American Water Works Association
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Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

April 3, 2015

Water Docket
U.S. Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Docket ID No. EPA-HQ-OW-2012-0217
Drinking Water Contaminant Candidate List 4 - Draft

Dear Docket:

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes over 3,900 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our nearly 50,000 total memberships represent the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

AWWA would like to thank the Environmental Protection Agency (EPA) for the opportunity to comment on the Contaminant Candidate List 4 (CCL4) – Draft as published in the February 4th *Federal Register*. AWWA has commented on each of the previous Contaminant Candidate Lists (CCLs) and has also submitted nominations during each CCL cycle. Each and every CCL is important, as each list serves as the start of the regulatory development process. Because it's the starting point, it's important to get the list right. The Safe Drinking Water Act (SDWA) requires the use of the best available, peer-reviewed science for the identification of new contaminants for potential regulation.

AWWA believes that many of the CCL3 "carryover" compounds should be reconsidered prior to putting them on the final CCL4. For its process for developing of the draft CCL4, EPA simply retained the compounds from CCL3 for which preliminary or final regulatory determinations had not been made. Although this can be thought of as a starting point, a CCL process that results in an ever growing list does not help EPA or others studying these compounds focus their efforts, from research or science policy perspectives. Optimally, we believe the CCL should contain

somewhere in the range of 20-50 compounds in order for it to be reasonably likely that EPA can study most of the compounds and fill the necessary data gaps between one CCL round and the next.

AWWA has several recommendations for making the CCL4 (as well as future CCL rounds) a more manageable size and help focus efforts on the compounds of greatest concern. First, EPA should identify all of the compounds for which any round of the unregulated contaminant monitoring rule (UCMR) had zero or a few detections nationally. A contaminant for which national monitoring has taken place but has not shown up at all (or only in one, two, or three systems) clearly does not warrant national regulation and could not be regulated under the process required by the 1996 SDWA amendments. Because it is already known that they do not occur in water systems, EPA's limited resources should be spent elsewhere. Whether removed through negative regulatory determinations or another "off ramp" or simply dropped from the final CCL4, at a minimum, the five compounds listed below should not be included in the final CCL4:

- Nitrobenzene;
- RDX (Hexahydro-1,3,5-trinitro-1,3,5-triazine);
- Disulfoton;
- Diuron; and
- Molinate.

Second, AWWA's CCL4 recommendations report details an alternative process by which water sector experts used the most current available information to select a list of compounds of greatest potential concern. Through this process, which is thoroughly documented in the report, AWWA's expert panels ultimately identified and grouped 40 compounds included in the draft CCL4, plus additional compounds. A detailed comparison between EPA's Draft CCL4 and AWWA's CCL4 Proposed list is included in the enclosed detailed comments.

AWWA would like to discuss our alternative process and how to best advance a collaborative approach for future CCLs with your office and representatives of state primacy agencies in the near future. We would appreciate your suggestion as to a path forward for this important and necessary dialogue. Please feel to call me or Alan Roberson, AWWA's director of Federal Relations, if you have any questions about these comments.

Yours Sincerely,

Tom Curtis
Deputy Chief Executive Officer

cc: Peter Grevatt – USEPA OGWDW
Eric Burneson – USEPA OGWDW
Meredith Russell – USEPA OGWDW
Hannah Holsinger – USEPA OGWDW

Comments by the American Water Works Association

On the Drinking Water Contaminant Candidate List 4 – Draft

The American Water Works Association (AWWA) would like to thank EPA's Office of Ground Water and Drinking Water (OGWDW) for the opportunity to comment on the February, 2015 *Federal Register* notice regarding the Drinking Water Contaminant Candidate List 4 - Draft.[1] AWWA has commented on each of the previous Contaminant Candidate Lists (CCLs) and has also submitted nominations during each CCL cycle. Each and every CCL is important, as each CCL is the start of the regulatory development process. Because it's the starting point, it's important to get the list right. The Safe Drinking Water Act (SDWA) requires the use of the best available, peer-reviewed science for the identification of new contaminants for potential regulation.

The comments below are divided into four sections:

1. Comments repeated from 2008 for the 2015 Draft CCL3;
2. General comments;
3. Comments on specific chemical contaminant on the Draft CCL4; and
4. Comments on specific microbial contaminants on the Draft CCL4.

1. Comments Repeated from 2008 for the 2015 Draft CCL3

A handful of AWWA's comments from 2008 on the Draft CCL3 are worth repeating as the underlying issues have not changed significantly between 2008 and 2015.

AWWA and the Environmental Protection Agency (EPA) should continue to rely on a science-driven CCL process to identify potential candidates for new drinking water regulations.

Section 1412(b)(1)(A) of the 1996 Safe Drinking Water Act (SDWA) lists three criteria for listing of contaminants for consideration for potential national drinking water regulations:

1. The contaminant may have an adverse health effect;
2. The contaminant occurs, or is likely to occur, at a level and frequency of public health concern; and
3. A national regulation provides a meaningful opportunity for health risk reduction.

The best available, peer-reviewed science must remain the foundation for the development of national drinking water regulations. As clearly articulated in the above SDWA criteria, occurrence of a particular contaminant in water does not, in and of itself, justify national regulation. This becomes increasingly important to recognize as continuously improving analytical technology leads to ever lower detection limits and consequently, greater numbers of contaminants being found. National drinking water regulations should not be driven by the "contaminant du jour."

[1] 80 FR 6076

Therefore, AWWA does not support the abbreviated draft CCL4 process that EPA has proposed. Presently, the draft CCL4 consists of

- Starting with the final CCL3;
- Removing contaminants that have a preliminary or final regulatory determination;
- Adding two of the nominated compounds

Although this approach is simple and does not require many resources, we believe that such an approach is flawed because it does not reassess whether the state of scientific knowledge on remaining CCL3 contaminants has or has not changed, nor does it identify other contaminants of emerging concern that may not have been nominated, such as nanoparticles. Instead, we believe that EPA should use the recommendations provided by the National Academy of Sciences in developing the final CCL4 and for cycles of future CCLs.

Additionally, AWWA believes that the CCL process, and the related follow-up on addressing research needs, can be enhanced through the use of modern technology. EPA could develop a system (or work with others to develop a system) that could identify new studies, research data, occurrence data, and other information about contaminants as they emerge to better focus ongoing efforts, better inform future CCL rounds, and to better involve the stakeholder community. Such a system would help to eliminate duplication of work and would add numerous efficiencies into the overall process of contaminant identification.

AWWA recommends that EPA develop criteria for evaluating the effectiveness of future CCLs in meeting the drinking water program's goals.

EPA's past work on developing performance indicators for two drinking water regulations (Arsenic and the Long-Term 2 Enhanced Surface Water Treatment Rule [LT2ESWTR]) was a small step in the right direction. More work is needed to develop performance indicators for the entire SDWA regulatory program and future CCLs should be included in this effort.

AWWA suggests the following categories and considerations for CCL success measures:

1. Systematic process
2. Process allows EPA to make timely regulatory determinations
3. Public health protection achieved with meaningful risk reduction
4. Consumer confidence in public drinking water systems
5. Has any retrospective study been conducted to assess the relative risk reduction (lives saved, cancer endpoints avoided, etc.) achieved by existing drinking water regulations?
6. Has there been a retrospective study comparing projected and realized cost/benefits for existing drinking water regulations?
7. Could such studies be extended to the CCL?
8. Do supplementary data need to support such assessment need to be considered early on in the regulatory development process, and be embedded in the regulation itself?

AWWA recommends that a table or other summary of research needs be developed for the final CCL4, similar to the research needs table in the final CCL1 and CCL3.

A table or other summary of research needs would be helpful to the overall CCL development process. Listing of specific compounds or classes of compounds would allow the research community to investigate areas which EPA sees as research needs.

For example, in CCL1, compounds that were listed included associated research needs such as analytical methods research, occurrence research, health effects research, and treatment research. AWWA suggests that the same categories of research needs formerly categorized on CCL1 be readopted for subsequent CCLs. Furthermore, AWWA suggests these research need categories not be limited to the compounds on the final CCL but should include compounds and associated research needs as identified in the process of moving compounds through Universe/PCCL/CCL (as stated above). AWWA recommends that EPA more clearly identify and document research needs for compounds throughout the CCL process. This includes compounds on CCL4 as well as compounds in the universe, and especially in the PCCL, which failed to move further through the process due to missing necessary data for decision-making.

Such a table or summary of research needs should be included in the formal release of CCL-related documents. This type of research summary would not only provide information for the wider research community but it would also allow public water systems to better prioritize their capital and operating budgets to address potential issues on the regulatory/research agenda. We believe there may be opportunities both for water sector experts and USEPA to develop such a table collaboratively, as well as opportunities for water sector experts and USEPA to address many of the research needs in a collaborative fashion.

2. General Comments

AWWA believes that many CCL3 "carryover" compounds should be reconsidered prior to putting them on the final CCL4

For its process for developing of the draft CCL4, EPA simply retained the compounds from CCL3 for which preliminary or final regulatory determinations had not been made. Although this can be thought of as a starting point, a CCL process that results in an ever growing list does not help EPA or others studying these compounds focus their efforts, from research or science policy perspectives. Optimally, we believe the CCL should contain somewhere in the range of 20-50 compounds in order for it to be reasonably likely that EPA can study most of the compounds and fill the necessary data gaps between one CCL round and the next.

AWWA has several recommendations for making the CCL4 (as well as future CCL rounds) a more manageable size and help focus efforts on the compounds of greatest concern. First, EPA should identify all of the compounds for which any round of the unregulated contaminant monitoring rule (UCMR) had zero or a few detections nationally. A contaminant for which national monitoring has taken place but has not shown up at all (or only in one, two, or three systems) clearly does not warrant national regulation and could not be regulated under the process required by the 1996 SDWA amendments. Because it is already known that they do not occur in water systems, EPA's limited resources should be spent elsewhere. Whether removed through negative regulatory determinations or another "off ramp" or simply dropped from the

final CCL4, at a minimum the five compounds listed below should not be included in the final CCL4:

- Nitrobenzene;
- RDX (Hexahydro-1,3,5-trinitro-1,3,5-triazine);
- Disulfoton;
- Diuron; and
- Molinate.

A peer-reviewed analysis of the national occurrence data used to inform regulatory decisions summarized the data from the first two UCMR assessment and screening monitoring.[2] This summary showed that these five have occurred either zero, one, two, or three times in a past robust national monitoring program. This extremely low level of occurrence would not provide any opportunity for a national regulation now or in the future. It is time for the Agency to step up and remove these five contaminants from the final CCL4 and not continue to carry over unnecessary and unwarranted compounds in future CCLs.

Second, AWWA's CCL4 recommendations report details an alternative process by which water sector experts used the most current available information to select a list of compounds of greatest potential concern.[3] Through this process, which is thoroughly documented in the report, AWWA's expert panels ultimately identified and grouped 40 compounds included in the draft CCL4, plus additional compounds. A detailed comparison between EPA's Draft CCL4 and AWWA's CCL4 Proposed list is included later in these comments.

Because EPA's pesticide office is doing work on human health assessment of many pesticides, we believe that most pesticides can be removed from the CCL4, and not be included in the final CCL4. The Office of Water should focus its limited resources on substances not already being studied by EPA's Office of Pesticide Programs.

Comparison of EPA Draft CCL4 versus AWWA CCL4 Proposed List

Compounds on both EPA Draft CCL4 and AWWA CCL4 Project - Forty of the 100 compounds on the EPA Draft CCL4 were also included in the AWWA CCL4 Proposed list. Of these 40 compounds on both EPA and AWWA lists, 25 were from the CCL3 Shortlist, six were CCL4 nominated compounds, and nine others were added by the AWWA Technical Advisory Workgroup (TAW) (Table 1).

Overall, AWWA recommends (and concurs with the EPA) that 32 of these 40 compounds be included on the USEPA Draft CCL4 (Table 1). AWWA recommends nine of these compounds as top priority for CCL4 (AWWA Group 1) (Table 1). These include six DBPs (including chlorate) that AWWA has binned in a "Supergroup" of DBPs. Also suggested as top priority are 1,4-dioxane, Molybdenum, and 1,1-dichloroethane. AWWA also recommends that 3-

[2] 2012, Roberson, J.A., Informing regulatory decisions using national occurrence data, Journal AWWA, 104:3:55, (http://www.awwa.org/publications/journal-awwa/abstract/articleid/30331651.aspx).
[3] 2015, Roberson, J.A., Bench, R., Adam, C., and Rosen, J. Development of AWWA's Contaminant Candidate List 4 (CCL4) Recommendations, (http://www.awwa.org/Portals/0/files/legreg/documents/2015CCLAWWAReport.pdf).

hydroxycarbofuran be included on CCL4 due to insufficient data existing for a regulatory determination (AWWA Group 2) (Table 2).

There are 23 compounds on the EPA Draft CCL4 for which the TAW believes there are sufficient data for a negative regulatory determination (Group 3) (Table 1). For the final CCL4, EPA has two options - inclusion of these compounds on CCL4, leading to a large number of negative regulatory determinations in the future, or removal of these compounds from the final CCL4. If the final CCL4 is to be reduced in number, then these Group 3 compounds could be removed from the final CCL4, and they should be documented to be unlikely candidates for future CCLs. Furthermore, AWWA recommends that eight of the compounds on the EPA Draft CCL4 not be included (AWWA Group 4 – with the exception of manganese – see discussion below), based on existing potency, magnitude and/or prevalence data that demonstrates that there is no need to further consider these compounds (Table 1).

Compounds in AWWA CCL4 Project but not on USEPA Draft CCL4- 79 compounds were considered within the AWWA CCL4 Project that were not on the EPA Draft CCL4. Of these 79 compounds, three were from the CCL3 shortlist, 45 were CCL4 nominated compounds, and 31 others were added by the AWWA TAW (Table 2).

Of the 79 compounds in the AWWA CCL4 Project and not on the USEPA Draft CCL4, a total of 31 were recommended by AWWA CCL TAW for inclusion in CCL4 (and the remaining 48 were not recommended for inclusion) (Table 2). Of the 31 recommended for inclusion by AWWA, 12 compounds were considered “top priority” (AWWA Group 1) for inclusion by AWWA (and included DBPs, pharmaceuticals and strontium), nine were recommended for inclusion in CCL4 due to insufficient data existing for a regulatory determination (AWWA Group 2) (and included cyanotoxins and pesticides), and 10 were recommended for inclusion as “there exists sufficient data for a negative regulatory determination (Group 3)” (Table 2).

AWWA recommends grouping all DBPs into a supergroup of DBPs for top priority inclusion in CCL4. This supergroup would have as key compounds halonitromethanes, iodo-DBPs and nitrosamines and other DBPs. Further, AWWA recommends that two pharmaceuticals, fluoxetine and gemfibrizol, also be included as top priority for CCL4. There is a high level of interest and concern in the public and scientific discourse on pharmaceuticals. AWWA considers fluoxetine and gemfibrizol as good choices to benchmark other pharmaceuticals against. That is, if these higher priority pharmaceuticals receive negative (or positive) regulatory determinations, it will help steer the discussion and decision for other pharmaceuticals with fact-based rational. A regulatory determination for two key pharmaceuticals would help to address the lingering issue and discussion of “drugs in our drinking water”.

Strontium was also considered a top priority compound by AWWA for CCL4. Many questions surround strontium. The preliminary positive determination for strontium in 2014 raised many issues that need to be thoughtfully considered prior to any potential final determination and/or moving forward with a potential strontium regulation. AWWA wants to re-emphasize that EPA needs to get the science right on strontium before moving forward with a final positive determination and/or a potential strontium regulation. EPA needs to take the time to get the science right on strontium.

Strontium (as with almost everything) meets the first statutory criterion in Section 1412(b)(1) of the Safe Drinking Water Act (SDWA) for regulatory determinations; *it may have an adverse effect on the health of persons*. At high enough concentrations, just about any compound **may** have an adverse health effect. The currently unresolved issues for a regulatory decision will be focused on the second criterion; that *the contaminant is known to occur or there is a substantial likelihood that the contaminant will occur at a frequency and at levels of public health concern,* and the third criterion; that *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.*

From a national cost of compliance perspective, strontium could be in the same range as arsenic, and the cost of compliance with the arsenic regulation was significant. The arsenic regulation impacted many groundwater systems, and many of these systems were small and very small systems. In the 2001 arsenic rule, EPA estimated that 5.3% of systems would be impacted by the revised arsenic MCL of 10 µg/L, with the national cost of compliance estimated at between $180.4 and $205.6 million per year (1999 dollars).[4] For systems serving 101-500 people, EPA estimated the mean annual cost per household for the additional treatment to be $14/month (1999 dollars). For systems, serving <100 people, the mean annual cost per household was estimated at $27/month (1999 dollars).

The Agency used a science-based approach to ensure that the health effects information used in the development of the arsenic regulation was the best available, peer-reviewed science. Using the NIRS data and the UCMR3 data for strontium as the boundary conditions, 4.9%-7.0% of systems could be potentially impacted by a strontium regulation at the HRL of 1,500 µg/L. The 5.3% of systems that EPA predicted would be impacted by the 2001 arsenic rule falls in between this range. EPA should undertake a similar research effort for strontium for additional health effects and treatment data, comparable to what was undertaken for arsenic in the 1990s prior to moving forward with a final positive determination and/or a potential strontium regulation

AWWA recommends all of the key variants (or analogues) of microcystins (MC-LR, –LA, -LW, -RR, and –YR) as well as cylindrospermopsin and anatoxin A be explicitly listed in CCL4. This recommendation is based on the concern that simply listing "cyanotoxins" on the CCL4 (as is on the EPA Draft CCL4 currently) leaves open the possibility that important microcystin analogues (in addition to MC-LR), cylindrospermopsin and/or anatoxin A could be left off consideration when each strongly warrants additional study from occurrence, toxicity, analysis, and treatment perspectives prior to a regulatory determination.

AWWA recommends 10 compounds that were not on the EPA Draft CCL4 for potential inclusion in CCL4 as "there exists sufficient data for a negative regulatory determination (Group 3)". AWWA is comfortable leaving these 10 compounds off the CCL4 altogether (as is consistent with the EPA Draft CCL4) if the number of compounds is to be limited.

Finally, 48 compounds were considered by the AWWA CCL4 project (and were not on the EPA Draft CCL4) that were recommended to not be included in the CCL4 (AWWA Group 4). The

[4] 66 FR 6975

basis for this recommendation was existing potency, magnitude and/or prevalence data that demonstrates that there is no need to consider further regulating these compounds. Note that saxitoxin and saxitoxins PSTs were binned by the AWWA CCL4 TAW in Group 4 based on their lower frequency of detection in water sources than the aforementioned cyanotoxins. This could change, however, and EPA may at some point want to consider saxitoxin and saxitoxin PSTs for inclusion in the CCL process.

Table 1. Forty compounds that are the USEPA draft CCL4 list, and also in the AWWA CCL4 Project.

	AWWA CCL4 Project		
Compounds	Category/Source in AWWA Study	Group	Sub-group
AWWA CCL4 PROJECT GROUP 1 COMPOUNDS - Top priority for inclusion in CCL4			
Chlorate	CCL3 Sh Lst	DBP	cVOC list
NDEA	CCL3 Sh Lst	DBP	
NDMA	CCL3 Sh Lst	DBP	
NDPA	CCL3 Sh Lst	DBP	cVOC list
NDPhA	CCL3 Sh Lst	DBP	
NPYR	CCL3 Sh Lst	DBP	
1,4-Dioxane	CCL3 Sh Lst	Industrial	
Molybdenum	CCL3 Sh Lst	Inorganic	Herbicide/Acetochlor + degradates
1,1-Dichloroethane	AWWA CCL3	VOC	Insecticide
AWWA CCL4 PROJECT GROUP 2 COMPOUNDS - Include in CCL4 but insufficient data exists for reg det			
3-Hydroxycarbofuran	AWWA CCL3	Pesticide	Herbicide/Alachlor + degradates
AWWA CCL4 PROJECT GROUP 3 COMPOUNDS – Include in CCL4 due to sufficient data for neg reg determinations			
Acrolein	AWWA CCL3	Industrial	
PFOA	CCL4NOM	Industrial	
PFOS	CCL3 Sh Lst	Industrial	
RDX	CCL3 Sh Lst	Industrial	
Acetochlor	CCL3 Sh Lst	Pesticide	Herbicide/Alachlor + degradates
Acetochlor ESA	CCL3 Sh Lst	Pesticide	Insecticide
Acetochlor OA	CCL3 Sh Lst	Pesticide	
Alachlor ESA	CCL3 Sh Lst	Pesticide	
Alachlor OA	CCL3 Sh Lst	Pesticide	
Alpha-Disulfoton	CCL4NOM CCL3 Sh Lst	Pesticide Pesticide	
Diuron	CCL3 Sh Lst	Pesticide	
Metolachlor	CCL3 Sh Lst	Pesticide	
Metolachlor ESA	CCL3 Sh Lst	Pesticide	
Metolachlor OA Deg	CCL3 Sh Lst	Pesticide	
Molinate	CCL3 Sh Lst	Pesticide	
Erythromycin	EC	PPCP	
1,1,1,2-Tetrachloroethane	CCL3 Sh Lst	VOC	
1,2,3-Trichloropropane	AWWA CCL3	VOC	Herbicide
Methyl bromide	AWWA CCL3	VOC	
MTBE	CCL4NOM	VOC	
Nitrobenzene	CCL3 Sh Lst	VOC	
AWWA CCL4 PROJECT GROUP 4 COMPOUNDS - Do not include in CCL4 based on existing P, M, and/or Pr data			
Nonylphenol	CCL4NOM	Industrial	
n-Propylbenzene	AWWA CCL3	Industrial	Insecticide
sec-Butylbenzene	AWWA CCL3	Industrial	
Manganese	CCL4NOM	Inorganic	
Tellurium	AWWA CCL3	Inorganic	Herbicide/Acetochlor + degradates
Vanadium	CCL3 Sh Lst	Inorganic	Herbicide/Acetochlor + degradates
Permethrin	CCL4NOM	Pesticide	
1,3-Dinitrobenzene	CCL3 Sh Lst	VOC	

Table 2. Seventy-nine (79) AWWA CCL4 study compounds that are not the EPA draft CCL4 list.

	AWWA CCL4 Project		
Compounds	**Category/Source in AWWA Study**	**Group**	**Sub-group**
AWWA CCL4 PROJECT GROUP 1 COMPOUNDS - Top priority for inclusion in CCL4			
BCIM	EC	DBP	Halomethane
BDCNM	EC	DBP	Halonitromethane
BDIM	EC	DBP	Halomethane
CDIM	EC	DBP	Halomethane
Chloropicrin (TCNM)	EC	DBP	Halonitromethane
DBCNM	EC	DBP	Halonitromethane
DBIM	EC	DBP	Halomethane
DCIM	EC	DBP	Halomethane
TIM	EC	DBP	Halomethane
Strontium	CCL3 Sh Lst	Inorganic	
Fluoxetine	EC	PPCP	Antidepressant
Gemfibrozil	EC	PPCP	Lipid regulator
AWWA CCL4 PROJECT GROUP 2 COMPOUNDS - Include in CCL4 but insufficient data exists for reg det			
Anatoxin A	EC	Cyanotoxin	
Cylindrospermopsin	EC	Cyanotoxin	
MC-LA	EC	Cyanotoxin	Microcystins
MC-LR	EC	Cyanotoxin	Microcystins
MC-LW	EC	Cyanotoxin	Microcystins
MC-RR	EC	Cyanotoxin	Microcystins
MC-YR	EC	Cyanotoxin	Microcystins
Azinphos-methyl	CCL4NOM	Pesticide	Insecticide
Chlorpyrifos	CCL4NOM	Pesticide	Insecticide
AWWA CCL4 PROJECT GROUP 3 COMPOUNDS – Include in CCL4 due to sufficient data for neg reg determinations			
Aldicarb	CCL4NOM	Pesticide	Insecticide
Dimethoate	CCL3 Sh Lst	Pesticide	Insecticide
Linuron	CCL4NOM	Pesticide	Herbicide
Methyl chloride	AWWA CCL3	VOC	
Terbufos	CCL3 Sh Lst	Pesticide	Terbufos + degradates
Terbufos Sulfone	AWWA CCL3	Pesticide	Terbufos + degradates
Progesterone	CCL4NOM	PPCP	Hormone
Sulfamethoxazole	EC	PPCP	Antibiotic
Testosterone	CCL4NOM	PPCP	Hormone
Triclosan	CCL4NOM	PPCP	Antibiotic

Table 2 (cont'd). Eighty AWWA CCL4 study compounds that are not the EPA draft CCL4 list.

AWWA CCL4 PROJECT GROUP 4 COMPOUNDS - Do not include in CCL4 based on existing P, M, and/or Pr data			
Saxitoxin	EC	Cyanotoxin	Saxitoxins
Saxitoxin related PST	EC	Cyanotoxin	Saxitoxins
Mutagen X	CCL4NOM	DBP	DBP
Benzyl butyl phthalate	CCL4NOM	Industrial	Phthalate
BHA	AWWA CCL3	Industrial	
Bisphenol A	CCL4NOM	Industrial	
Dibutyl phthalate	CCL4NOM	Industrial	Phthalate
Dicyclohexyl phthalate	CCL4NOM	Industrial	Phthalate
Diethyl phthalate	CCL4NOM	Industrial	Phthalate
Di-isononyl phthalate	CCL4NOM	Industrial	Phthalate
Dimethyl phthalate	CCL4NOM	Industrial	Phthalate
Di-n-octyl phthalate	CCL4NOM	Industrial	Phthalate
Nonylphenol ethoxylate	CCL4NOM	Industrial	Alkylphenol ethoxylates
Octylphenol	CCL4NOM	Industrial	Alkylphenol
Octylphenol ethoxylate	CCL4NOM	Industrial	Alkylphenol
Perchlorate	AWWA CCL3	Industrial	
Cesium 137	CCL4NOM	Inorganic	
Radon	CCL4NOM	Inorganic	
Bentazone	CCL4NOM	Pesticide	Herbicide
Carbaryl	CCL4NOM	Pesticide	Insecticide
Chlorothalonil	CCL4NOM	Pesticide	Fungicide
Dicamba	CCL4NOM	Pesticide	Herbicide
Dichlorvos	CCL4NOM	Pesticide	Insecticide
Dicofol	CCL4NOM	Pesticide	Insecticide
Endosulfan	CCL4NOM	Pesticide	Insecticide
Ethoprophos	AWWA CCL3	Pesticide	Insecticide
Fluometuron	CCL4NOM	Pesticide	Herbicide
Malathion	CCL4NOM	Pesticide	Insecticide
Methyl parathion	CCL4NOM	Pesticide	Insecticide
Phosmet	CCL4NOM	Pesticide	Insecticide
Trichlorfon	CCL4NOM	Pesticide	Insecticide
Acetaminophen	EC	PPCP	Pain reliever (not NSAID)
Amoxicillin	CCL4NOM	PPCP	Antibiotic
Bacitracin zinc	CCL4NOM	PPCP	Antibiotic
Bromoxynil	CCL4NOM	PPCP	Herbicide
Ciprofloxacin	EC	PPCP	Antibiotic
Ibuprofen	EC	PPCP	NSAID
Linezolid	CCL4NOM	PPCP	Antibiotic
Methicillin	CCL4NOM	PPCP	Antibiotic
Naproxen	EC	PPCP	NSAID
Oxacillin	CCL4NOM	PPCP	Antibiotic
Penicillin	CCL4NOM	PPCP	Antibiotic
Spiramycin	CCL4NOM	PPCP	Antibiotic
Sulfamethazine	EC	PPCP	Antibiotic
Triclocarban	CCL4NOM	PPCP	Antibiotic
Tylosin	CCL4NOM	PPCP	Antibiotic
Vancomycin	CCL4NOM	PPCP	Antibiotic
Virginiamycin	CCL4NOM	PPCP	Antibiotic

Additional considerations for CCL5

Recognizing that the CCL cycle is relatively short and EPA will have to begin planning for Fifth Contaminant Candidate List (CCL5) shortly after completing CCL4, AWWA would like to make the following additional recommendations for consideration in the development of CCL5.

First, we believe that EPA needs to invest additional resources for CCL5 like what was done for CCL3. The draft CCL4 process (essentially the CCL3 list plus a few minor adjustments) is not a robust process. We believe that EPA should always use a robust process grounded in the best available science for the development of the CCL, and EPA should pursue this for CCL5. It is especially imperative if EPA does not use a robust process for the final CCL4.

AWWA believes there are many appropriate points for collaboration in the development of CCL5. AWWA has been committed to the CCL process for many years. Our CCL Technical Advisory Workgroup (TAW) has mined and organized a significant amount of data in an effort to identify contaminants that should be considered for regulatory management. As part of these efforts the AWWA CCL TAW developed a standard methodology and format for organizing and evaluating contaminants. This methodology has been documented in the peer-reviewed literature.[5,6] This approach, which is based on the recommendations of the National Drinking Water Advisory Council (NDWAC), organizes all the available data for each contaminant related to occurrence and to health effects. These data are then presented in standardized dossiers that support the deliberations of the TAW and expert evaluation is applied to the contaminants. This process is restarted every 5 years when it is time to consider a new CCL development.

In AWWA's opinion, it is time that the data for the development of the CCL, and the development of the data dossiers and other supporting tools for the development of the CCL be standardized and maintained on an ongoing basis. To meet this end, members of the AWWA CCL TAW have initiated a program to store all of the relevant data on chemicals in a standard format on a cloud based information system. The information system should include all the known information and references on a chemical, and the information system should produce a variety of standard reports including the CCL dossiers that have been used by the CCL TAW in its deliberations. AWWA and others are discussing how to begin processes and programs to continuously mine and update the data in this cloud based system. As new contaminants are identified, the intent is the information on the new contaminants will be added to the cloud based system. A cohesive system is planned be set up for the on-going review and update of the CCL data. The intent is to develop standard operating procedures and to distribute them to any researchers supporting these efforts promoting consistent research approaches, documentation and interpretation. The hope is that programs will be initiated at a number of universities with active drinking water education programs. Professors are planned to be identified to oversee the work and train students in recording and quality assuring data and information about contaminants in the cloud based system. A series of student assistantships would be developed

[5] 2007, Rosen, J.S. and Roberson, J.A., A simplified approach to developing future contaminant candidate lists. Journal AWWA, 99:3:66 (http://www.awwa.org/publications/journal-awwa/abstract/articleid/15621.aspx).
[6] 2009, Roberson, J.A., Risk indexes for draft CCL3 chemicals, Journal AWWA, 101:9:64, (http://www.awwa.org/publications/journal-awwa/abstract/articleid/21770.aspx).

and administered by these professors. Research would continue on developing algorithms for identifying contaminants most appropriate for regulation.

This same system could also contain significant information on contaminants that are identified in specific zones of critical concern for water utilities. This integration of information and the development of a mechanism for maintaining and updating these information systems will result in an ongoing evaluation of contaminants of concern both relative to the CCL and to protecting the source waters of the US. This process will dramatically reduce the costs and the time that will be required to meet the CCL requirements while improving the data content and the decision process. AWWA would like to invite EPA to partner on the development, maintenance and funding of these efforts to improve the CCL process for all stakeholders.

3. Comments on Specific Chemical Contaminants

Manganese

AWWA supports the inclusion of manganese in the Draft (and Final) CCL4. As knowledge evolved for manganese in 2014 and early 2015, the CCL TAW decided to shift manganese from Group 4 to Group 2 so that robust national occurrence data could be collected through a future UCMR. The levels at which manganese occurs in the environment vary substantially, so robust national occurrence data is needed, as well as a more thorough understanding of the levels at which adverse health effects could occur. New health effects data showing potential adverse neurological effects was a factor in this evolution and the TAW's decision to shift manganese. The level at which these potential adverse neurological effects occur compared to typical environmental levels is key to developing an understanding whether or not manganese should potentially move forward in the regulatory development process.

Cyanotoxins

AWWA supports the inclusion of cyanotoxins in the Draft (and Final) CCL4, but recommends that EPA not list cyanotoxins as a broad group in the Final CCL4. Rather, EPA should list the following cyanotoxins individually in order to move them forward more expeditiously in the regulatory development process:

- Anatoxin-A
- Cylindrospermopsin
- MC-LA
- MC-LR
- MC-LW
- MC-RR
- MC-YR

AWWA believes that listing the above cyanotoxins in the Final CCL4 is the more appropriate approach within the regulatory development process than listing them as a group. Listing specific cyanotoxins will provide focus for the necessary research on health effects, analytical methods, occurrence, and treatment. Limited progress will be made in the regulatory development process without the appropriate research on the most important cyanotoxins, and AWWA believes that listing these specific cyanotoxins provides the appropriate and necessary focus.

4. Comments on Specific Microbial Contaminants

Substantial improvements have been made in the prevention waterborne disease since the SDWA was introduced, but waterborne pathogens continue to cause illnesses in the United States. The majority of recognized outbreaks are caused by pathogens rather than chemical contaminants. [7] The numbers of individuals with recognized waterborne disease attributable to potable water tend to be greater than outbreaks associated with chemical contaminants.[8] Consequently, continued vigilance is necessary to control the remaining risk presented by waterborne pathogens.

The CCL is intended to set the stage for the SDWA regulatory determination process; however, after four CCLs and 17 years the EPA has not made a regulatory determination on a single pathogen. Some pathogens have been listed for 17 years with no progress towards a regulatory determination. The Agency's follow-through on microbes listed in previous CCLs has proven inadequate. Consequently, AWWA recommends much greater emphasis should be placed on advancing CCL pathogens toward analysis of the risk they may pose and where appropriate, identify risk reduction alternatives. EPA must build a program of activity with realistic and achievable goals and interim milestones in order to break the cycle of CCL-listing followed by inaction for the CCL4 pathogens.

Preparing a Credible Plan to Advance Priority Pathogens

Lack of resources to study all of the CCL4 contaminants is recognized as a central challenge for EPA. Consequently, the Agency must prioritize contaminants for research and information gathering. In finalizing CCL4, EPA should identify the high priority pathogens listed on the draft CCL4. As has been past practice, the Agency should identify the information gaps associated with each contaminant that must be addressed to allow regulatory determinations to be made.

Additionally, in its *Federal Register* notice for the final CCL4, EPA should describe an open and collaborative process for both prioritizing and subsequently collecting the information needed to advance microbial contaminants from the CCL4 to regulatory determinations. The process should identify high priority contaminants and include an information needs assessment and pathogen-specific research plan for the high priority pathogens that end up on the final CCL4. To be effective, the research needs assessment should be developed through a process that is open to the public, actively engage experts from outside the Agency, and result in a publicly available document. The assessment should be completed within a reasonably short timeframe following the final CCL4 notice, and when completed, include an estimate of funding needs, as well as decision-relevant information requirements. To the extent possible, the needs assessment should communicate dependencies between research needs so that the Agency and outside entities can develop information on priority topics in a logical and consistent order (e.g., method development would proceed to occurrence monitoring under the Unregulated Contaminants Monitoring Rule).

[7] 2013, CDC, Surveillance for Waterborne Disease Outbreaks Associated with Drinking Water and Other Nonrecreational Water — United States, 2009–2010

[8] Ibid.

Overcoming the Lack of Suitable Analytical Methods

The lack of robust analytical methods for conducting occurrence studies is a critical challenge for all CCL contaminants, but the absence of methods appropriate for characterizing CCL pathogen occurrence has been central to the EPA's lack of progress in evaluating CCL pathogens. Consequently, analytical method development should be featured heavily in the research needs assessments and research plans developed subsequent to the final CCL4.

In order for methods to advance, EPA and the water microbiological community need to clearly understand performance objectives and the method validation required to assure analytical methods are sufficiently robust. For occurrence studies to be credible, the analytical methods that are used must have realistic performance and acceptance criteria. For example, in a stakeholder meeting in preparation for UCMR4, EPA indicated ongoing precision and recovery for its best *Helicobacter* method ranging from detection (zero) to 482%. This level of performance indicates that the method is not ready for use in a national occurrence study that could be used in a future regulatory development process. Similarly, there is a growing reliance on the use of molecular techniques to quantify microbe occurrence; molecular techniques (as well as culture techniques) must be able to accurately quantitate organisms. Having a common set of expectations both for EPA and the larger research community will speed the method development process and ensure that the resulting methods are indeed sufficient for UCMR and/or specialized research studies necessary to inform risk management decision-making.

Creating a New Analytical Method Development Paradigm

Given EPA's resource constraints, the Agency lacks the capacity to develop and validate the analytical methods needed to collect robust occurrence data for CCL organisms. Moreover, the credibility of any analytical method comes from familiarity and use by a wide cross-section of the laboratory community. In order to leverage limited Agency resources to develop microbial methods and build consensus around particular analytical methods, EPA should adopt a collaborative method development process that includes Agency staff, method developers, and users from water utilities and research laboratories. This collaboration would likely be conducted through workshops, web conferences, and document circulation. EPA could develop a program of its own, or utilize existing method development processes like Standard Methods. The essential components of a robust analytical method are articulated in a number of governmental and independent organization protocols that establish the requirements that must be fulfilled before microbiological methods should be used for routine testing.[9,10 11,12] Sound analytical methods have well-documented performance measures consistent with the method's intended use and a shared appreciation within the user community of the method's performance. Consequently, the following principles are essential to a collaborative method development process:

1. Agreement on an established protocol for evaluating new methods or method modifications, including design of spiking studies, types and number of test matrices,

[9] 2009, EPA, Method Validation of U.S. Environmental Protection Agency Microbiological Methods of Analysis
[10] 2010, EPA, Microbiological Alternate Test Procedure Protocol for Drinking Water, Ambient Water, and Wastewater Monitoring Methods
[11] 2011, FDA. FDA Methods Validation Guidelines for Microbial Pathogens
[12] 2002, AOAC International, Guidelines for collaborative study procedures to validate characteristics of a method of analysis

number of replicates, number of spike concentrations, number of laboratories in round robin validation studies, etc.
2. Common agreement on method performance objectives such as acceptable recovery efficiency with respect to particular target microbes.
3. All methods regardless of who develops the method are subjected to the same level of scrutiny (e.g., testing protocol for a culture-based test will be different from a PCR-based test, but the level of scrutiny is comparable).
4. Open and transparent sharing of data from method validation testing.
5. Full round-robin testing engaging laboratories with skill levels comparable to those in the target pool of user laboratories.

CCL4 Pathogens

The pathogens listed in CCL4 are unchanged from those listed in CCL3. As AWWA noted in its comments on CCL3, EPA's process for identifying microbes for inclusion in the CCL development process is basically sound.[13] While there are opportunities to further improve the CCL development process, a much more pressing need for the regulatory development process is prioritization of the pathogens included in the CCL for data collection in order to support regulatory determinations.

While AWWA did not repeat the full evaluation of pathogens for the current round of the CCL it conducted for CCL3, several new development need to be considered in finalizing CCL4.[14] Since CCL3 there have been a number of significant outbreaks that impact the rankings posited by AWWA in 2008. Numerous outbreaks of legionellosis in a variety of buildings (e.g., hospitals, hotels, etc.) with complex potable water plumbing systems have occurred both in the U.S. and in Canada. Two instances of amoebic meningitis caused by *Naegleria fowleri* infection were linked to use of potable water.[15] Also, two drinking water systems in Louisiana have been placed on boil water notices following observation of *N. fowleri* in water distribution system samples. These recent events warrant placing a high priority on understanding the potential risks posed by pathogens on CCL4 that are harbored in premise plumbing systems and distribution system biofilms. Three microbes that are important from this perspective are: *Legionella pneumophila, Mycobacteria avium, and N. fowleri*.

Preparing an effective research program for evaluation of these biofilm-associated organisms will be different from the approach taken by the agency to-date for CCL contaminants. Existing disinfection practice, utility operational practices, proliferation in premise plumbing, and atypical exposure scenarios all complicate risk management strategies for these organisms. Consequently, the research needs assessment for these organisms must balance understanding occurrence with more pragmatic information necessary to evaluate current treatment practices. EPA should be aware that the Water Research Foundation and AWWA are currently engaged in a project to construct a decision-relevant research agenda for

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[13] 2008, AWWA, AWWA Comments on Proposed Drinking Water Contaminant Candidate List 3

[14] 2009, Hoffman et al., Prioritizing Pathogens for Potential Future Regulation in Drinking Water, Environ. Sci. Technol. 43, 5165–5170

[15] 2015 (download), CDC, Number of case - reports of Primary Amebic Meningoencephalitis, by month of illness onset and probable water exposure — United States, 1962 – 2013 (http://www.cdc.gov/parasites/naegleria/pdf/naegleria-case-reports-by-onset-and-exposure-2013.pdf)

emerging pathogens associated with distribution systems. AWWA anticipates that this research effort will include, if not focus on, biofilm organisms.

While emerging science warrants a greater emphasis on biofilm organisms, no new information suggests that viruses are less of a potential concern than previously identified in AWWA's comments on CCL3. EPA has collected a limited amount of data on the occurrence of enteroviruses and noroviruses through the third Unregulated Contaminants Monitoring Rule. It is important to realize that this data collection effort was a pre-screening test of EPA Analytical Method 1615 and sample site selection. Even though UCMR3 is not yet complete, external reviewers are questioning the quality of this data set. Consequently, the limited data acquired to-date are insufficient to adequately inform a regulatory determination. Enteroviruses in source waters continue to be high priority CCL pathogens. Emphasizing human enteroviruses over other viruses may lead to more meaningful data since they represent a broader group of viruses.

Role of Treatment in Setting Priorities

Although susceptibility to treatment is not considered as part of the CCL process, and a large part of the U.S. population is still drinking non-disinfected water, AWWA strongly recommends that CCL4 microbes that are known to be inactivated or removed by conventional treatment processes should be given lesser priority in methods development and risk assessment. An expert panel convened by EPA in 2006 recommended that microbes should be removed from further consideration if conventional water treatment protects public health. As a practical matter, where organisms that can be readily disinfected are a problem, there is already a well understood solution both for site-specific solutions and for state and federal policy making.

Therefore, AWWA continues to recommend that microbes like *Salmonella*, *Shigella*, and toxigenic *E. coli* not be given priority when allocating the limited research and information collection funds available at EPA and within the water sector more broadly.

Future CCLs Should Address Changing Nature of Water Supply

To meet increasing water demands, the industry is turning towards alternative and nontraditional source water supplies. These include brackish and saline sources as well as treated municipal wastewater for direct potable reuse (DPR). The use of nontraditional source waters necessitates additional treatment prior to drinking water treatment. For these sources, a combination of membrane filtration and various chemical and non-chemical disinfectants are typically employed. Under these scenarios, the fecal indicator bacteria paradigm currently guiding drinking water treatment may not be applicable. Despite engineered treatment barrier redundancy for DPR plants, viruses remain a challenge and the greatest potential risk to public health. This is due to several factors, including their potentially high concentrations in wastewater sources, typically low infectious dose, small size and potential for membrane breakthrough, and uncertainties regarding association with organic matter and disinfection efficacy. EPA is currently exploring the treatment considerations associated with direct potable reuse. AWWA recommends that in developing CCL5, EPA explicitly evaluate microbial contaminants in the context of the nation's emerging reliance on increasingly diverse water supplies that present

influent water quality paradigms not actively considered by the current CCL evaluation of pathogen occurrence.