UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

January 29, 2009

EPA-SAB-09-011

The Honorable Lisa P. Jackson
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 Jackson,

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.

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

- For chemicals, the list is too large to achieve the stated objectives of the CCL process or to review by the DWC in the time allocated. To fulfill the Agency's objectives of choosing chemicals that have the greatest opportunity for improving the safety of drinking water and protecting public health, the Committee recommends additional prioritization of the current list. A shorter list will clarify which chemicals have a reasonable probability of being selected for regulatory determination.

- For pathogens, the waterborne disease outbreak data base was used to address both occurrence and health effects. This data base does not adequately address whether there is a substantial likelihood that the pathogen will occur in public water systems with a frequency and at levels of public health concern. The Committee recommends that occurrence be based on endemic disease data and published literature on occurrence.

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

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

Sincerely,

/Signed/ ***/Signed/***

Dr. Deborah L. Swackhamer, Chair
Science Advisory Board

Dr. Joan B. Rose, Chair
Drinking Water Committee

Enclosure

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Executive Summary

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

1. Please comment on whether the Federal Register Notice 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.

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

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

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

In regard to whether the Federal Register Notice (FRN, EPA 2008) 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, i.e., the FRN, is not transparent. Committee members with decades of experience reviewing and analyzing EPA regulatory documents could not follow specific contaminants through the process as presented in the FRN. The document is not clear. Interpretation by several Committee members of the published CCL 3 processes differed and were only clarified after discussion with EPA staff.** The lack of clarity in the process led to frustration, and Committee members who tried to follow the decision-making process for one or more contaminants could not do so. The Committee recommends that both the FRN and the EPA web sites contain citations for all documents used in the process, and that the web site post the documents and/or hyperlinks directly to each document, as well as the location of the regulatory docket.

The Committee recommends that EPA develop CCL 3 process flow charts for chemicals and pathogens. These flow charts should include links to other documents (data and models) used, as well as delineate where expert judgment was used to go from the universe of contaminants (Universe) to the Preliminary CCL (PCCL) to the CCL 3. Developing flowcharts that a stakeholder can use to track the progress of a contaminant through the system (with the appropriate references and URLs for each step) would not only make the process more transparent, but they might also highlight decisions that might suggest improvements for future CCL processes. The Committee also recommends that EPA document and justify why certain

contaminants that were included on previous CCL lists were excluded from the draft CCL 3. This will improve readers' understanding of the evolution of the process as well as its transparency.

In regard to whether the draft CCL 3 list represents those contaminants that have the highest potential to occur in public water systems and cause adverse human health effects, t**he CCL 3 does not clearly achieve the stated objectives of the CCL process for prioritization.** If the goal is to consider at least five contaminants per five-year review cycle for regulatory determinations, a process that yields 104 contaminants has not whittled the Universe sufficiently to be efficient or effective. Such a large list can not clearly communicate which contaminants might – or might not – be considered for regulatory determination. The Committee has several specific recommendations. For chemicals, explanations should be attached to each bullet (Section III.A.4; page 9644 of the FRN), as it moves from the PCCL to the CCL, so that the decision rules are more clearly explicated for the high, medium, and low uncertainty bins. It is further recommended by the Committee that EPA should "re-train" the model, this time using only chemicals that would fall into the medium certainty bin. Certainty and data should drive the prioritization of the contaminants, where there is sufficient information to make a regulatory determination. For pathogens, the cutoff for moving from the PCCL to the CCL 3 was arbitrary and not determined based on priority. The Committee recommends that occurrence based on endemic disease data and published literature on occurrence be used to modify the priorities/rankings of the pathogen PCCL.

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

- For chemical contaminants, the Committee recommends that EPA should evaluate whether pesticides that have been or are about to be cancelled completely should be on the list for additional SDWA regulation. This determination could be made after some assessment of use, occurrence (transport and fate), and particularly persistence, which will help to determine if the agent as used previously would have any ongoing contamination issues. This will assist in the determination of whether the contaminant should be considered for a regulatory determination or not. In some cases, these types of pesticides may not require additional regulation and should be excluded from the CCL process. The Committee recognizes that at least some evaluation of cancelled pesticides would be necessary.

- The Committee also recommends that N-nitrosodimethylamine (NDMA), methyl tertiary butyl ether (MTBE), perchlorate, and perfluorooctanoic acid (PFOA) should be a high

priority for consideration by the Agency, because there is a higher degree of certainty about their toxicity, occurrence, and treatability.

- For pathogenic contaminants, the Committee noted that two globally important waterborne pathogens, *Adenovirus* and *Mycobacteria*, were excluded from the draft CCL 3. These pathogens should be on the list. Other pathogens, *Vibrio cholera* and *Entamoeba*, were included and should be excluded from the list. Rare outbreaks, and the outbreak data base in general, were used in determining the ranking and placement on the CCL 3. The Committee recommends that endemic disease data sets, numbers of outbreaks, geographical distribution of outbreaks and outbreak venues, as well as the peer-reviewed literature (which would better inform occurrence in U.S. waters), be used for the pathogens. Both the use of more of the publicly available data, as well as more comprehensive use of the databases already used to develop the CCL process, would improve the ranking.

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

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

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

1.0 Background and Introduction

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

> "Section 1412(b) (1) of SDWA, as amended in 1996, requires EPA to publish the Contaminant Candidate List every five years. SDWA specifies that the list must include contaminants that are not subject to any proposed or promulgated NPDWRs, are known or anticipated to occur in public water systems (PWSs), and may require regulation under SDWA.
>
> "The 1996 SDWA Amendments also specify three criteria to determine whether a contaminant may require regulation:
>
> - The contaminant may have an adverse effect on the health of persons;
> - The contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
> - In the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems."

EPA's web page titled, "Drinking Water Contaminant Candidate List and Regulatory Determinations," (available at: http://www.epa.gov/safewater/ccl/ccl3.html#overview) states:

> "In developing the draft CCL 3, we implemented a different process from that used for CCL 1 and CCL 2. This new process builds on evaluations used for previous CCLs and was based on substantial expert input and recommendations from the National Academy of Science's National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC).
>
> "We used a multi-step CCL process to identify contaminants for inclusion on the draft CCL 3. The key steps include:
>
> - Identifying a broad universe of potential drinking water contaminants (called the CCL 3 Universe). We initially considered approximately 7,500 potential chemical and microbial contaminants.

- Applying screening criteria to the universe we identified 560 of those contaminants that should be further evaluated (the preliminary CCL or PCCL) based on a contaminant's potential to occur in public water systems and the potential for public health concern.

- We then selected 104 contaminants from the PCCL to include on the CCL based on more detailed evaluation of occurrence and health effects and expert judgment applied in a transparent reproducible manner.

- We incorporated information from the public, expert input, and expert review in the CCL process."

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

The DWC of EPA's SAB met in a public session on April 23 – 24, 2008 in Washington, DC, to review the draft CCL 3. The Committee held a subsequent teleconference call on August 13, 2008 to discuss its draft advisory report. The Chartered SAB conducted quality reviews of this document on October 28, 2008 in Washington, DC and approved the report on December 16, 2008 by teleconference.

2.0 EPA's Charge Questions

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

1. Please comment on whether the Federal Register Notice 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.

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

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

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

3.0 Response to Charge Questions

3.1 Charge Question 1

Please comment on whether the Federal Register Notice 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.

Committee Response

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

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

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

The Committee found that use of an only data-supported process, i.e., without professional judgment, for the CCL 3 (as described in the FRN) generated a list of contaminants that is suboptimal. Based on the changes made by EPA's panel of internal experts, the Committee infers that EPA's scientists also agreed that expert judgment was necessary at several points in the process for developing the CCL 3. Therefore, EPA requested the opinions of

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

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

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

The lack of clarity in the process led to frustration, as Committee members attempted to determine why specific contaminants on the PCCL were retained or removed from the group of contaminants that would become the draft CCL 3. **Committee members who tried to follow the decision-making process for one or more contaminants could not do so.** The process for selecting the chemicals was quite clear and logically presented until after the three models were run and the resulting lists were created. At that point, the presentation became very murky. Committee members expressed the difficulty in determining what supporting data were used for each of the chemicals that did get onto the list. For example, it is not shown what level of certainty "bin" each came from, what the data were in the exposure and health effects category, and what the modeled list-not list determinations were. A table presenting these results is recommended. In addition, it would be helpful to show similar results for at least a subset of the chemicals that remained on the PCCL, to help inform the reader as to why these were not

selected. The Committee specifically raised numerous questions about the bullet points in section 4 on p. 9644 of the FRN. It was not clear from the text that the 36 chemicals in the high certainty bin, for example, were included irrespective of the model results, whereas the 24 pesticides chosen from the medium certainty bin included only those with an "L" or an "L-L?" ranking. This information needs to be clarified. In addition, there needs to be a clearly written justification for diverging from the results of the model at the end of the process.

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

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

Other recommendations for the chemical selection process include:

- To further improve the clarity of the process, approaches that were discarded should be moved to the end of the document, perhaps in an appendix.

- The training set used for the initial calibration of the model for chemicals should be readily available in the documentation via links to the web site.

- Additional deficiencies should be corrected in the details of the presentation of the process. Details are lacking, for example, as to how fate parameters like the octanol/water partition coefficients were used in the evaluation.

- All parameters should include the appropriate units, e.g., on LD_{50} and related parameters in Exhibit 9.

The process for selection of pathogen contaminants, as outlined in the FRN, was overall judged a relatively transparent one. However, derivation of the relative numerical rankings was not clear. An analytical protocol was employed; however, it did not discretely quantify potency,

for example, in terms of dose-response relationship as it had for the chemicals proposed for CCL 3 inclusion. The sources of information and data that were used in candidate selection are clear, and the effort to be inclusive in receiving information from non-government organizations (NGOs), the public, professional organizations, and municipalities is apparent. The development of the Universe and the PCCL were data driven.

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

3.2 Charge Question 2

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

Committee Response

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

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

and addressed in the future include: sensitivity analysis of models and data; data uncertainty; and data quality.

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

3.2.1 Models and Selection Processes

Chemical Contaminants

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

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

Pathogen Contaminants

The process for moving pathogens from the PCCL to CCL does not sufficiently address priority of occurrence or of health impacts. In particular, it is somewhat ambiguous as to how the ultimate pathogen scores for this process were developed. For pathogens, it appears that the internal EPA experts adjusted the scoring system. **This adjustment by expert judgment should be presented more prominently, and the decision rules explained in more detail.** The Committee concludes decisions regarding the selection of data sets, and the level of resolution of the information within those data sets, was partially responsible for the suboptimal results. The relative weighting of Center for Disease Control and Prevention (CDC) Waterborne Disease Outbreaks (WBDO) "Occurrence" and "Health Effect Scoring", as well as data normalization, is described, but not necessarily adequate, for addressing the most important pathogens. The Committee recommends that the limitations of WBDO data sets be articulated clearly. Such limitations, for example, include underestimation of waterborne disease via a passive surveillance and the percentages of outbreaks where no etiological agent is identified. Exhibit 15 of the FRN shows evidence of WBDO using the CDC surveillance database. Over the more than three-decade period in question, the scoring system does not differentiate between pathogens that have caused many outbreaks and those that caused only two outbreaks. Furthermore, scoring of the WBDO data does not appear to take into account the geographic dispersion of the outbreaks. Also lacking are data on specific, identified pathogens for the majority of studied outbreaks. Furthermore, a rudimentary sensitivity analysis of the pathogen-weighting criteria would have demonstrated that the results are not robust to small changes in the scoring. For example, a change of only "1" unit in WBDO score would move some organisms on or off the list. Also, the use of "Occurrence" data does not appear to be a quantitatively robust term, i.e., the 1-to-3 ranking scale may have less utility than initially expected. An occurrence term of 3 appears only to mean that it has been found in U.S. drinking water, but not that it is found with any type of frequency or geographic distribution in U.S. drinking waters. In fact, a score of 3 may mean that it was only found once in drinking water. Outbreak data were not independent of occurrence, as an outbreak would by itself imply that the organism had been found in drinking water and influence that score. This interrelationship gave the WBDO a greater weight in the ranking. If the pathogen were only detected once, the exposure potential, and therefore the risk, may be quite low.

3.2.2 Decisions Regarding Data Sets

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

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

Chemical Contaminants

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

Pathogen Contaminants

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

The WBDO has several limitations that are not addressed in the FRN. This data base does not distinguish between an organism that has caused outbreaks in the Marshall Islands (*Cholera*) and an organism that has caused several outbreaks in the continental U.S. (norovirus and *Campylobacter*). The potential problems caused by highly endemic diseases that are never detected as outbreaks (and therefore not in the WBDO) are not fully explained by the Agency in the FRN. A supplementary table containing the published, waterborne-attributed, case reports for each of the organisms would be useful. There is also a lack of data and discussion about the prevalence of organisms in sewage and wastewater. As a result, organisms such as *Naegleria* or *Vibrio* may receive a pathogen PCCL score higher than expected because of this weighting for "Occurrence," which is tied to whether there has been an outbreak. An environmental frequency or distribution score for pathogens, rather than or in addition to its "Occurrence"

score, is needed. The ranking and the cut-off level that separated the PCCL from the CCL seemed arbitrary and should be better described (Exhibit 18).

The potential effect of the information that was not used is less clear. As EPA is aware, the CDC is the premier organization in reporting disease statistics and occurrence for organisms typically associated with waterborne disease. EPA has partnered well with CDC, including evaluating the likelihood of disease outbreaks, as the consequences of global environmental change become manifest. CDC also partners with many other organizations and associations in disease surveillance. Perhaps most notable are state public health offices, responsible for first response in reporting disease associated with water and food-borne exposure. EPA should explore methods for accessing such data. CDC accesses a broader base of data, which may or may not be immediately available to the EPA, as data indicators for PCCL consideration. Some of these sources include United States Geological Service (USGS) well-monitoring programs, and the National Environmental Health Association (NEHA). NEHA also has many partner organizations such as the Council for State and Territorial Epidemiologists (CSTE). Other organizations such as the Bureau of Environmental Epidemiology (Florida) or the New York City Department of Environmental Protection, Waterborne Disease Risk Assessment Program, may prove useful, as other data or sentinel sources of information on outbreaks.

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

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

There was discussion in the FRN about not using susceptibility to water treatment to guide the selection list. This may be appropriate for the PCCL as well as the CCL. However, as with the chemicals, further prioritization is recommended for the CCL 3 with regard to sufficiency of the data for regulatory determination as compared with investment in generating more data (on methods, occurrence, and health effects). For example, if the Agency demonstrates that the Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) or the Ground Water Rule (GWR) already address risk management for specific pathogens, this fact

could be articulated and influence selection for the CCL. Neither public health nor water science benefits from having a number of pathogens on a CCL that can readily be removed once they are formally articulated as "controlled", when is no need to formally establish an MCL or treatment technique due to current drinking water treatment which reduces the risk already. The large numbers of *Legionella* cases, and the fact that no current regulatory approach can be documented to reduce this risk, for example, suggest that this type of pathogen be given a higher priority on the CCL.

3.2.3 Use of the CCL for Regulatory Decisions

The CCL 3, as currently defined, serves two distinct purposes. The first is to identify unregulated contaminants that might have sufficiently high occurrence and produce adverse effects of concern, so that resources might be directed to obtaining more information. Toward this end, either data on occurrence or data on adverse effects could lead to development of sufficiency to move to a regulatory determination. In contrast, the second goal is to select those contaminants that should be considered for imminent regulatory determination. In general, such action would require the existence of, rather than the generation of, information on both occurrence and health effects. Priority setting within the draft CCL 3 should use such criteria. Absent this prioritization, the CCL 3 will not achieve its stated goal.

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

3.3 Charge Question 3

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

Committee Response

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

The DWC concluded that the list of chemicals on the CCL 3 is too large and that it may be appropriate for some to remain on the PCCL. Additional priority ranking based on, for example, availability of data necessary for a regulatory determination, should be undertaken. The CCL serves both to guide the future safety of drinking water via regulatory determinations, to focus research (into methods for detection, methods of water treatment, and assessing health

effects), and to interface with other rules such as the Unregulated Contaminant Monitoring Rule (UCMR). It is one of the most critical and important activities within the EPA and thus certainly deserves the efforts that the Agency has devoted to it. The final list must be viewed within that context.

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

Knowledge about a pesticide's regulatory status under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and FQPA, might obviate retention in a process designed to determine whether a regulatory determination is necessary under SDWA. Cancelled pesticides, or those for which cancellation is underway, should be considered differently than those expected to be used for a longer time. For example, all uses of nitrofen (which is on the draft CCL 3) were cancelled in 1983, and existing stocks were depleted within a few years. It appears that nitrofen is on the draft CCL 3 because it was listed as a Toxics Release Inventory (TRI) release from just one site in just one year. The Committee does not agree that such limited data constitutes an appropriate surrogate for exposure for decisions regarding decision on the development of a national drinking water standard. Similarly, the Committee questions the value of considering, for additional SDWA regulation, those pesticides for which cancellation of all or many uses is in progress (e.g., molinate and some organophosphates). The Committee recognizes that at least some evaluation of cancelled pesticides would be necessary, so as not to be shortsighted on the Agency's part. The Committee recommends that pesticides no longer in use should be removed from the CCL unless an assessment determines that they present ongoing contamination issues such as: (1) the potential longevity of pesticides in ecosystems; or (2) fate and transport data. In addition, proposed CCL chemicals such as germanium, hexane, and quinoline appear to be on the list mainly because they scored highly in one category (e.g., production volume for hexane and toxicity for germanium). The Committee recommends that such chemicals not be considered for regulatory determinations at this time.

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

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

3.4 Charge Question 4

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

Committee Response

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

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

EPA should consider addressing the cumulative effects of chemicals with similar sources and mechanisms (or modes) of action, and microbial pathogens with similar potency and disease endpoints (for example, diarrhea, pneumonia, or meningitis). The draft CCL 3 was constructed with consideration only about individual chemicals and pathogens. Grouping has been used for other drinking water contaminants (e.g., trihalomethanes and haloacetic acids) because occurrence, health effects, and/or treatment options are related. In the draft CCL 3, (1) perflourochemicals and (2) acetochlor, metolachlor, and their degradates are examples where it may be helpful to list the compounds as a group. Not all of the compounds in the group may be released from the same source, nor would they likely always occur together. A group could

consist of "exposure groups" similar in sources, transport, or solubility. Similarly, "health groups" would be composed of contaminants with similar toxicity or adverse health effects. Thus, some agents not on the CCL 3 would join their appropriate groups. Additionally, the Committee recommends that EPA consider groups of chemicals where only some have been considered for regulation because others are not yet in common use. The Committee is concerned that, if the group is not considered as a whole, users could substitute a non-regulated chemical for a regulated one and, thus, escape regulatory concern. Some groups of chemicals may need to be considered in different ways depending on the goal of the analysis. For example, many nitrosamines have similar toxicities and carcinogenicities. Therefore, they should be considered together when they co-occur in the same drinking water samples when evaluating risk. If they do not occur together, if they can not be used as substitutes, or if they require different treatment methods for removal, grouping for these purposes is not recommended.

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

The Committee recommends that EPA include the DWC earlier in the process. Requesting advice from the DWC at critical junctures throughout the process (e.g., when decisions are being made to modify the initially established process), and not just at the end, would allow EPA to take better advantage of the expertise of the DWC.

Chemical Contaminants

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

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

Pathogen Contaminants

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

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

4.0 References

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Enclosure A

Drinking Water Contaminant Candidate List 3 - Draft
Charge to the EPA Science Advisory Board
March 10, 2008

Overview

On February 21, 2008, EPA announced its third drinking water Contaminant Candidate List (CCL 3). The purpose of this action was to:

- present EPA's draft list of contaminants listed on the third CCL (CCL 3);
- describe the process and basis for selecting the contaminants for the CCL 3; and
- request public comments on the draft CCL 3.

EPA's Office of Water seeks advice from the Science Advisory Board Drinking Water Committee (DWC) regarding the draft CCL 3. Specific charge questions are presented below in addition to background information regarding the development of the CCL3.

Background

The 1996 SDWA Amendments require EPA to publish a list of currently unregulated contaminants which are known or anticipated to occur in public water systems and may require regulation in drinking water. This list is known as the Contaminant Candidate List (or CCL) and SDWA requires EPA to publish the list every five years. Two such lists have already been developed and were published in 1998 and 2005. The Act also requires "consultation with the scientific community, including the Science Advisory Board," prior to publishing the CCL. SDWA also requires that EPA make determinations on whether to regulate at least five contaminants from the list with a national primary drinking water regulation (also on a five year cycle).

In 1998, the Agency sought advice from the National Academy of Sciences' National Research Council (NRC) on how to improve the CCL process. The NRC published its recommendations on the CCL process in 2001. The NRC proposed a broader, more reproducible process to identify the CCL than the process used by EPA in the first CCL. The NRC recommended that EPA develop and use a multi-step process for creating CCL 3 and future CCLs, whereby a broadly defined "universe" of potential drinking water contaminants is identified, assessed, and reduced to a preliminary CCL using simple screening criteria. All of the contaminants on the PCCL would then be assessed in more detail using a classification tool to evaluate the likelihood that specific contaminants could occur in drinking water at levels and at frequencies that pose a public health concern.

In 2002, the Agency sought input from the National Drinking Water Advisory Council (NDWAC) on how to implement the NRC's recommendations to improve the CCL process. NDWAC is comprised of members from the general public, State and local agencies, and private groups concerned with safe drinking water. It advises the Administrator on key aspects of the Agency's drinking water program. NDWAC agreed that EPA should proceed with the NRC's recommendations and provided some additional considerations, including the overarching

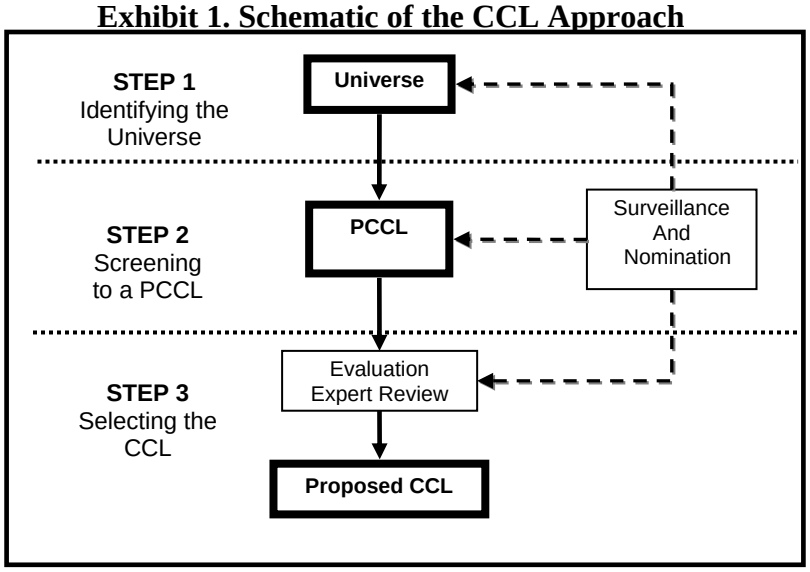
principles the Agency should follow. The NDWAC issued its recommendations in "The National Drinking Water Advisory Council Report on the CCL Classification Process to the U.S. Environmental Protection Agency."

In October of 2006 EPA requested the public to nominate chemical and microbial contaminants that should be considered for CCL 3 in the Federal Register. The Agency compiled the information from the nominations process to identify the contaminants nominated, the rationale for the nomination, and to compare the supporting data to information already gathered by EPA. The nominations process identified 150 chemical and 24 microbial contaminants from 11 organizations and individuals. Only 29 of the 174 nominated contaminants were not already identified in the CCL process. Each of the 174 nominated contaminants was then evaluated in the CCL process.

Chemicals

EPA implemented a multi-step process (as shown in Exhibit 1) to develop the draft third CCL (CCL 3). The multi-step process includes the following primary phases:

Exhibit 1. Schematic of the CCL Approach



Step 1: Identifying the Universe. Building a broad CCL Universe of potential drinking water contaminants for consideration EPA identified and evaluated 39 data sources with information on contaminant health effects and occurrence. The resulting "CCL Universe of Chemicals" consisted of approximately 6,000 chemicals from these data sources.

*Step 2: Screening the Universe of Chemicals to a PCCL***.** EPA developed conservative criteria to screen chemicals with health effects and occurrence data elements at levels of concern in order to narrow the Chemical Universe to a Preliminary CCL (PCCL) of 532 chemicals. EPA used conservative criteria to narrow the universe and identify contaminants with greater potential to occur in drinking water and greater potential for public health concern for further evaluation. EPA selected form several data elements to represent a chemical's potential to occur in drinking water and its potential to cause health effects on humans.

Step 3: Classifying the PCCL to Develop a Proposed. CCL. EPA further analyzed and prepared the PCCL chemicals for the classification approach and the development of the proposed CCL. EPA developed an approach for classifying potential drinking water contaminants that uses decision support tools to aid in the development of the CCL. EPA chose four attributes; Potency, Severity, Prevalence, and Magnitude, as its key factors in evaluating chemicals. EPA developed attribute scoring protocols to normalize the available data for the various types of available data. This relative assessment of contaminants used different data measures and defined scoring mechanisms for potential drinking water contaminants. The scores were then used as input for classification models calibrated using regulated contaminants. This approach ensured that attributes were used and applied consistently among potential contaminants. Using the structured classification approach (e.g., a classification model) as a tool, along with expert judgment, EPA evaluated the results from the classification models to select contaminants for the draft CCL.

Microbial Pathogens

EPA's approach in establishing the draft CCL3 builds on the NRC and NDWAC recommendation to generate, assess, and reduce a universe of microbial pathogens to formulate a subset of microorganisms that would constitute the CCL. The universe for CCL3 includes a survey of human pathogens published by Taylor *et al.* and pathogens nominated to EPA from the public Nominations process. Screening criteria are used to indicate the potential for waterborne transmission and identify microorganisms to move to the PCCL. A classification approach and tools along with expert judgment were used to evaluate the likelihood that specific microbial pathogens could occur in drinking water at levels and at frequencies that pose a public health risk. For example, all of the contaminants on the PCCL are assessed using attributes (e.g., waterborne disease outbreaks, occurrence, health effects) to characterize the potential for the microbial pathogen to occur in PWS, cause waterborne disease outbreaks and adverse health effects. The outcome of the detailed approach resulted in the microorganisms on the draft CCL 3.

Past Reviews

EPA convened several external expert panels at integral stages during the development of the Draft CCL 3. Five separate panels reviewed the draft chemical CCL 3 list, the microbial CCL 3 list, and the processes used to develop them. EPA sought to convene panels that included members that had a variety of disciplines and expertise. Panel members were encouraged to provide comments based upon their expertise and background and provide comments as individuals, not as representatives of their respective organizational affiliations. The results from these panels are discussed in the *Federal Register* Notice and documented in the EPA Water Docket.

Charge to Reviewers

Review Draft CCL 3 and the specific chemicals and microbial pathogens on the list with a focus on the following questions:

5. Please comment on whether the Federal Register Notice 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?

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

7. Please provide any data that may suggest that contaminants which are currently on the draft CCL3 list should not be listed?

8. Please provide any data that may suggest that contaminants which are currently not on the draft CCL3 list should be listed?