



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 Committee) provide advice on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL 3) and the process used to derive it. EPA is required to publish this Contaminant Candidate List (CCL) every five years. This draft CCL 3 includes 93 chemicals or chemical groups and 11 microbiological contaminants that are known or anticipated to occur in public water systems. Contaminants on the CCL will be considered by the Agency for a regulatory determination.

The Committee believes that the process used to produce the draft CCL 3 represents an improvement over the former processes. While the draft CCL 3 uses a more data-driven and systematic approach, internal EPA expert panels were used to identify potential shortcomings of the data analysis, and ultimately, many decisions were still based on the expert judgment of EPA staff. The Committee views the current process as a first step toward a reformed CCL process, and acknowledges that, as recommended by EPA's National Drinking Water Advisory Council (NDWAC), the process should be designed as an adaptive process that will improve with further experience and data. The Committee's comments on the limitations of the current process should be viewed in this context.

The Committee believes that the documentation of processes that produced the draft CCL 3 still lacks transparency. EPA used professional judgments of its internal experts to revise the

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1 process in a way that was designed to change the contaminants on the list. The Committee was
2 not concerned that the process underwent mid-course corrections, because such changes are part
3 of the desired, adaptive assessment process. However, the Committee was concerned that these
4 modifications by Agency staff were not readily apparent in the current documentation. The
5 Committee expressed some concern that the lack of clarity could impede the ability of others to
6 understand the basis for decisions about the CCL, an enunciated criterion for transparency made
7 during the reviews by the National Research Council and NDWAC. The Committee also
8 recommends that EPA document and justify why certain contaminants which were included on
9 previous CCL lists were excluded from the draft CCL 3. This will improve readers'
10 understanding of the evolution of the process as well as its transparency.

11
12 In addition to increasing the transparency of the process, the Committee has
13 recommendations for improving the CCL selection process. The Committee believes that the
14 draft CCL 3 includes contaminants that should not be considered for regulation and excludes
15 contaminants that should be considered for regulation. For example for chemicals, the
16 Committee suggested that the EPA should evaluate whether pesticides that were about to be
17 cancelled completely should be on the list for additional SDWA regulation. This determination
18 could be made after some assessment of use, occurrence (transport and fate), and particularly
19 persistence, which will help to determine if the agent as used previously would have any ongoing
20 contamination issues. This will assist in the determination in whether the agent should be
21 regulated or not; in some cases, these types of pesticides may not require regulation. The
22 Committee recognizes that at least some evaluation of cancelled pesticides would be necessary so
23 as not to be shortsighted on the Agency's part. For pathogens, the Committee noted that two
24 globally important waterborne pathogens, *Adenovirus* and *Mycobacteria*, were excluded from the
25 draft CCL 3 and other pathogens, *Vibrio cholera* and *Entamoeba*, were included. Rare
26 outbreaks, and the outbreak data base in general, played a significant part in placement on the
27 list, and the Committee has suggestions both for the use of more of the publicly available data, as
28 well as for more comprehensive use of the databases already used in the CCL process. The
29 Committee acknowledges that any list will have some contaminants that a panel of experts would
30 prefer to add or to remove. Nonetheless, there was general agreement that the current process
31 could be improved to generate a better list.

32
33 The current process also does not evaluate some of the less direct, potential hazards of
34 contaminants. Exposure to antibiotics may lead to antibiotic resistant pathogens. The current
35 CCL process would not identify this impact as a threat to human health. Similarly, secondary
36 transmission of pathogens by vectors other than drinking water would also not be expected to be
37 detected as a problem through the current process.

38
39 The Committee believes that the draft CCL 3 may be too large to fulfill the objectives of
40 the Agency without prioritizing between the need for regulatory determination and the need for
41 collection of additional data. For some of the contaminants on the list, there is already ample
42 evidence of occurrence in public water supplies at concentrations that pose public health
43 concerns. In some cases, failure of the Agency to make regulatory determination on these
44 contaminants is causing uncertainty among utilities and has led to individual states setting action
45 levels or guidelines. To alleviate some of these uncertainties and to assure protection of public
46 water supplies throughout the entire nation, EPA needs to place a high priority on making

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1 regulatory determinations, or the collection of data critical to making final regulatory
2 determinations, as part of the CCL process. Many other contaminants on the draft CCL 3 have
3 been included mainly due to a lack of basic data on occurrence and toxicity. These contaminants
4 should be included in the CCL process. However, the purpose of listing these contaminants is
5 different and pertains mainly to the manner in which EPA allocates resources for toxicology
6 research and the collection of occurrence data.

7
8 Thank you for the opportunity to provide advice on this important process. The SAB
9 Drinking Water Committee looks forward to receiving your response regarding this advisory.

10
11
12 Sincerely,

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16
17 Dr. Deborah Swackhamer, Chair
18 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
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7 the Agency. This report has not been reviewed for approval by the Agency and, hence, the
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1 **Introduction**
2

3 The 1996 Safe Drinking Water Act (SDWA) Amendments require EPA to publish a list
4 of heretofore unregulated contaminants that are known or anticipated to occur in public water
5 systems and may require regulation in drinking water in order to protect public health. EPA is
6 required to publish this Contaminant Candidate List (or CCL) every five years. Following
7 publication of the first list (CCL 1) in 1998, the Agency requested a review of the CCL process
8 from the National Academy of Sciences' National Research Council (NRC), and their
9 recommendations were published in 2001. NRC proposed a broader, more reproducible process
10 to identify the CCL. In 2004, EPA's National Drinking Water Advisory Council (NDWAC)
11 provided suggestions on how to implement the NRC's recommendations to be used for the CCL
12 3. As this approach was being developed, the second list, CCL 2, was published in 2005. Based
13 on recommendations from NRC and NDWAC, EPA developed a more data-driven CCL
14 selection process which was used for development of the CCL 3. The Agency also requested
15 public nominations for chemical and microbial contaminants for the upcoming CCL 3.
16 Information regarding the CCL processes and lists can be accessed through the CCL web page
17 at: <http://www.epa.gov/safewater/ccl/index.html>.

18
19 Both the new process developed in response to the recommendations of the NRC and
20 NDWAC, as well as the specific chemicals and microbial pathogens on the draft CCL 3 list,
21 were subject to review. The charge questions posed by EPA were as follows.
22

- 23 1. Please comment on whether the Federal Register Notice and support documents are clear,
24 transparent, and adequate to provide an understanding of the overall processes and
25 selection of contaminants for the draft CCL 3.
26
- 27 2. Please comment on whether the draft CCL 3 list represents those contaminants that have
28 the highest potential to occur in public water systems and cause adverse human health
29 effects.
30
- 31 3. Please provide any data that may suggest that contaminants which are currently on the
32 draft CCL 3 list should not be listed.
33
- 34 4. Please provide any data that may suggest that contaminants which are currently not on
35 the draft CCL 3 list should be listed.
36

37 The Drinking Water Committee (hereafter, the DWC or Committee) of EPA's Science
38 Advisory Board (SAB) met in a public session on April 23 – 24, 2008 in Washington, DC, to
39 review the draft CCL 3. The Committee held a subsequent teleconference call on August 13,
40 2008 to discuss its draft advisory report. The first section of this report presents the general
41 comments and overall conclusions of the Committee. The second section discusses
42 recommendations for steps that will make the current process more transparent. The third
43 section provides suggestions to improve the process when it is used for future CCLs. In the
44 fourth section, recommendations with regard to specific contaminants are discussed. The fifth
45 section highlights emerging issues and research needs.

1 **1. General Comments from the Committee**
2

3 The Committee believes that the process used to produce the CCL 3 (EPA, 2008)
4 represents a major improvement from the processes used to generate CCL 1 and CCL 2. The
5 process used to generate the first two lists relied heavily upon expert opinion and best
6 professional judgment, as well as stakeholder nominations, with the potential health risk
7 contributing to the first part of the assessment followed secondarily by whether the contaminant
8 occurred in drinking water. The process for the CCL 3 outlined in the Federal Register Notice
9 (FRN; EPA, 2008) uses a data-driven, systematic approach, focusing on assessing the
10 information, including surrogate information to identify contaminants based on both the potential
11 or known occurrence in drinking water and their potential or known ability to cause adverse
12 effects in people. As recommended by the NRC and NDWAC, the CCL 3 process attempted to
13 address the Universe of contaminants and developed a Preliminary CCL (PCCL), using a more
14 data-driven process. Expert panels were used along the way as part of the review of the
15 approach. During the assessment, 6000 chemical contaminants and 1400 pathogens were
16 identified. The Committee views the current process as a first step toward this data-derived
17 CCL, and acknowledges that, as recommended by the NDWAC, the process should be designed
18 as an adaptive process that will improve and develop with further experience and data. The
19 Committee's comments on the limitations of the current process should be viewed in this
20 context.
21

22 There are numerous challenges that must be overcome when whittling the initial
23 "Universe" of contaminants down to a CCL. EPA has documented its decision-making process
24 and has described its attempts to identify biases in that process and to obtain expert feedback on
25 the process. In general, the approach is scientifically justified and, particularly for the chemical
26 list, is an intensified documented process and includes the development of models to create the
27 chemical list.
28

29 The Committee found that use only of the data-supported process of the CCL 3 (as
30 described in the FRN) generated a list of contaminants that was viewed as suboptimal. Based on
31 the changes made by EPA's panel of internal experts, the Committee infers that EPA's scientists
32 also agreed that expert judgment was necessary at this time for developing a CCL. Therefore,
33 EPA requested the opinions of internal experts for professional assessment of chemicals or
34 pathogens to revise the process and therefore the contaminants on the draft CCL 3. The
35 Committee was not concerned that, in developing the process, a review was needed and mid-
36 course corrections were undertaken. Rather, the Committee was more concerned that these
37 modifications (or suggestions) by Agency staff that were accepted or rejected were not readily
38 apparent as the Committee reviewed the documentation in the FRN. In addition, the
39 justifications for the decisions in which expert opinion was accepted or rejected were not
40 articulated. The Committee expressed some concern that the areas of the process without full
41 transparency could impede the ability of others to go through the same exercise as the EPA with
42 the same results when data drove the primary outcome and with a clear understanding of where
43 experts were used to address key decisions in the process. Such reproducibility was an
44 enunciated criterion for transparency made by the NRC and NDWAC.
45

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1 Moreover, this apparent lack of clarity or transparency in the process led to frustration as
2 Committee members attempted to determine why specific contaminants were retained or
3 removed from the group of contaminants that would become the draft CCL 3. Committee
4 members who tried to follow the decision-making process for one or more contaminants could
5 not do so. Some of the confusion arose from the previously mentioned role of EPA experts in
6 the process that was not clear to the Committee. Additionally, some of the information about
7 individual contaminants that had been organized by EPA was only available in the regulatory
8 docket. Committee members either did not know that the docket might contain that information
9 or had difficulty locating the docket and/or the information desired. The Committee
10 recommends that both the FRN and the EPA web sites contain citations for all of these
11 documents, and that the web site post the documents and/or hyperlinks directly to each
12 document, as well as the location of the regulatory docket.
13

14 In addition to improving the transparency of the process in the written documentation, the
15 Committee had recommendations for the existing and future CCL selection processes. These
16 suggestions were often based on concerns about contaminants that were either retained or
17 removed from the evolving CCL. In particular, an explanation should be included for those
18 contaminants that were on the CCL 1 or CCL 2 but were not included in the new list via the new
19 process, with the appropriate justification. The DWC acknowledges that any list of contaminants
20 would have some contaminants that each expert would prefer to add or to remove. Nonetheless,
21 there was general agreement that the current process could be improved to generate a list that
22 would contain fewer surprises. For example, members believed that even a cursory sensitivity
23 analysis could be used to improve the scoring systems and justify the cut-off points that were
24 used to retain contaminants. Also, knowledge about a pesticide's regulatory status under the
25 Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and Food Quality Protection Act
26 (FQPA), particularly whether or not cancellation of all or many uses has been completed or is
27 underway (e.g., molinate, the organophosphates), might obviate retention in a process designed
28 to determine whether regulatory action is necessary under SDWA. For example, in the draft
29 CCL 3, all uses of nitrofen were cancelled in 1983, with use of existing stocks phased out within
30 a few years. Depending upon Toxics Release Inventory (TRI) releases from just one site in one
31 year as a surrogate for exposure does not constitute a rationale for considering development of a
32 national drinking water standard. Pesticides that were no longer in use could be removed from
33 the list after some preliminary assessment to determine whether the agent previously used had
34 any ongoing contamination issues. This would include occurrence as well as fate and transport
35 data, and could be used to help determine whether the contaminant needed to be regulated or not
36 under SDWA. The Committee recognizes that at least some evaluation of cancelled pesticides
37 would be necessary, so as not to be shortsighted on the Agency's part.
38

39 The DWC further believes the list of chemicals on the CCL 3 is too large. Additional
40 priority ranking based on, for example, availability of data necessary for a regulatory
41 determination, should be undertaken before chemicals are selected for regulatory review. This
42 list serves to guide the future safety of drinking water via regulation, to focus research into
43 methods of water treatment, and to interface with other rules such as the Unregulated
44 Contaminant Monitoring Rule (UCMR). It is one of the most critical and important activities
45 within the EPA and thus certainly deserves the efforts that the Agency has devoted to it. The
46 final list must be viewed within that context.

1
2 The Committee members also had suggestions for the use of more of the publicly
3 available data and for the more comprehensive use of the databases already in the CCL 3. In
4 particular, information in the peer-reviewed, published literature could be effectively used at
5 certain junctures of the process, especially when the list of chemicals or pathogens considered
6 for a particular decision is sufficiently small to reduce the burden of a literature search and
7 retrieval. Similarly, the increasing use of wastewater affected sources of drinking water suggests
8 that databases containing information on contaminants in wastewater effluents would inform the
9 CCL process.

10
11 The Committee discussed specific ways in which the CCL process might need to be
12 modified in the future. For example, general exposure to antibiotics may lead to antibiotic-
13 resistant pathogens, but the current CCL process for chemicals would not identify this adverse
14 effect. Similarly, secondary transmission of pathogens by vectors other than drinking water
15 would also not be expected to be identified as a problem through the current process.

16
17 Finally, the Committee’s discussions highlighted emerging issues and research needs for
18 consideration by EPA for the future. This included, in particular, the identification and obtaining
19 of data that are appropriate for decisions that are necessary for the optimal operation of the CCL
20 process.

23 **2. Clarifications Regarding Steps In The Process That Will Make It More Transparent**

24
25 Obtaining the list of contaminants for the draft CCL 3 involved development of a new
26 contaminant-selection process. The goal of this process was to use data, not just expert opinion,
27 to derive the list of contaminants. The developing process and the available data affect each
28 other. Determination of the questions to be answered and the issues to be resolved identify the
29 essential data. Selection of the databases with specific attributes can determine whether
30 parameters are estimated directly or when surrogates must be used. Lack of readily available
31 data can constrain the decision options within the process. The DWC considered these aspects of
32 the CCL process, as well as their implications on the selection of chemicals and pathogens for
33 potential regulation.

34 35 Models and Selection Processes

36
37 The process of selecting the CCL 3 involved three major steps: (1) identifying the
38 “Universe” of contaminants that might be of concern; (2) using data on occurrence and potential
39 to cause adverse effects to obtain a “Preliminary Contaminant Candidate List” (PCCL); and (3)
40 using data, processes, and opinions from EPA’s internal experts to refine the selection into a
41 draft CCL. To improve transparency between CCL 2 and CCL 3, the Committee recommends
42 that EPA list all contaminants from CCL 2 that are not included in CCL 3, and provide the
43 reason the contaminant is not on CCL 3.

44
45 The improvements in the selection process that were recommended by EPA’s internal
46 experts are consistent with the theme of adaptive management recommended by NWDAC and

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1 endorsed in the FRN. Thus, the methodology for the listings can be adapted as more experience
2 with the CCL-listing process is gained. The use of internal EPA panels of experts to modify the
3 process, however, was not clear and transparent to the Committee members. These revised
4 procedures that were the basis for the recommended CCL 3 need to be more fully explained.
5 Furthermore, Committee members thought that the CCL 3 list, as modified by the internal
6 experts, might have been more acceptable if external experts' opinions had also been sought. A
7 schematic flowchart could be developed which shows where in the process experts (internal or
8 external) were used (see below).

9
10 *Chemical Contaminants*

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

25
26 The DWC suggests developing one or more flowcharts that a stakeholder can use to track
27 the progress of a contaminant through the system, with the appropriate references and URLs for
28 each step. Such flowcharts would not only make the process more transparent, but they might
29 also highlight decisions that might suggest improvements for future CCL processes. Also,
30 parameters chosen for the models, as well as the stopping rules or specification decisions, should
31 be provided (in more detail than is provided in Appendix E). To further improve the clarity of
32 the process, approaches that were discarded should be moved to the end of the document,
33 perhaps in an appendix. The training set used for calibration should be readily available in the
34 documentation via links to the web site.

35
36 The Committee noted that the draft CCL 3 gives equal weight to all chemicals, although
37 some chemicals are likely to be ready for regulatory determination, while others will require a
38 significant amount of additional research before a regulatory determination can be made.
39 Therefore, prioritization within the current CCL is considered important. Additional data and
40 processes should be used to priority rank those chemicals, by a method that will select chemicals
41 that have sufficient existing information for a data-based regulatory decision. Priority ranking
42 contaminants may also require reformulating or retraining the algorithms, since the dependent
43 variable of the algorithm must now indicate whether a contaminant should be studied for listing,
44 and with what urgency the contaminant should be studied.

1 The Committee also noted some deficiencies in presentation of the process. Details are
2 lacking, for example, as to how fate parameters like the octanol/water partition coefficients were
3 used in the evaluation. Also, all parameters should include the appropriate units, e.g., on LD₅₀
4 and related parameters in Exhibit 9.

5
6 *Pathogen Contaminants*
7

8 The process for selection of pathogen contaminants, as outlined in the FRN
9 documentation, was overall judged a relatively transparent one, however issues emerged with the
10 approach used that were not resolved. There was an analytical protocol employed; however, it
11 did not discretely quantify potency, for example, in terms of dose-response relationship as it had
12 for the chemicals proposed for CCL 3 inclusion. Nonetheless, there was much more of a
13 quantitative underpinning that was superior to previous CCL formulations that appeared much
14 more subjective. The sources of information and data that were used in candidate selection are
15 clear, and the effort to be inclusive in receiving information from non-government organizations
16 (NGOs), the public, professional organizations, and municipalities is apparent. The development
17 of the Universe and the PCCL were data driven. However, the resolution of the details of the
18 information that was used to assign a numerical rating to the pathogen was limited.

19
20 The process for moving pathogens from the PCCL to CCL is not sufficiently clear. In
21 particular, it is somewhat ambiguous as to how the ultimate pathogen scores for this process
22 were developed. For pathogens, it appears that the internal EPA experts adjusted the scoring
23 system. This adjustment should be presented more prominently. The Committee believes
24 decisions regarding the selection of data sets and resolution of the information within those data
25 sets (as discussed further in the next section) were partially responsible for the suboptimal
26 results. The Committee believes that the relative weighting of Center for Disease Control and
27 Prevention (CDC) Waterborne Disease Outbreaks (WBDO), “Occurrence,” and “Health Effect
28 Scoring,” as well as data normalization, is described, but not necessarily transparent. It is
29 recommended that the limitation of WBDO data sets be articulated clearly, for example, in
30 regard to underestimation of waterborne disease via a passive surveillance and the percentages of
31 outbreaks where no etiological agent is identified. Exhibit 15 shows evidence of WBDO using
32 the CDC surveillance database. Over the more than three-decade period in question, the scoring
33 system does not differentiate between pathogens that have caused many outbreaks and those that
34 caused only two outbreaks. Furthermore, scoring of the WBDO data does not appear to take into
35 account the geographic dispersion of the outbreaks. Also lacking are data on specific, identified
36 pathogens for the majority of studied outbreaks. Furthermore, a rudimentary sensitivity analysis
37 of the pathogen-weighting criteria would have demonstrated that the results are not robust to
38 small changes in the scoring. For example, a change of only "1" unit in WBDO score would
39 move some organisms on or off the list. Also, the use of “Occurrence” data does not appear to
40 be a quantitatively robust term, i.e., the 1-to-3 ranking scale may have less utility than initially
41 expected. An occurrence term of 3 appears only to mean that it has been found in U.S. drinking
42 water, but not that it is found with any type of frequency or geographic distribution in U.S.
43 drinking waters. In fact, a score of 3 may mean that it was only found once in drinking water.
44 Outbreak data were not independent of occurrence, as an outbreak would in and of itself suggest
45 that the organism had been found in drinking water and influenced that score. This gave the

1 WBDO a greater weight in the ranking. If it were only detected once, the exposure potential,
2 and therefore the risk, may be quite low.

3
4 Decisions Regarding Data Sets

5
6 In several places EPA appears to use data that may not be optimal for its stated intent of
7 offering equal protection to water consumers. For example, on page 9640 of the FRN,
8 prevalence is defined as "...the percent of public water systems or monitoring sites across the
9 nation with detections, number of states with releases..." Neither of these measures takes into
10 account the number of people who are potentially exposed to contaminants through these
11 drinking water systems. A contaminant that is found in two or three small states could receive
12 greater weighting than one found in a large, populous state. The reasons for and implications of
13 such decisions should be discussed.

14
15 *Chemical Contaminants*

16
17 EPA also used a hierarchical approach for data sources to indicate health effects. For full
18 transparency, the order in this hierarchy of references should be clearly presented. Furthermore,
19 for food-use pesticides, it would seem more appropriate to use the population-adjusted dose
20 (PAD), i.e., the dose that incorporates the additional uncertainty factor for children under the
21 FQPA, rather than the reference dose (RfD) in the calculation of a health reference level (HRL).
22 Therefore, the Committee recommends that the Agency recalculate the health-concentration
23 ratios for those pesticides on the PCCL that have PADs smaller than their respective RfDs. It is
24 possible that additional substances may qualify for inclusion on the draft CCL 3 because their
25 revised ratio could now be 10 or less.

26
27 *Pathogen Contaminants*

28
29 The data used (or more specifically, the data not used) and the resulting pathogens
30 selected, were not necessarily the optimal set to consider for regulation. For example, a choice
31 was made by EPA to primarily rely on national data sources and use only data sources with
32 entries (in this case, for recorded outbreaks) for all of the organisms. This led to heavy reliance
33 on CDC databases and lack of use of the peer-reviewed, published scientific literature. This
34 process does not necessarily represent the "best available science." While there was general
35 agreement that the existence of a WBDO should bring special attention to a microbial pathogen,
36 the WBDO grading system did not appear to be able to provide a resolution regarding details to
37 the scoring algorithm; thus, the full breadth or range of data available was not used. For
38 example, there is no resolution between organisms which have caused outbreaks in the Marshall
39 Islands [*Cholera*] and an organism that has caused several outbreaks in the continental U.S.
40 [norovirus and *Campylobacter*]. The potential problems caused by highly endemic diseases that
41 are never detected as outbreaks are not fully explained. A supplementary table containing the
42 published, waterborne-attributed, case reports for each of the organisms would be useful. There
43 is also a lack of data and discussion about the prevalence of organisms in sewage and
44 wastewater. As a result, organisms such as *Naegleria* or *Vibrio* may receive a pathogen PCCL
45 score higher than expected because of this weighting for "Occurrence," which is tied to whether
46 there has been an outbreak. An environmental frequency or distribution score for pathogens,

1 rather than or in addition to its “Occurrence” score, is needed. The ranking and the line that
2 separated the PCCL from the CCL seemed arbitrary and should be better described (Exhibit 18).

3
4 Perhaps what is less clear are the effects of the information that was not used in
5 developing candidates for CCL inclusion. As EPA is aware, the CDC represents the premier
6 organization in reporting disease statistics and occurrence for organisms typically associated
7 with waterborne disease. EPA has partnered well with CDC, including evaluating the likelihood
8 of disease outbreaks, as the consequences of global environmental change become manifest.
9 CDC also partners with many other organizations and associations in disease surveillance.
10 Perhaps most notable are state public health offices, responsible for first response in reporting
11 disease associated with water and food borne exposure. It is presumed that these data are
12 directly available to the EPA. CDC accesses a boarder base of data, which may or may not be
13 immediately available to the EPA, as data indicators for PCCL consideration. Some of these
14 sources include United States Geological Service (USGS) well monitoring programs, or the
15 National Environmental Health Association (NEHA). NEHA itself has many partner
16 organizations such as the Council for State and Territorial Epidemiologists (CSTE). Other
17 organizations such as the Bureau of Environmental Epidemiology (Florida) or the New York
18 City Department of Environmental Protection, Waterborne Disease Risk Assessment Program,
19 may prove useful, as other data or sentinel sources of information on outbreaks.

20
21 At the international level the United Nations Food and Agricultural Organization (UN-
22 FAO) and World Health Organization (WHO) monitor and report relevant outbreak and disease
23 incidence. Significantly the European counterpart to the CDC, the European Center for Disease
24 Prevention and Control (ECDC), continues to develop its waterborne disease and monitoring
25 program and makes data relatively available through its Enter-net databases for waterborne
26 disease organisms. It is likely the EPA is aware of all these sources, but it may wish to
27 investigate whether these and other information channels could facilitate more robust and
28 quantitative tools in assessment of PCCL consideration and CCL listing.

29
30 Peer reviewed research articles in journals and periodicals received less attention as data
31 sources than disease monitoring or surveillance data from other agencies, state, or municipal
32 sources. Given the relatively limited number of microbial pathogens proposed for inclusion on
33 the CCL, reviews of the scientific literature are desirable in addition to the sources that were
34 used to develop this draft CCL 3. Exceptions to the process whereby journal articles were used
35 for bacteria included publications on *Arcobacter* and *Mycobacterium avium* complex (MAC). It
36 is likely that other organisms would change position, if outside data and internal and outside
37 professional judgment were used. The literature may also be more current with respect to
38 sensitivity, selectivity, and specificity than those derived from some more standard methods.

39
40 There was discussion in the document about not using susceptibility to water treatment to
41 guide the selection list. This may be appropriate for the PCCL as well as the CCL. However, as
42 with the chemicals, prioritization and discussion should be addressed for the list created in regard
43 to investment in generating more data (on methods, occurrence, and health effects) or rule
44 development. Thus, if it is believed that the Long Term 2 Enhanced Surface Water Treatment
45 Rule (LT2ESWTR) or the Ground Water Rule (GWR), for example, already addresses risk
46 management for specific pathogens, this could begin to be articulated. It does not benefit public

1 health or water science to have a number of pathogens on a CCL that can just be taken off once
2 they are “controlled” without formally establishing an MCL or treatment technique. Thus, for
3 example, the large numbers of *Legionella* cases and the fact that no current regulatory approach
4 can be documented to reduce this risk may place this type of pathogen in a higher priority
5 category on the CCL.

7 Use Of The CCL For Regulatory Decisions

9 The CCL 3, as currently defined, serves two distinct purposes. The first is to identify
10 unregulated chemicals that might have sufficiently high occurrence and produce adverse effects
11 of concern that resources might be directed to obtaining more information. Toward this end,
12 either data on occurrence or data on adverse effects could lead to development of a regulatory
13 control. In contrast, the second goal is to select those contaminants that should be considered for
14 imminent regulatory action. In general, such action would require the existence of, rather than
15 the generation of, information on both occurrence and adversity. Priority setting should use this
16 criterion, as absent this information, future CCLs will not achieve their stated goal.

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

24 **3. Suggestions To Improve The Process For Future CCLs**

26 If EPA uses this process again, the Committee believes that it will be important to
27 incorporate the lessons learned in generating the next CCL. For example for chemicals, the
28 models will need to take into consideration the level of certainty, and also some measure of the
29 ratio between the level of concern and the potential drinking water level.

31 The databases used by the EPA in the CCL 3 analyses do not include much of the journal
32 literature that could be a rich source of information. While these sources might be difficult to
33 search for the “Universe” of chemicals, these data could more easily be included in the PCCL to
34 CCL process, especially for the limited number of pathogens. The use of advanced text-
35 processing software should be investigated for this application. E-government initiatives
36 throughout the federal government, as well as a lively and innovative academic community, are
37 potential sources of help for EPA in pursuing this approach. Similarly, use of available
38 computational toxicology data might improve the selection of chemical contaminants.

40 EPA should consider regulating chemicals with similar sources and mechanisms (or
41 modes) of action and microbial pathogens with similar potency and disease endpoints (for
42 example, diarrhea, pneumonia, or meningitis) as groups. The proposed CCL 3 list was
43 constructed with consideration only about individual chemicals and pathogens. Grouping has
44 been used for other drinking water contaminants (e.g., trihalomethanes and haloacetic acids)
45 because occurrence, health effects, and treatment options are related. In the draft CCL 3, (1)
46 perflourochemicals and (2) acetochlor, metolachlor, and their degradates are two examples

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1 where it may be helpful to list the compounds as a group. In both cases, not all of the
2 compounds in the group are released from the same source, nor would they likely always occur
3 together. However, within each group, users could substitute a non-regulated compound for a
4 regulated one and escape regulatory concern if these contaminants were not grouped.
5 Additionally, some groups of chemicals may need to be considered in different ways depending
6 on the goal of the analysis. For example, many nitrosamines have similar toxicities and
7 carcinogenicities. Therefore, they should be considered together when they co-occur in the same
8 drinking water samples when evaluating risk. If they do not occur together, if they can not be
9 used as substitutes, or if they require different treatment methods for removal, grouping for these
10 purposes is not recommended.

11
12 The Committee agreed that it will be important to consider information regarding
13 wastewater concentrations on the exposure side of the assessment. This will be important both
14 because wastewater discharges are increasingly a greater percentage of water supplies and
15 because they are being processed into potable water. Also, wastewater contains a wide variety of
16 contaminants including pharmaceuticals, personal care products, enteric pathogens, and other
17 emerging contaminants. In the case of pharmaceuticals, perflourinated surfactants, and other
18 contaminants that are prevalent in wastewater effluent, EPA may want to consider using data
19 obtained in wastewater effluent monitoring programs for the CCL screening process. Large
20 water systems may be subjected to significant discharges of wastewater effluent, and it is likely
21 that the concentrations of contaminants measured in wastewater effluent could be used as a
22 surrogate for concentrations in raw water. An approach for predicting the role of unplanned
23 wastewater reuse that may be appropriate for predicting concentrations in raw water sources is
24 presented in Anderson et al. (2004).

25
26 The listing criteria for chemicals should also consider including an element that evaluates
27 analytical methods used to quantify the chemical contaminant concentrations in occurrence data.
28 Without a “standard” method and an established detection limit, the quality of the occurrence
29 data will reflect the self-documented capabilities of the laboratories doing the analytical work.
30 There can be significant differences in the analytical capabilities of the laboratories that must be
31 accounted for when reviewing the occurrence data. As a result, some members of the Committee
32 cautioned against using the 90th percentile of the measured water concentrations in combination
33 with a 10-fold ratio. It is clear that, for the very skewed distributions of contaminant
34 concentrations in water, some water utilities could be in a zone of concern, and the chemical
35 would still be screened off the list, using the existing criteria and algorithm.

36
37 Significant limitations in understanding which microbial pathogens were considered for
38 the CCL 3 list include the lack of occurrence data, very limited surveillance for most of the
39 microbial pathogens, and the broad range of potential health effects. The CDC WBDO database,
40 for example, is widely acknowledged to be an incomplete reflection of the true number of
41 outbreaks, and it does not capture the burden of disease relating to endemic, lower level
42 transmission. Thus, the Committee considers its concerns regarding the pathogens selected for
43 the CCL 3 to be a signal for the acquisition of better data on occurrence and surveillance
44 regarding human disease. In general, given the small numbers of pathogens, greater details from
45 the data sets could be used as well as endemic disease rates. Data on occurrence is particularly
46 poor, and thus the literature on surveys will require more scrutiny. The Committee recommends

1 that same exceptions made for *Aerobacter* and MAC in how a WBSO is defined should be
2 applied to the other pathogens for which there is are high-quality, peer-reviewed reports.

3
4 Some contaminants that may be considered in the future may need a different algorithm
5 for the selection process. For example, concern about general exposure to antibiotics includes
6 the development of antibiotic-resistant pathogens that would not be measured in the current score
7 for adverse effects. Similarly, secondary transmission of pathogens and that effect on burden of
8 disease might require additional considerations. While the index case might be due to exposure
9 from drinking water, subsequent transmission might be by a variety of vectors. This issue is
10 neither discussed in the document nor addressed in the current process.

11
12 We recommend that EPA to include the DWC earlier in the process. Requesting advice
13 from the DWC throughout the process, and not just at the end, would allow EPA to take better
14 advantage of the expertise of the DWC.

15 16 **4. Contaminant-specific Recommendations**

17
18 The Committee members were surprised by some of the chemicals and pathogens that
19 made the list, and by some that did not. The members acknowledge that any procedure would
20 likely include contaminants that individual experts believe should or should not be included in
21 the CCL. Furthermore, the members did not attempt to recreate the CCL process. Nonetheless,
22 the Committee recommended reconsideration of certain aspects of the process that might
23 enhance the utility of the CCL.

24
25 The Committee experts in pathogens had not expected to see *Entamoeba histolytica* and
26 *Vibrio cholerae* on the CCL list, and they were surprised not to see *Adenovirus* or *Mycobacteria*.
27 As discussed earlier, the weighting of documented outbreaks on health effects, and the approach
28 used regarding occurrence ranking, moved *Entamoeba* and *Vibrio* higher on the list. If endemic
29 disease, numbers of outbreaks, and geographic locations and venues, as well as better assessment
30 on occurrence had been used, these two globally important waterborne pathogens would have
31 moved off the list for the U.S. Information on endemic disease and occurrence in water, based
32 on the literature, would have moved the *Adenovirus* and *Mycobacteria* on to the list. Expert
33 opinion, both internal and external, would likely have questioned *Vibrio* and *Entamoeba* on the
34 CCL. Other countries' environmental agencies look to the EPA's CCL. Thus, when the system
35 that is used reveals pathogens that are no longer considered waterborne disease risks in the U.S.,
36 the reasons for this should be addressed and the data based numerical approach should be
37 investigated and corrected. Health effect scoring should distinguish acute from chronic effects.
38 The potential for pathogen occurrence in ambient waters could be considered based on
39 contaminants occurrence in wastewater (as described in the previous selections). Thus, the
40 Committee believes that the data sets selected, the scoring process used, and the poor occurrence
41 information may have significantly influenced these results and it is clear that the process can be
42 improved.

43
44 The Committee experts in chemicals had not expected to see pesticides for which all uses
45 had been cancelled on the CCL (e.g., nitrofen; see earlier comment). Similarly, they questioned
46 the value of considering, for additional SDWA regulation, those pesticides for which

1 cancellation of all or many uses is in progress (e.g., molinate, the organophosphates). The
2 isomers of hexachlorocyclohexane that were on or off the list did not appear appropriate, and
3 other pesticides that did not appear on the CCL 3 that were mentioned as potentially worthy of
4 listing included some for which information was provided to EPA by public commenters. The
5 absence of data on the occurrence of pharmaceuticals in surface waters was also noted, and it
6 was thought that use of the data from the USGS, or any of the numerous studies in the peer-
7 reviewed literature, would have included these chemicals. Also, is a consensus among experts
8 that N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether (MTBE), perchlorate, and
9 perfluorooctanoic acid (PFOA) should be a high priority for consideration by the Agency,
10 because there is a higher degree of certainty about their toxicity, occurrence, and treatability. In
11 contrast, proposed CCL chemicals such as germanium, hexane, and quinoline appear to be on the
12 list mainly because they scored highly in one category (e.g., production volume for hexane and
13 toxicity for germanium). The Committee believes that these chemicals may be of a lower
14 priority for regulatory action at this time.

17 **5. The Future: Emerging Issues and Data Needs**

18
19 As discussed in the previous sections, the Committee concluded that the CCL 3 is a major
20 improvement on the previous CCL process. While some of the limitations may be overcome by
21 using existing data more effectively, the Committee recognizes that additional data would serve
22 to increase the effectiveness of selection of contaminants both for priority research and/or
23 possible regulation. Key areas to improve the process must be explored and addressed in the
24 future include: sensitivity analysis, data uncertainty, and data quality.

25
26 There are also some clear categories of contaminants that need special attention. These may
27 be on the PCCL or in the Universe. These include pharmaceuticals, personal care products,
28 endocrine disruptors, antibiotics, and algal toxins. Opportunistic pathogens (e.g., *Serratia* and
29 *Pseudomonas*) should also be addressed in the future, as waterborne disease in hospital settings
30 has been documented.

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