
13 **have a sufficiently high priority to be on the draft CCL 3, and suggest reasons why the**
14 **current process excluded them.**
15

16 The DWC concluded that the list of chemicals on the CCL 3 is too large and that it may
17 be appropriate for some to remain on the PCCL. Additional priority ranking based on, for
18 example, availability of data necessary for a regulatory determination, should be undertaken.
19 The CCL serves both to guide the future safety of drinking water via regulatory determinations,
20 to focus research (into methods for detection, methods of water treatment, and assessing health
21 effects), and to interface with other rules such as the Unregulated Contaminant Monitoring Rule
22 (UCMR). It is one of the most critical and important activities within the EPA and thus certainly
23 deserves the efforts that the Agency has devoted to it. The final list must be viewed within that
24 context.
25

26 The DWC acknowledges that any list of contaminants would have some contaminants
27 that each expert would prefer to add or to remove. Nonetheless, there was general agreement
28 that the current process could be improved to generate a list that would contain fewer surprises.
29 For example, members conclude that even a cursory sensitivity analysis could be used to
30 improve the scoring systems and justify the cut-off points that were used to retain contaminants.
31

32 Knowledge about a pesticide's regulatory status under the Federal Insecticide, Fungicide
33 and Rodenticide Act (FIFRA) and FQPA, might obviate retention in a process designed to
34 determine whether a regulatory determination is necessary under SDWA. Cancelled pesticides,
35 or those for which cancellation is underway, should be considered differently than those
36 expected to be used for a longer time. For example, all uses of nitrofen (which is on the draft
37 CCL 3) were cancelled in 1983, and existing stocks were depleted within a few years. It appears
38 that nitrofen is on the draft CCL 3 because it was listed as a Toxics Release Inventory (TRI)
39 release from just one site in just one year. The Committee does not agree that such limited data
40 constitutes an appropriate surrogate for exposure for decisions regarding decision on the
41 development of a national drinking water standard. Similarly, the Committee questions the value
42 of considering, for additional SDWA regulation, those pesticides for which cancellation of all or
43 many uses is in progress (e.g., molinate and some organophosphates). The Committee
44 recognizes that at least some evaluation of cancelled pesticides would be necessary, so as not to
45 be shortsighted on the Agency's part. The Committee recommends that pesticides no longer in
46 use should be removed from the CCL unless an assessment determines that they present ongoing

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1 contamination issues such as: (1) the potential longevity of pesticides in ecosystems; or (2) fate
2 and transport data. In addition, proposed CCL chemicals such as germanium, hexane, and
3 quinoline appear to be on the list mainly because they scored highly in one category (e.g.,
4 production volume for hexane and toxicity for germanium). The Committee recommends that
5 such chemicals not be considered for regulatory determinations at this time.

6
7 For the chemical contaminants, the Committee recommends that the models take into
8 consideration the level of certainty, and also some measure of the ratio between the
9 concentration of concern and the potential drinking water concentration. Thus, some chemicals
10 on the draft CCL 3 might remain on the PCCL, as the current data suggest their occurrence in
11 public water systems is not at a frequency and concentration that would be of public health
12 concern. Furthermore, the databases used by the EPA in the CCL 3 analyses do not include
13 much of the journal literature that could be a rich source of information. While these sources
14 might be difficult to search for the Universe, these data could more easily be included in the
15 PCCL to CCL process, especially for the limited number of pathogens. The use of advanced
16 text-processing software should be investigated for this application. E-government initiatives
17 throughout the Federal government, as well as a lively and innovative academic community, are
18 potential sources of help for EPA in pursuing this approach. Similarly, use of available
19 computational toxicology data might improve the selection of chemical contaminants.

20
21 The Committee experts in pathogens had not expected to see *Entamoeba histolytica* and
22 *Vibrio cholerae* on the draft CCL. Other countries' environmental agencies look to the EPA's
23 CCL. Thus, when the system that is used reveals pathogens that are no longer considered
24 waterborne disease risks in the U.S., the reasons for this should be addressed, and the data-based
25 numerical approach should be investigated and corrected. The Committee recommends that
26 EPA examine data on endemic disease, numbers of outbreaks (dates), and geographic locations
27 (Marshall Islands), and venues (the *Entamoeba* outbreak was listed with other pathogens in a
28 prison where sexual transmission is known to occur), as well as provide a better assessment on
29 the frequency of occurrence in drinking water supplies in the U.S. These microbial contaminants
30 are not likely to occur in public water systems with a frequency and concentration of public
31 health concern. Clearly, these are globally important, waterborne pathogens; however, for U.S.
32 waters their inclusion on the CCL 3 is not warranted.

1 **Charge Question 4**
2

3 **Please provide any data that may suggest that contaminants which are currently not**
4 **on the draft CCL 3 list should be listed.**
5

6 **Committee Response**
7

8 **Given, as stated in the response to the previous question, the draft CCL 3 was too**
9 **long to review the contaminants efficiently, it was not feasible for the DWC to consider all**
10 **possible additional contaminants that might warrant a higher priority for consideration for**
11 **regulatory determination through the CCL process. Moreover, as the FRN was neither**
12 **transparent nor clear, it would not have been possible for the Committee members to have**
13 **provided appropriate data to justify their selection of additional contaminants prior to**
14 **discussion with EPA at the primary review of the document in April. Thus, the DWC**
15 **chose to provide critical examples of contaminants that, given their experience and**
16 **expertise, they expected to be on the draft CCL 3 and suggest – to the best of their current**
17 **understanding of the process – why they might not have made it through the current**
18 **process.**
19

20 The Committee recommends that an explanation be included for those contaminants that
21 are on the CCL 1 or CCL 2, but were not included in the new list via the new process, with the
22 appropriate justification. As already stated, this will improve transparency and understanding of
23 the evolution of the process.
24

25 EPA should consider addressing the cumulative effects of chemicals with similar sources
26 and mechanisms (or modes) of action, and microbial pathogens with similar potency and disease
27 endpoints (for example, diarrhea, pneumonia, or meningitis). The draft CCL 3 was constructed
28 with consideration only about individual chemicals and pathogens. Grouping has been used for
29 other drinking water contaminants (e.g., trihalomethanes and haloacetic acids) because
30 occurrence, health effects, and/or treatment options are related. In the draft CCL 3, (1)
31 perflourochemicals and (2) acetochlor, metolachlor, and their degradates are examples where it
32 may be helpful to list the compounds as a group. Not all of the compounds in the group may be
33 released from the same source, nor would they likely always occur together. A group could
34 consist of “exposure groups” similar in sources, transport, or solubility. Similarly, “health
35 groups” would be composed of contaminants with similar toxicity or adverse health effects.
36 Thus, some agents not on the CCL 3 would join their appropriate groups. Additionally, the
37 Committee recommends that EPA consider groups of chemicals where only some have been
38 considered for regulation because others are not yet in common use. The Committee is
39 concerned that, if the group is not considered as a whole, users could substitute a non-regulated
40 chemical for a regulated one and, thus, escape regulatory concern. Some groups of chemicals
41 may need to be considered in different ways depending on the goal of the analysis. For example,
42 many nitrosamines have similar toxicities and carcinogenicities. Therefore, they should be
43 considered together when they co-occur in the same drinking water samples when evaluating
44 risk. If they do not occur together, if they can not be used as substitutes, or if they require
45 different treatment methods for removal, grouping for these purposes is not recommended.
46

1 The Committee concludes that it will be important to consider information regarding
2 wastewater concentrations when evaluating potential exposure in the CCL process. In some
3 areas of the country, wastewater discharges are increasingly a greater percentage of water
4 supplies, and they are being processed into potable water. Wastewater contains a wide variety of
5 contaminants including pharmaceuticals, personal care products, enteric pathogens, and other
6 emerging contaminants. In the case of pharmaceuticals, perfluorinated surfactants, and other
7 contaminants that are prevalent in wastewater effluent, EPA may want to consider using data
8 obtained in specialized wastewater effluent monitoring programs for the CCL screening process.
9 Large water systems may be subjected to significant discharges of wastewater effluent, and
10 concentrations of contaminants measured in wastewater effluent could be used as a surrogate for
11 concentrations in raw water. An approach for predicting the role of unplanned wastewater reuse
12 that may be appropriate for predicting concentrations in raw water sources is presented in
13 Anderson et al. (2004).

14
15 The Committee recommends that EPA include the DWC earlier in the process.
16 Requesting advice from the DWC at critical junctures throughout the process, and not just at the
17 end, would allow EPA to take better advantage of the expertise of the DWC.

18
19 *Chemical Contaminants*

20
21 The Committee experts in health effects of chemicals conclude that the isomers of
22 hexachlorocyclohexane that were on or off the list did not appear appropriate. Pesticides that did
23 not appear on the CCL 3 that were mentioned as potentially worthy of listing included some for
24 which information was provided to EPA by public commenters, e.g., degradation products of
25 dacthal and DDT; Fonofos; Terbacil; s-ethyl dipropylthiocarbamate (EPTC); and 1,3-
26 dichloropropene (Telone). The absence of data on the occurrence of pharmaceuticals in surface
27 waters was also noted. The Committee recommends use of the data from the USGS, or any of
28 the numerous studies in the peer-reviewed literature, to include these chemicals. Also, the
29 Committee recommends that N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether
30 (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high priority for
31 consideration by the Agency, because there is a higher degree of certainty about their toxicity,
32 occurrence, and treatability.

33
34 The listing criteria for chemicals should consider including a parameter that evaluates
35 analytical methods used to quantify the chemical concentrations in occurrence data. Without a
36 “standard” method including an established limit of detection, the quality of the occurrence data
37 will reflect the capabilities of the analytical laboratories. The potentially significant differences
38 in the analytical capabilities should be a component of evaluating the occurrence data. As a
39 result, the Committee cautions against using the 90th percentile of the measured water
40 concentrations as the denominator in a potency-to-concentration ratio where the cut-off value for
41 listing is less than or equal to 10. It is clear that, for the very skewed distributions of
42 contaminant concentrations in water, some water utilities could be in a zone of concern, and the
43 chemical would still be screened off the list, using the existing, above-stated algorithm and
44 criterion for listing.

1 Pathogen Contaminants

2
3 Significant limitations in understanding which microbial pathogens were considered for
4 the CCL 3 list include: the lack of occurrence data; very limited surveillance for most of the
5 microbial pathogens; and the broad range of potential health effects. The CDC WBDO database,
6 for example, is widely acknowledged to be an incomplete reflection of the true number of
7 outbreaks. The WBDO does not capture the burden of disease relating to endemic pathogens
8 with lower level transmissions. Thus, the Committee recommends the acquisition of better data
9 on occurrence and surveillance regarding human disease. In general, given the small numbers of
10 pathogens, greater details from the data sets could be used, as well as endemic disease rates.
11 Data on occurrence is particularly poor, and thus the literature on surveys will require more
12 scrutiny. The Committee recommends that the same exceptions made for *Arcobacter* and MAC
13 in how a WBSO is defined should be applied to the other pathogens for which there is are high-
14 quality, peer-reviewed reports.

15
16 *Adenovirus* and *Mycobacteria* should be considered for inclusion in the CCL 3. As
17 discussed earlier, the weighting of documented outbreaks on health effects, and the approach
18 used regarding occurrence ranking, moved *Entamoeba* and *Vibrio* higher on the list. The
19 Committee recommends that information on endemic disease and occurrence in water, based on
20 the literature, be examined for *Adenovirus* and *Mycobacteria*. Health effect scoring should also
21 distinguish acute from chronic effects. The potential for pathogen occurrence in ambient waters
22 could be considered based on contaminants occurrence in wastewater (as described in the
23 previous sections). Thus, the Committee concludes that the data sets selected, the scoring
24 process used, and the poor occurrence information may have significantly influenced these
25 results. It is clear that the process can be improved.

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