Chemical Expert Input and Review for the Third Contaminant Candidate List

Office of Water (4607M) EPA 815-R-08-0009 February 2008 – Draft www.epa.gov/safewater

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List of Acronyms and Abbreviations

≤	Less than or equal to
CCL	Contaminant Candidate List
CCL 1	EPA's first contaminant candidate list
CCL 2	EPA's second Contaminant Candidate List
CCL 3	EPA's third Contaminant Candidate List
EPA	United States Environmental Protection Agency
HRL	Health reference level
LD_{50}	Lethal dose 50; an estimate of a single dose that is expected to cause the death of 50 percent of the exposed animals; it is derived from experimental data.
LOAEL	Lowest observed adverse effect level
NAS	National Academy of Sciences
NDWAC	National Drinking Water Advisory Council
NOAEL	No observed adverse effect level
OGWDW	Office of Ground Water and Drinking Water
RfD	Reference Dose
SDWA	Safe Drinking Water Act
TDS	Training Data Set
US	United States of America

1.0 Introduction

As part of the process of establishing a chemical Contaminant Candidate List (CCL), the U.S. Environmental Protection Agency (EPA) sought expert input on its approach to identifying and prioritizing contaminants. On March 21 and 22, 2007, an expert panel convened in Washington, D.C. at EPA Headquarters to provide input and review of the draft CCL3 chemical prioritization process. A panel of 6 experts was selected based on their experience in the fields of public health, toxicology, and epidemiology; and familiarity with the Safe Drinking Water Act regulations and the CCL regulatory process. This document provides a summary of the proceedings of the two-day workshop, organized and facilitated by Horsley & Witten, Inc. The workshop agenda is included in section 4.0 of this report.

2.0 Background

The Safe Drinking Water Act (SDWA) includes a process that the EPA must follow to identify new contaminants that may require regulation. According to the SDWA, EPA must periodically release a CCL of unregulated contaminants that are known to or anticipated to occur in drinking water at levels that may pose a risk to public health; and therefore, may require regulation. EPA typically conducts an extensive research and data collection effort, and solicits comments from experts and the general public (via the Federal Register), on unregulated contaminants to develop a CCL. These contaminants are then further evaluated by EPA to determine whether they should be regulated. When making this determination, the SDWA specifies three criteria to determine whether a contaminant may require regulation:

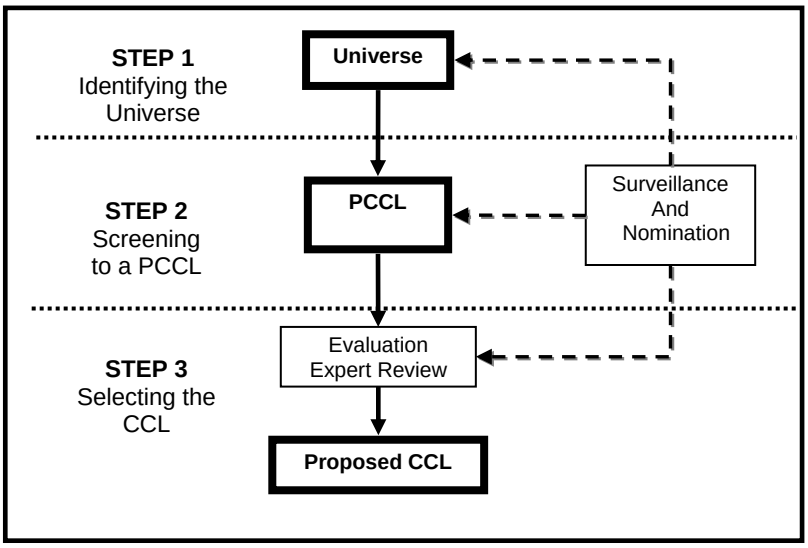
- the contaminant may have an adverse effect on the health of persons;
- the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and
- in the sole judgment of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The first CCL (CCL1), established in March of 1998, contained 60 contaminants (50 chemical and 10 microbial) that were chosen based on expert opinion. EPA then made their regulatory determinations on the CCL1 and ultimately decided ***not*** to regulate 9 contaminants, based on their evaluation of "significant risk reduction" as described in the SDWA. The second CCL (CCL2), established in February 2005, carried forward the remaining 51 contaminants from CCL1 (9 microbiological contaminants and 42 chemical contaminants). During this time, EPA provided an update on the Agency's work to improve future CCL review processes that is based, in part, on recommendations from the National Research Council (NRC) and the National Drinking Water Advisory Council (NDWAC).

NDWAC and the National Academies of Science (NAS) proposed a broader, more comprehensive evaluation process than previously utilized by EPA to assist the Agency in identifying contaminants for the CCL. They recommended that EPA develop and use a process

for creating future CCLs. As a result, a broad universe of potential drinking water contaminants were established, assessed, and reduced to a preliminary CCL (PCCL), using simple screening criteria. The screening criteria indicate public health risk and the likelihood of occurrence in drinking water. All of the contaminants on the PCCL would then be assessed in more detail using a classification approach and tools, along with expert judgment, to evaluate the likelihood that specific contaminants could occur in drinking water at levels and at frequencies that pose a public health risk. The outcome of the detailed classification approach results in the draft CCL. Exhibit 1 provides a flow chart below outlines this new process:

Exhibit 1: Schematic of CCL 3 Classification Process



EPA developed the third CCL (CCL3) using the new procedures described above. During this process, they identified 284 data sources for consideration in the CCL3 process, including some contaminants from the CCL2. Each universe (microbial and chemical) was narrowed down to a PCCL using simple screening criteria, based on a contaminant's potential to occur in water systems and to cause adverse human health effects.

EPA identified and evaluated 39 data sources with information on contaminant health effects and occurrence. EPA identified a "CCL Universe of Chemicals" consisting of approximately 6,000 chemicals from these data sources. EPA used several data elements to represent a chemical's potential to occur in drinking water and its potential to cause health effects on humans, including measured concentrations in water, amount released to the environment, amount produced, and persistence in water. The data elements also included measured toxicity values such as the reference dose (RfD), carcinogenicity values, the lowest or no observed adverse effect levels (LOAEL or NOAEL), lethal dose (LD_{50}), and categorical cancer data. EPA developed criteria to screen chemicals with health effects and occurrence data elements at levels of concern in order to narrow the Chemical Universe to a PCCL of 532 chemicals.

Using the NRC/NDWAC recommendations, EPA developed an approach for classifying potential drinking water contaminants that uses decision support tools to aid in the development of the draft CCL. EPA chose four attributes; Potency, Severity, Prevalence, and Magnitude, as its key decision criteria in evaluating chemicals. The approach ensured that key decision criteria were used and applied consistently among potential contaminants, when deciding whether or not to list a contaminant on CCL. In order to evaluate, categorize, and prioritize the PCCL contaminants in selecting the CCL, one must be able to interrelate the data that represent measures of the attributes. This relative assessment using different data measures involved the need to normalize the available data by developing scales for the various types of attribute data, and scoring mechanisms (Attribute Scoring Protocols) for potential drinking water contaminants.

EPA developed, tested, and evaluated the results of several classification models to assess their usefulness and identify which ones might provide the best decision support tools. Classification models are often described as pattern recognition algorithms. These models develop statistical relationships (to recognize patterns) among input variables (Attributes) of drinking water contaminants to predict their classification (List-Not List). To evaluate the classification models, EPA developed a data set, called the "training data set" (TDS), to train or teach the models to mimic List-Not List decisions made by experts. The classification algorithm develops the relationship, or rule, for the classification model based on the decisions made on the TDS. After the attributes for the PCCL contaminants are scored, the classification model is then used to classify PCCL contaminants into List-Not List categories and develop the draft CCL.

3.0 Project Summary

The goal of this project was to obtain expert input on the approach EPA is using to establish the chemical CCL3. Specifically, the focus of this review was to provide comment on the draft list of chemical contaminants, the screening process, and scoring protocols used to establish the list. Horsley & Witten, Inc. was contracted by EPA to coordinate the expert review of the CCL3 for chemical contaminants. A pool of potential experts recommended by their peers from national drinking water organizations such as the American Public Health Association, Association of State Drinking Water Administrators, National Science Foundation, and universities with strong public health and medical programs were evaluated.

Horsely & Witten selected 6 experts to participate in the chemical review. Experts were selected based on their experience in the fields of public health, toxicology, and epidemiology; their familiarity with the Safe Drinking Water Act regulations and the CCL regulatory process; as well as their level of interest. Horsely & Witten organized and facilitated a two-day chemical workshop that was held in Washington, D.C. at EPA Headquarters (March 21- 22 2007), where the experts served on panels to discuss their findings regarding the draft CCL3 chemical process. The workshop agenda is included in this report under the workshop section.

Experts received an organized packet of information prior to the workshop, which included the workshop agenda and all CCL3 associated materials including documentation of the compilation of the CCL Universe, screening process, scoring process, and contaminant dossiers. Experts answered all questions posed by EPA and engaged in productive discussions regarding contaminants and whether the draft CCL lists developed by EPA were acceptable, based on the screening and scoring process. A detailed summary of the workshop is included in this document.

4.0 Chemical Workshop

Exhibit 2: Meeting Agenda for Wednesday, March 21 - Thursday, March 22, 2007

DAY 1		
Time	**Topic**	**Speaker**
9:00 – 9:30 AM	Introductions Welcome	Facilitator: Mark Nelson, Horsley Witten, Inc. Pamela Barr, Director, Standards and Risk Management Division, EPA Office of Ground Water and Drinking Water (OGWDW)
9:30 - 10:00 AM	Meeting Objectives, Procedures, and Logistics	Mark Nelson, Facilitator
10:00 – 10:15 AM	Overview of the CCL 3 Approach	Yvette Selby-Mohamadu, EPA OGWDW
10:15 – 10:30 AM: BREAK		
10:30 – 11:15 AM	Overview of the CCL3 Chemical Universe to Preliminary CCL (PCCL)	Yvette Selby-Mohamadu, EPA OGWDW
11:15 – 12:30 AM	Overview of the CCL3 PCCL to the CCL	Zeno Bain and Michael Messner, EPA OGWDW
12:30 – 1:30 PM: LUNCH		
1:30 – 2:15 PM	EPA Internal Evaluation Review Process	Joyce Donohue, OST, EPA
2:15 – 4:45 PM **Including Break**	Present and Discuss Charge Questions *Are there other factors that should be considered, as part of post-Model processing, in deciding on the Preliminary Draft CCL 3?* *Are you in agreement with how EPA evaluated uncertainty and types of data used for occurrence (i.e., finished water, ambient water, release, and production volume data) and health effects (i.e., RfD or equivalent, cancer slope factor, NOAEL, LOAEL, and LD_{50}) in constructing the Preliminary Draft CCL 3?*	Experts
4:45 – 5:00 PM	Wrap-Up	Mark Nelson

DAY 2		
Time	**Topic**	**Speaker**
8:00 – 8:15 AM	Review of Previous Day & Agenda for Day 2	EPA OGWDW
8:15 – 11:30 AM ***Including Break***	Discuss Charge Questions (continuation) Does the Preliminary Draft CCL 3 chemical list represent those contaminants that have the highest potential to occur in public water systems and cause adverse human health effects? *Are there chemical contaminants on the Preliminary Draft CCL 3 list that **should not** be listed?* *Are there chemical contaminants not on the Preliminary Draft CCL 3 list that **should** be listed?* *Do you agree with EPA's assumption that the CCL is also a vehicle for identifying chemicals that are regional or local problems and require new or updated health advisories?*	Experts
11:30 – 12:30 PM: LUNCH		
12:30 – 4:30 PM ***Including Break***	Complete Discussion of Charge Questions	Experts Facilitated by Mark Nelson
4:30 – 5:00 PM	Wrap-Up	Mark Nelson

Introduction - Mark Nelson, Horsley & Witten, Facilitator

Expert Panel:
Caroline Baier-Anderson, Ph.D., University of Maryland & Environmental Defense
Shane Snyder, Ph.D., Southern Nevada Water Auth.
Ann Marie Gebhart, Ph.D., Underwriters Laboratories
John Gaston, P.E., CH2M HILL Consultants
Lloyd R Wilson, Ph.D., New York State Department of Health
Michael J Focazio, Ph.D., U.S. Geological Survey

Welcome – Pamela Barr, Director, EPA Standards and Risk Management Division

Ms. Barr discussed the background of the chemical CCL 3. The contaminants on the list are known or anticipated to occur in drinking water and are most likely to cause public health concerns. EPA agreed with the NAS recommendation on how the review process should be transparent, reproducible, and comprehensive. Ms. Barr explained that the reviewers' goal for this workshop is to review the draft list to see if they agree with EPA's conclusions regarding the contaminants.

Ms. Barr reminded the group that the list, and the other workbook materials they received are internal agency deliberative documents and asked the reviewers not to cite or distribute the information. She explained that EPA is looking for individual expertise, not information from the viewpoint of reviewer's organizations. Ms. Barr stated that EPA planned to publish the draft list in the Federal Register in February 2008, and the final list is expected to be completed in August of 2009.

Overview of the CCL 3 Approach – Yvette Selby-Mohamadu, EPA Office of Ground Water and Drinking Water

Ms. Selby-Mohamadu provided an overview of EPA's approach to the CCL 3 process. She stated that the approach is focused on finding a balance between health effects and occurrence. The first three steps of the process are data-driven, so there remains the possibility that contaminants lacking toxicity and/or occurrence data may get overlooked. The surveillance and nominations process is a significant component to the process to catch emerging contaminants and/or contaminants that may have lacked data in the data sources used in the first three steps. Ms. Selby-Mohamadu specified that the focus of this workshop is on the selection of a CCL 3 based on the model output.

Overview of the CCL 3 - Chemical Universe to Preliminary CCL 3 (PCCL 3) – Yvette Selby-Mohamadu, EPA Office of Ground Water and Drinking Water

Ms. Selby-Mohamadu described EPA's process of selecting the PCCL 3 from the CCL 3 chemical universe. The first step was building a universe of data sources to be used to define the universe of chemicals. Each data source was reviewed for the following:

- Relevance (does this data source contain demonstrated or potential health effects or occurrence or surrogate information?);
- Completeness (does this data source have the minimum requirements – contact name, description of the data elements, and how the data were obtained, and how the data were obtained?);
- Redundancy (does this data source contain identical information as other more comprehensive sources?); and
- Retrievability (is the data in this source formatted for automated retrieval?).

Once the CCL 3 chemical data source universe was built, the CCL 3 universe of chemicals was determined, based on the quality and quantity of health effects and occurrence data within these data sources. In total, approximately 6,000 chemicals were chosen for the chemical universe. The chemicals within the CCL 3 universe were then categorized by toxicity and occurrence. The health effects and occurrence categories were used to develop a screen separating chemicals that would pass to the PCCL from those that would remain in the universe. After completion of the data screening, approximately nine percent of the CCL universe made it into the draft PCCL.

Overview of the CCL 3 - PCCL 3 to CCL 3 – Zeno Bain and Michael Messner, EPA Office of Ground Water and Drinking Water, Joyce Donahue, EPA Office of Science and Technology

Mr. Bain and Dr. Messner presented EPA's process of selecting a draft CCL 3 from the PCCL. Each of the contaminants within the PCCL was analyzed based on four attributes: Prevalence, Magnitude, Potency and Severity. Prevalence and Magnitude are measures of Occurrence, and Potency and Severity are both measures of Health Effects. When a measure of magnitude (e.g., concentration, pounds released) was not available, Persistence-Mobility was used as a surrogate. Once the attributes were assigned, a TDS of contaminants was selected to train or teach classification models to mimic expert list/no list decisions. The TDS has two components for each chemical: Contaminant Attribute Scores and a List/No List Decision (formed through consensus). The models that performed well with the TDS were ANN, Linear, and QUEST. These three models were used to evaluate the remainder of the PCCL contaminants, and their predictions were averaged to provide a final decision and ranking for each contaminant. Dr. Joyce Donahue described how the model results were then evaluated by a team of evaluators composed of individuals from multiple EPA offices and multiple disciplines. Each PCCL contaminant was assigned a numeric score of confidence, which was taken into account when selecting the draft CCL 3. Also, supplemental data relevant to drinking water was obtained and utilized as part of the post-model process. The draft CCL 3 included the following:

- Contaminants with a Health Reference Level (HRL)/Concentration ratio of $\leq$ 10 from contaminants with finished, ambient or modeled water data;
- Contaminants with List (L) or L? model outcomes, release data, and medium certainty;
- Nominated contaminants that meet the listing criteria after evaluation of submitted data; and
- Contaminants with L or L? Model projections and low certainty were not selected for the draft CCL, but are recognized as possible candidates for research.

In total, 95 chemicals were chosen for the draft CCL 3.

Discussion of Questions:

Question #1: Are there other factors that should be considered, as part of post-model processing, in deciding on the Preliminary Draft CCL 3?

Experts Summary Answer to Question #1:

The panel agreed that the professional judgment of the EPA team developing the CCL should be an additional tool used to analyze and process the results from the screening models. However, it is important to keep in mind that professional judgment must be defendable and transparent. A number of examples of professional judgment were discussed and the panel recommended that EPA consider them in finalizing the CCL. They were:

- A recognition that the production volumes of some chemicals may increase in the future and any information on potential production increases should be used to determine if a future production value would alter the listing determination for a particular compound;

- A recognition that changing technologies or processes may need to be considered in the final review of a compound. An example given was the potential for future disinfection processes that may create new compounds and/or increase the concentrations of known byproducts;
- A recommendation that blood and body burden data should be considered in the final evaluation of a compound, such as the blood testing data showing 100% occurrence in samples for Perfluorooctanesulfonic acid (PFOS); In addition, the body burden data should be considered earlier in the process (similar to release data) for the next round.
- Toxic Release Inventory release data, as well as the physical properties of each chemical, especially gases, should be analyzed to determine if model results would change if surface water release information was used instead of total release data;
- The reference doses based on use of an oral response dose calculated from inhalation data without appropriate physiologically based kinetic modeling should be used with caution. It was recommended that the uncertainty tags for this information could be increased, and;
- Finished and ambient water quality data should be sorted into ground water and surface water categories and these separate groups should be analyzed to determine if this sorting significantly impacts the final list results. If so, this sorting process should be considered in updating the modeling protocols in developing CCL 4.

Question #2: Are you in agreement with how EPA evaluated uncertainty and types of data used for occurrence (i.e., finished water, ambient water, release, and production volume data) and health effects (i.e., RfD or equivalent, cancer slope factor, NOAEL, and LD_{50}) in constructing preliminary Draft CCL 3?

Experts Summary Answer to Question #2:

The panel was comfortable with the overall approach to calculating and applying the uncertainty tags as part of the post-model processing. Two issues were identified during the discussion of the uncertainty process:

- There was a recommendation to more clearly explain the rationale for selecting nominated chemicals so their inclusion on the CCL could be better understood, and;

The panel expressed caution on the use of the release data results, especially for compounds where there is no data on their actual presence in drinking water or ambient water. It was suggested that a paragraph be included in the final CCL to express this sense of caution and describe how release data were analyzed. Also, occurrence data (e.g., the Information Collection Rule (61 *FR* 24354) should be looked at more closely to identify whether chemicals could be moved out of the release category.

Question #3: Does the Preliminary Draft CCL 3 chemical list represent those contaminants that have the highest potential to occur in public water systems and cause adverse human health effects?

Experts Summary Answer to Question #3:

Given the limitations in existing databases and interpretations, the panel agreed that the Preliminary Draft CCL 3 chemical list represents those unregulated contaminants that have the highest potential to occur in public water systems and to have adverse health effects. This opinion of the panel was based on the information provided to them by EPA and is a result of their review of the CCL development process as explained by EPA staff during the two-day workshop. The panel also agreed that EPA efforts to update data and research will be critical to the success of future CCLs.

The panel all recognized the level of effort and detail that went into the development of the modeling process used to create the draft list and complimented EPA on their efforts in putting it together.

Question #4: Are there chemical contaminants on the Preliminary Draft CCL 3 list that *should not* be listed?

Experts Summary Answer to Question #4:

The panel then reviewed the full CCL based on the four uncertainty groups used by EPA to develop the final list. These are:

- 33 chemicals in the high certainty bin, those with finished water data and an HRL/concentration ratio of $\leq$ 10;
- 25 pesticide chemicals in the medium certainty bin, those with modeled surface and/or ground water data that yielded a HRL/concentration ratio of $\leq$ 10;
- 28 chemicals in the medium certainty bin, those with release data that gave modeled L or L? rankings; and
- 7 chemicals in the low certainty bin that were nominated with supplied new information.

The panel agreed with the selection of the 33 high certainty compounds and the 25 medium certainty pesticide compounds. There was greater discussion and review of the 28 compounds included based on release data, and the 7 nominated compounds. A concern was expressed that chemicals selected based only on release data are included even though there is no information as to whether or not they are present in drinking water. It was recommended that the final CCL include information highlighting these chemicals and state that there is no data available to determine if they are present in drinking water. Further it was recommended that chemicals in the list should also be tagged to represent those needing health effects data or research on analytical methods.

No chemicals were recommended for removal from the list. The panel did recommend that the data for the compound HFCC-22 be evaluated to see if using data on release to surface water versus total release data would change its ranking and, therefore, inclusion on the list. This was recommended because the compound is a gas, and looking at the release to surface water data may indicate there is less likelihood it would occur in water.

Question #5: Are there chemical contaminants not on the Preliminary Draft CCL 3 list that *should* be listed?

Experts Summary Answer to Question #5:

The panel requested that EPA further review the decision to not list PFOS, as this compound has been found in 100 % of tested blood samples and may be considered to have a higher occurrence and toxicity then PFOA, which is listed.

Haloacetic acids 6-9 were identified by the panel as a group of chemicals that did not make it onto the CCL list, and potentially should be added. EPA responded that these chemicals recently came through the nomination process and that their data are being evaluated now.

Question #6: Do you agree with EPA's assumption that the CCL is also a vehicle for identifying chemicals that are regional or local problems and require new or updated health advisories?

Experts Summary Answer to Question #6:

The review panel agreed that the CCL was a useful tool for identifying chemicals that may require a health advisory to support management of local or regional problems. They also thought that the screening process used to develop the CCL from the PCCL may be used, along with other information, to determine if a health advisory is needed for a chemical that did not get selected for the CCL.

Other Comments:

- The panel recommended that EPA consider a strong outreach process as the final CCL is published to highlight the significant modeling and decision making processes used in its development. As part of the outreach effort, the panel suggested that EPA create an interactive web-based chemical database for public use.
- The panel suggested that the relationships between the CCL and the Unregulated Contaminant Monitoring Regulation lists be explained in the draft documents to clarify confusion in how the lists are developed and used.
- The panel recommended that current data gaps (i.e., chemicals that were made a lower priority based on lack of occurrence or toxicity data) be publicized as research needs. However, if the CCL was made transparent enough so that the public could easily identify these research needs, a formal need to publish data gaps may not be required. Although this was not the charge for this expert panel, there was interest in determining how to fill the data gaps and what generates momentum to fill them.

- For the workshop itself, and for future outreach efforts, it would be helpful to have an introductory chart that went through all the steps from the universe to the CCL, and how chemicals were weeded out, in order to understand the process better.

4.1 Materials Provided

In addition to the chemicals listed on the Preliminary Draft CCL 3, EPA provided drafts of the support documents developed for the Draft CCL 3. Comments provided by reviewers have been incorporated in to the documents that are now included in the docket. The following documents and their appendixes were included in the Expert Review Workshop notebooks provided to each reviewer:

- Assessment of Data Sources
- Nominations for the CCL 3
- Screening the CCL 3 Chemical Universe
- Classification Process to Select the Chemical CCL 3