ASDWA
Association of State Drinking Water Administrators

April 17, 2020

Mr. David Ross
Assistant Administrator for Water
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Subject: Preliminary Fourth Regulatory Determinations [Docket # EPA–HQ–OW–2019–0583]

Dear Assistant Administrator Ross:

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to provide comments on EPA's Preliminary Fourth Regulatory Determinations. ASDWA is the professional association that serves the men and women (and their staff) who lead and implement the 57 state and territorial drinking water programs. Formed in 1984 to address a growing need for state administrators to have national representation, ASDWA has become a respected voice for states with Congress, EPA, and other Federal agencies.

ASDWA's members are coregulators with EPA for the National Primary Drinking Water Regulations (NPDWRs), and this partnership has been critical for the successful implementation of all the NPDWRs. ASDWA looks forward to continuing this partnership in the years following the publication of the final Fourth Regulatory Determinations and the resultant regulations.

This cover letter summarizes the enclosed detailed comments. ASDWA commends and supports EPA for making positive preliminary regulatory determinations for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). ASDWA recommends that when finalizing this regulatory determination, EPA also include positive determinations for four additional long-chain PFAS compounds with PFOA and PFOS: Perfluoroonanoic acid (PFNA), Perfluorohexanesulfonic acid (PFHxS), Perfluoroheptanoic acid (PFHpA), and Perfluorodecanoic acid (PFDA). Including all six PFAS would be similar to current state regulatory approaches by Massachusetts, Vermont, Connecticut, New Hampshire, Minnesota, and Michigan. ASDWA supports EPA in using its flexibility as detailed in the *Federal Register* notice to expedite the regulatory development process based on a positive final regulatory determination for the six PFAS, so that the proposed and final regulation is developed as soon as possible.

ASDWA recommends that EPA thoroughly consider state standards and guidelines with significantly lower PFAS levels than EPA's Health Advisory Level (HAL) of 70 parts per trillion (ppt) for combined concentrations of PFOA and PFOS. At least eight states are moving forward

1401 WILSON BLVD · SUITE 1225 · ARLINGTON, VA 22209
PHONE (703) 812-9505 · FAX (703) 812-9506 · info@asdwa.org · www.asdwa.org

with their own state standards or guidelines using significantly lower PFAS levels than EPA's HAL, which will be in place well before EPA develops a final NPDWR.

ASDWA recommends that EPA consider a two-pronged regulatory approach that allows for:

1. Future PFAS regulatory development efforts that use grouping and/or treatment technique approaches for lesser known PFAS with little or no available health effects and occurrence information; and
2. Moving forward now with this regulatory determination for PFOA and PFOS and four additional PFAS with known health effects and occurrence data and information.

ASDWA commends EPA for continuing to conduct research and collect data and information on PFAS with other federal agencies, states, universities, industry, and other stakeholders. ASDWA recommends that EPA prioritize this research to focus on compounds that water systems are currently monitoring for using available analytical methods and that will likely be monitored for in the Fifth Unregulated Contaminant Monitoring Rule (UCMR5).

ASDWA recommends that EPA continue to use using the authorities under the Toxic Substance Control Act (TSCA) to regulate PFAS and to prevent the entry of such compounds into the environment. State drinking water programs and water utilities are stepping up to protect the public's health by removing these harmful compounds from drinking water, often at great cost, essentially cleaning up an environmental disaster they did not cause and could have been prevented by EPA. State drinking water programs and water utilities deserve recognition and respect for taking on this effort while the chemical manufacturers continue to profit from the use and sale of PFAS compounds.

ASDWA supports EPA's negative regulatory determinations for 1,1-Dichloroethane, Acetochlor, Methyl Bromide (Bromomethane), Metolachlor, Nitrobenzene, and RDX. ASDWA supports EPA's conclusions that each of these contaminants does not present a meaningful opportunity for health risk reduction through a National Primary Drinking Water Regulation (NPDWR).

Finally, ASDWA recommends two approaches for EPA to consider for the final Fourth Regulatory Determinations and for the Draft Ffith Contaminant Candidate List (CCL5) that is scheduled to be proposed later in 2020:

1. Additional regulatory determinations should be made for CCL4 contaminants with either zero, one or two detections from national occurrence data.
2. The Draft CCL4 needs to be shorter than previous CCLs to more appropriately focus the research, resulting in more informed decision-making in the future.

On behalf of the 57 states, territories and tribes we represent and the 150,000 drinking water systems they oversee, which serve 300 million Americans, we thank you for the opportunity to provide this input to this important step in the SDWA regulatory development process. ASWDA looks forward to continuing its dialogue with EPA on the development of the resultant regulations. Please feel free to contact me (email aroberson@asdwa.org; Phone 703-812-9507) if you would like to discuss these comments in more detail.

Sincerely,

J. Alan Roberson, P.E.
Executive Director
Association of State Drinking Water Administrators (ASDWA)

Cc: Jennifer McLain – OGWDW
Eric Burneson – OGWDW
Alexandra Dunn - OPPTS

Comments by the Association of State Drinking Water Administrators (ASDWA) On EPA's Preliminary Fourth Regulatory Determination Docket ID EPA-HQ-OW-2019-0583

The Association of State Drinking Water Administrators (ASDWA) appreciates the opportunity to provide comments on the preliminary Fourth Regulatory Determination. ASDWA is the professional association that serves the men and women (and their staff) who lead and implement the 57 state and territorial drinking water programs. Formed in 1984 to address a growing need for state administrators to have national representation, ASDWA has become a respected voice for states with Congress, the Environmental Protection Agency (EPA), other Federal agencies, and professional organizations in the water sector.

ASDWA's members are coregulators with EPA for the National Primary Drinking Water Regulations (NPDWRs), therefore the following comments are based on many years of participation in the Safe Drinking Water Act (SDWA) regulatory development process. ASDWA commends EPA for the Agency's efforts in completing and publishing the preliminary regulatory determinations from the Fourth Contaminant Candidate List (CCL4). ASDWA recognizes that making regulatory determinations is a complex decision-making process.

As detailed in the *Federal Register* notice, SDWA Section 1412(b)(1)(B)(ii) requires EPA to determine whether to regulate at least five contaminants from the Contaminant Candidate List (CCL) every five years. This *Federal Register* notice provides an opportunity for ASDWA to provide its perspective on the SDWA regulatory development process, including the CCL, the Unregulated Contaminant Monitoring Rule (UCMR) and regulatory determinations. Those overarching comments are at the end of this document, following ASDWA's comments on the preliminary regulatory determinations for PFOA and PFOS, for six other contaminants, and the status updates on three other contaminants.

Specifically for per- and polyfluoroalkyl substances (PFAS), ASDWA has provided multiple comment letters to EPA and ASDWA wants to reiterate our recommendation that EPA should work closely with other Federal agencies on a holistic PFAS approach to coordinate and administer all possible federal regulatory authorities to understand, assess, address, and remove PFAS from the environment or prevent PFAS from entering the environment, from all contributing media. This approach must include considerations for drinking water treatment and used media regeneration and disposal; disposal of PFAS in wastewater, sludge, and biosolids applications; and at landfills, in leachate, and in air emissions from incineration; as well as proper incineration protocols to ensure complete removal of PFAS from the environment. This holistic federal approach is needed to assess and address PFAS in drinking water and all media.

Comments on Preliminary Positive Regulatory Determinations for PFOA and PFOS

ASDWA commends and supports EPA for making positive preliminary regulatory determinations for perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS). ASDWA's members face many challenges as they work with public water systems (PWSs) to assess and address per- and polyfluoroalkyl substances (PFAS) in drinking water. Without a NPDWR, some states are implementing EPA's health advisory levels for PFOA and PFOS or setting their own state level standards for the first time. This regulatory action by EPA is a step in the right direction to provide national leadership and consistency for assessing and addressing PFAS in drinking water throughout the country. As EPA moves forward with these efforts, ASDWA would like to reiterate the importance of including and involving state drinking water programs and other stakeholders in each step of the decision-making processes for determining

and developing this regulatory determination, the proposed regulation, the final regulation, and potential regulations for other PFAS in the future.

EPA Regulatory Approaches

EPA is seeking feedback on potential regulatory approaches to address PFAS to support the potential development of a PFOA and PFOS regulation (pending final regulatory determinations) or in future PFAS regulatory actions. EPA continues to explore how to best use the available information when developing potential regulatory approaches for PFAS. Three potential regulatory approach options include: 1) evaluate each additional PFAS on an individual basis; 2) evaluate additional PFAS by different grouping approaches; and 3) evaluate PFAS based on drinking water treatment techniques.

ASDWA recommends that EPA consider a two-pronged approach that allows for:

1. Future PFAS regulatory development efforts that use grouping and/or treatment technique approaches for lesser known PFAS with little or no available health effects and occurrence information; and
2. Moving forward now with this regulatory determination for PFOA and PFOS and four additional PFAS with known health effects and occurrence data and information.

Grouping and Treatment Techniques for Lesser Known PFAS in Future Regulatory Actions

ASDWA recommends that EPA consider grouping and treatment technique approaches for PFAS compounds (beyond PFOA and PFOS and those that were included in UCMR3) that do not have enough health effects studies and/or occurrence data. These approaches are preferable options to evaluating each additional PFAS on an individual basis, which is unfeasible for assessing and addressing the universe of thousands of PFAS known to be in existence, or even the 602 commercially active PFAS from the retrospective reporting requirements of the Toxic Substances Control Act (TSCA) Inventory Notification Rule as detailed in the preamble language.

- *Grouping Approaches:* ASDWA supports EPA moving forward with its efforts to consider a science-based class approach, or new high throughput and computational approaches, for grouping PFAS with little or no known health effects studies and occurrence data. As noted in the preamble language, this would allow for a hazard assessment that divides a large group into smaller subclasses for different chemical categories of PFAS based on structure, degradation, co-occurrence, or a combination of characteristics. Grouping compounds for this regulatory determination and for future PFAS regulatory actions will allow for a more holistic approach rather than focusing on one compound at a time.

- *Drinking Water Treatment Techniques:* In the future, ASDWA recommends that EPA consider developing a treatment technique rule for other PFAS for which there may or not be analytical methods available to measure the level of each PFAS or total PFAS, and where there is not enough health effects or occurrence information to determine a Maximum Contaminant Level Goal (MCLG) or to set an enforceable maximum contaminant level (MCL) standard.

- *Other drinking water treatment technique considerations:* In the proposed regulation, EPA should ensure that treatment techniques consider redundancy and operational practices to reliably and consistently deliver safe water. This assessment is important for technologies like carbon adsorption and ion exchange that work very well when properly designed and operated but could be subject to treatment breakthrough.

Specific Compounds to Include with PFOA and PFOS for this Regulatory Determination

Recommendation for Four Additional PFAS for NPDWR	
PFNA	Perfluoroonanoic acid
PFHxS	Perfluorohexanesulfonic acid
PFHpA	Perfluoroheptanoic acid
PFDA	Perfluorodecanoic acid

ASDWA recommends that when finalizing this regulatory determination, EPA also include positive determinations for four additional long-chain PFAS compounds with PFOA and PFOS: PFNA, PFHxS, PFHpA, and PFDA. Including all six PFAS would be similar to current state approaches by Massachusetts, Vermont, Connecticut, New Hampshire, Minnesota, and Michigan to develop regulations and guidance for multiple compounds. The following factors (as described in the *ECOS Processes & Considerations for Setting State PFAS Standards White Paper*) support ASDWA's recommendation for including these additional compounds:

- PFOA, PFOS, PFNA, PFHxS, PFHpA, and PFBS were the six PFAS included in the EPA's third round of the Unregulated Contaminant Monitoring Rule (UCMR3). These PFAS have been researched to the extent that some states have developed (or are developing) guidelines or regulations. Though PFHpA has minimal toxicity data available and PFDA was not in UCMR3, some states are regulating both compounds with the other six long-chain PFAS based on close structural similarity. In addition, based on EPA's toxicity assessment for PFBS, a few states have derived a different risk level for the associated health effects and therefore have chosen not to move forward with guidelines or regulations that are similar to the other PFAS in UCMR3.
- These four long-chain compounds have similar chemical structures to PFOA and PFOS.
- These compounds are often found together in the environment and have characteristically similar bio-accumulative patterns and fate and transport mechanisms.
- Human exposures to these PFAS often are correlated, making it difficult to differentiate the contributions of the individual PFAS to health effects observed in humans.
- The toxicity for these compounds is assumed to be additive with similar toxicological effects, long serum half-lives in humans, and similar health effects in humans.
- These compounds have similar limits for lab detection via EPA Method 537 and 533, and there is a minimal cost difference between analyzing one or multiple compounds, so regulating and requiring testing for more analytes does not increase the cost and lessens the potential for the need to resample in the future.
- These compounds have high (and similar) removal rates for known treatment methods such as granular activated carbon (GAC), powdered activated carbon (PAC), anion exchange resins (Ion Exchange), nanofiltration and reverse osmosis.
- The *Massachusetts Technical Support Document* for its "Updated Subgroup Approach to Groundwater and Drinking Water Values" supports the relative potency evaluations published by states and other groups using National Toxicology Program (NTP) data for treating this subgroup of six PFAS (in ASDWA's recommendation) as being equipotent. This is because the relative potency estimates overlap across various endpoints and data did not demonstrate clear quantitative differences in potencies and mode(s) of action between these compounds.

The next step after a final positive regulatory determination for this group of six PFAS that would ultimately result in a NPDWR could vary. EPA could use different paths in the regulatory development process for the proposed and final regulations:

- Publish amended preliminary and final regulatory determinations to include all six PFAS, that would then allow EPA to proceed with a subsequent proposed regulation for all six PFAS; or
- Publish a final regulatory determination that includes the six PFAS; or

- Including the six PFAS in the regulatory development process to move forward with the proposed regulation for the six PFAS.

Other paths in the regulatory development process are possible and ASDWA is agnostic on any specific path if the development of the regulatory is expedited. Given the preamble language in the preliminary regulatory determination, EPA has the flexibility to move forward with the development of a proposed regulation for the six PFAS as soon as possible. ASDWA supports EPA in using this flexibility to expedite the regulatory development process.

Expediting the Regulatory Process for PFAS

ASDWA recommends that EPA finalize this regulatory determination for six PFAS as soon as possible. ASDWA further recommends that EPA expedite a proper and deliberative process for moving forward with developing a proposed regulation for the six PFAS, and then promulgating a final PFAS regulation sooner than the maximum amount of time allowed for this process (24 months plus 18 months, respectively). While EPA must follow the requirements in the SDWA in developing its rules, the slow process for doing this, which may have been understandable in the twentieth century, is less so today and the public is losing faith in the effectiveness of SDWA. Given that some states have developed or are developing their own PFAS regulations on a much shorter timescale, the current timeline for EPA to develop a NPDWR for PFOA and PFOS (and the other four compounds recommended for inclusion by ASDWA) is not timely. Expediting the process must also include using sound science and available data for determining drinking water treatment feasibility; conducting public health and economic cost/benefit analysis; determining the number of PWSs that are (and are not) impacted by PFAS; and ensuring laboratory capacity for compliance monitoring.

However, for expediting the process, ASDWA recommends that EPA move forward with developing this regulatory proposal while acknowledging that some of this data and analysis may be limited and allowing room for making decisions based on informed assumptions and the expectation that more data and information will be forthcoming. This will be particularly important for evaluating PFAS toxicity and health effects information and calculating cost/benefit analysis. For example, this regulatory proposal should proceed simultaneously with its efforts to continue evaluating PFNA, PFHxS, PFHpA and PFDA, with the expectation that more information and toxicity assessments will be forthcoming and available to feed into the regulatory process as it progresses. In addition, states that are developing PFAS standards and guidelines have made confident decisions based on the calculation of real costs as part of a cost/benefit analysis, while acknowledging the lack of robust data available to analyze and quantify the full array of benefits.

Need for Continued Research and Data Collection

ASDWA commends EPA for continuing to conduct research and collect data and information on PFAS with other federal agencies, states, universities, industry, and other stakeholders. This leadership and coordination are important for all current and future EPA PFAS actions and regulatory considerations. ASDWA recommends that EPA prioritize this research to focus on compounds that water systems are currently monitoring for using available analytical methods and that will likely be monitored for in the Fifth Unregulated Contaminant Monitoring Rule (UCMR5). As water systems sample for these compounds, it is essential for them to understand and communicate potential health effects with their customers.

Consideration for Alternative Standards and Precursors

Alternative Standards: ASDWA recommends that EPA also consider options for this regulatory proposal with respect to acute and chronic health effects and long-term versus short-term exposure for different levels of PFAS. Alternative models or different approaches could be used to provide safe drinking water to households served year-round by public water systems versus transient non-community water systems (TNCWSs) such as restaurants, hotels, and parks where human exposure and associated health effects would be significantly different. EPA should consider that while the populations that consume water at these public water systems is considered transient in nature, workers and regular patrons at these locations can be frequently exposed to drinking water contaminants. These workers and regular patrons could include pregnant women and other vulnerable populations.

EPA should develop a firm rationale for its decisions in this regard realizing that the field of environmental toxicology now has sophisticated tools to evaluate health effects far beyond the traditional focus on acute gastrointestinal illness or cancer that form the basis for many of the MCLs in the SDWA. Today, toxicologists evaluate impacts to organ function, the brain and central nervous system, immune system, endocrine system and skeletal system. Toxicologists are also focusing on different and sensitive life stages including pregnancy, fetal development and impacts that may not be apparent until adolescence. They are seeing that short-term exposures can lead to long-term health effects. These considerations deserve profound reflection by EPA and mechanisms need to be developed that account for this changed approach in toxicology in how the SDWA is applied. EPA should evaluate better ways to communicate health risks and relative risk in the public notice aspects of a future PFAS rule so that the public is aware when drinking water may be contaminated but better understands the actual health risk.

Precursors: It is also important for EPA to account for the potential presence of a PFAS precursor pool in drinking water that may lead to underestimates of PFAS exposure when developing health-based values for groups or individual PFAS. The precursors of these compounds may not be detected using standard drinking water methods but may have similar toxic profiles and/or be transformed through biological and environmental processes, which can increase the concentration of the analytes of concern.

Consideration for Existing State PFAS Standards

ASDWA recommends that EPA thoroughly consider state standards and guidelines with significantly lower PFAS levels than EPA's Health Advisory Level (HAL) of 70 parts per trillion (ppt) for combined concentrations of PFOA and PFOS for this regulatory determination. At least eight states are moving forward with their own state standards or guidelines using significantly lower PFAS levels than EPA's HAL, which will be in place well before EPA develops a final NPDWR. Six of these states are also including other PFAS at lower levels in their requirements for water systems, such as the four PFAS ASDWA is recommending EPA consider adding for this regulatory determination. These states that are requiring response actions by their water systems at lower PFAS levels are very concerned about the potential discrepancy if EPA develops a higher-level federal PFAS standard (e.g., at EPA's current HAL of 70 ppt). Considering these lower level state PFAS standards will be essential to ensure national consistency and to provide a unified national message for assessing and addressing PFAS in drinking water throughout the country.

Monitoring Considerations

Alternative Monitoring Approaches and Waivers: ASDWA commends EPA for its consideration of alternative monitoring approaches and waivers for this regulatory determination and regulatory

development process that also accounts for proximity to facilities with historical or on-going use of PFAS and fire-fighting foam (e.g., airports, military bases, landfills, and industrial sites). Monitoring waivers will need to be a significant component of the proposed regulation, particularly for some states where water systems have previously monitored for PFAS and/or have no known sources of PFAS nearby that could cause potential contamination.

Alternative monitoring approaches and waivers, in coordination with state primacy agencies, will be critical to minimizing the substantial administrative burden and costs for states to process waivers and track and provide assistance to systems with alternative monitoring approaches, such as for small rural groundwater systems that are geographically isolated from any potential PFAS contamination sources and for Transient Non-Community Water Systems (TNCWSs). It is not fiscally feasible or responsible to require every PWS to conduct an initial round of four quarters of monitoring when systems are isolated from potential PFAS contamination sources. Assuming $500 for each PFAS sample, an initial round of monitoring (four quarterly samples) for community water systems (CWSs) and non-community, non-transient water systems (NTNCWSs) would cost approximately $272,000,000 assuming an average of two sources per water system. This estimate is probably low as many groundwater systems have multiple wells, and while some wells draw from the same aquifer, many do not and would require more than two samples per system, depending on the number of entry points into the distribution system.

Minimum Reporting Limits: EPA should include using the lowest minimum reporting limits for each PFAS in the monitoring requirements for the proposed PFAS regulation. Having low detection limits (e.g., at 5 ppt or lower) would capture a more comprehensive data set from which to analyze occurrence and trends. This would also capture water systems that were found to have PFAS detections at lower levels than were used for the UCMR3, after they had no detections for UCMR3 at the higher detection level (e.g., at 20 ppt).

Laboratory Capacity: EPA must ensure that there are enough certified laboratories to conduct compliance sampling across the country and that certified laboratories have the capacity to analyze for PFAS. In addition, new validated methods for both drinking water and other media continue to be needed to provide consistent sample test results for many different PFAS compounds at very low minimum reporting levels for the large and growing number of PFAS being found in the environment.

Using Additional Regulatory Authorities to Keep PFAS Out of the Environment

ASDWA recommends that EPA continue to use the authorities under the Toxic Substance Control Act (TSCA) to regulate PFAS and to prevent the entry of such compounds into the environment. State drinking water programs and water utilities are stepping up to protect the public's health by removing these harmful compounds from drinking water, often at great cost, essentially cleaning up an environmental disaster they did not cause and could have been prevented by EPA. State drinking water programs and water utilities deserve recognition and respect for taking on this effort while the chemical manufacturers continue to profit from the use and sale of PFAS compounds.

Comments on Negative Regulatory Determinations for 1,1-Dichloroethane, Acetochlor, Methyl Bromide (Bromomethane), Metolachlor, Nitrobenzene, and RDX

ASDWA supports EPA's negative regulatory determinations for 1,1-Dichloroethane, Acetochlor, Methyl Bromide (Bromomethane), Metolachlor, Nitrobenzene, and RDX. ASDWA supports EPA's conclusions

that each of these contaminants does not present a meaningful opportunity for health risk reduction through a National Primary Drinking Water Regulation (NPDWR).

Comments on Status of the Agency's Evaluation of Strontium, 1,4-Dioxane, and 1,2,3-Trichloropropane

ASDWA commends EPA for the update on strontium in the *Federal Register* notice. ASDWA supports EPA continuing its efforts to better understand the potential adverse health effects from strontium. ASDWA looks forward to EPA's updated health assessment based on its updated literature search and systematic review of the most recent health effects information on strontium.

ASDWA commends EPA for the update on 1,4-dioxane in the *Federal Register* notice, and further commends EPA for recognizing that several of ASDWA's members (such as California and New York) have taken steps to control exposure from 1,4-dixoane in drinking water. ASDWA looks forward to EPA finalizing its draft risk evaluation, including the Canadian guideline and other relevant science, prior to making a regulatory determination.

ASDWA commends EPA for the update on 1,2,3-trichloropropane in the *Federal Register* notice. The details provided on the 75-fold difference between the Health Reference Level (HRL) of 0.0004 µg/L and the Minimum Reporting Level (MRL) of 0.03 µg/L in the Third Unregulated Contaminant Monitoring Rule (UCMR3) present significant challenges in using the UCMR3 data to determine if regulating 1,2,3-trichlororopropane would provide a meaningful opportunity for health risk reduction. ASDWA agrees with EPA that additional low-level national occurrence data is needed prior to making a preliminary regulatory determination for 1,2,3-trichloropropane. For the above reasons, ASDWA recommends that EPA finalize its regulatory determinations for strontium, 1,4-dioxane and 1,2,3-tricholopropane as soon as practical.

General Comments on Regulatory Determinations and the Regulatory Development Process

This *Federal Register* notice provides an opportunity for ASDWA and other stakeholders to provide its perspective on the SDWA regulatory development process, including the CCL and regulatory determinations. ASDWA commends EPA for its efforts in the regulatory development process, starting with the 1998 First Contaminant Candidate List (CCL1) through this *Federal Register* notice in 2020 as summarized below:

	First	**Second**	**Third**	**Fourth**
CCL	1998	2005	2009	2016
	60 contaminants	51 contaminants	116 contaminants	109 contaminants
UCMR	1999	2007	2012	2016
	26 contaminants	25 contaminants	30 contaminants	30 contaminants
Regulatory	2003	2008	2014	Prelim. -3/10/20
Determination	9-not regulated	11-not regulated	4-not regulated 1-needs more research	2-regulate 6-not regulate

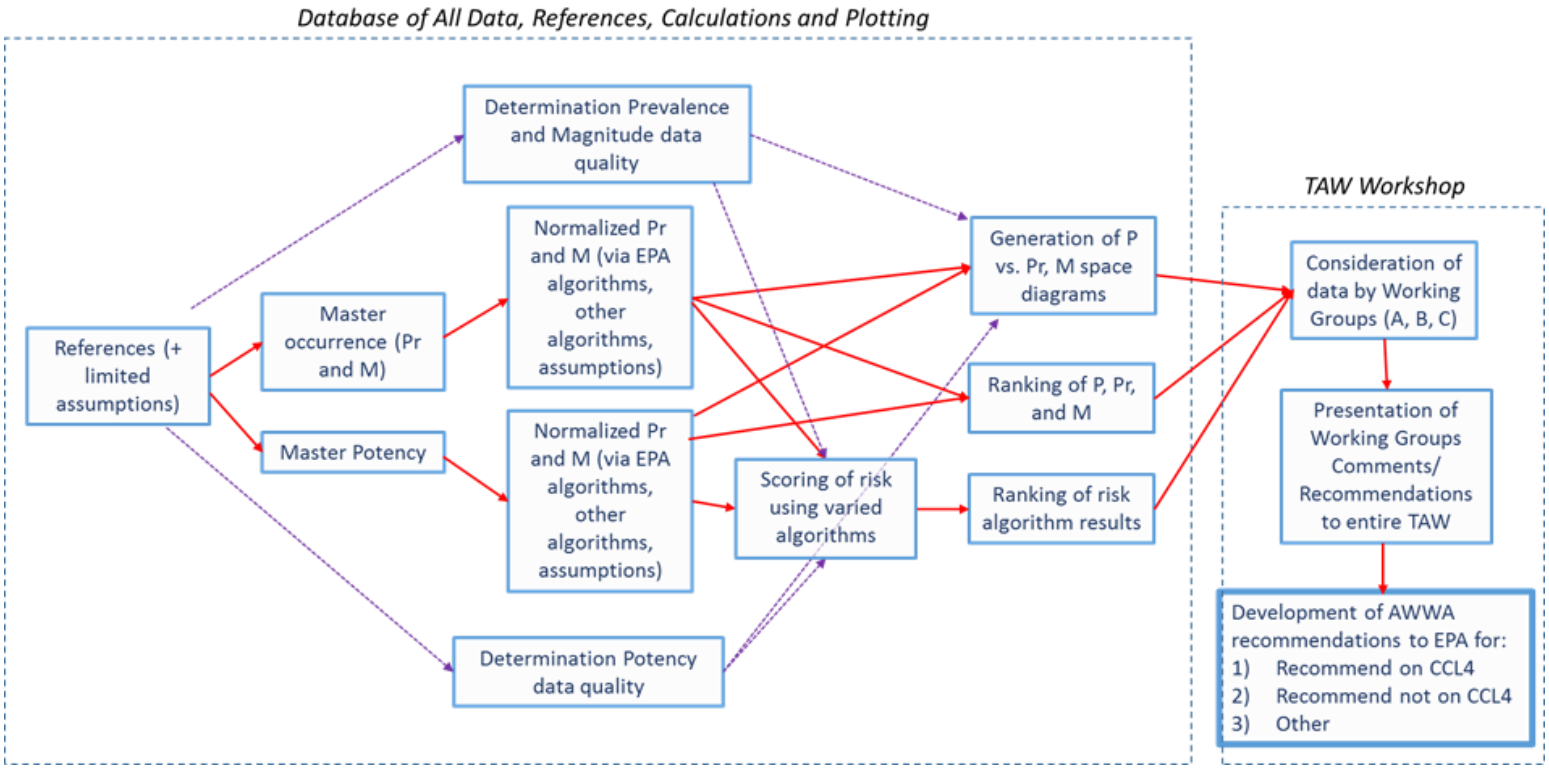
The summary table doesn't include the Agency's final positive regulatory determination for perchlorate in 2011. On June 26, 2019, EPA proposed a perchlorate MCL of 56 µg/L, as well as asking for comments on alternative MCLs of 18 µg/L and 90 µg/L and a withdrawal of the positive regulatory determination.

While this table shows the Agency's earnest efforts in the meeting the SDWA regulatory deadlines, the regulatory development process in Section 1412(b) has not regulated in any new NPDWRs, noting that "new" regulations should be the sole metric of the success of the SDWA. EPA has a court deadline of June 19, 2020 for the Agency's final action on perchlorate, either a national regulation using one of the three numbers or a withdrawal of the positive regulatory determination.

There are likely several alternative mechanisms to streamline SDWA regulatory development and ultimately, it's the Agency's decision on its approach to the regulatory development process. ASDWA recommends two approaches for EPA to consider for the final Fourth Regulatory Determinations and for the Draft Fifth Contaminant Candidate List (CCL5) that is scheduled to be proposed later in 2020:

1. Additional negative regulatory determinations should be made for eight CCL4 contaminants with either zero, one or two detections from national occurrence data. Published regulatory research from 2012 (*Journal-AWWA* paper enclosed as Appendix A to these comments) found eight additional contaminants (1,3-Dintrobenzene, nitrobenzene, dimethoate, disulfoton, diuron, molinate, terbufos, and terbufos sulfone) with zero, one, or two detections. Such limited national occurrence logically leads to negative regulatory determinations and EPA making those additional negative regulatory determinations would streamline future CCLs with a shorter list of contaminants.

2. Future CCLs, including CCL5, need to be shorter. Published regulatory research from 2015 (*Journal-AWWA* paper enclosed as Appendix B to these comments) found 55 contaminants where there was no need to consider further in the CCL process. A group of subject matter experts compiled three categories of data (or attributes) for each compound studied: potency, magnitude and prevalence as these attributes as the ones used by EPA. A fourth attribute, severity, was also used by EPA, but it was not used in this research as it was considered too subjective and/or required information that was not readily available to the researchers. The process schematic for the decision-making process is shown on the next page:



Using a combination of space diagrams and nine algorithms from published regulatory research in 2015, the researchers recommended that one volatile organic chemical (VOC), 16 industrial chemicals, four inorganics, four radionuclides, 16 pharmaceuticals, and 15 pesticides not be considered further in the CCL process and should be delisted.

Both of the above recommendations would significantly reduce the number of CCL contaminants, which would allow EPA to more appropriately focus it regulatory efforts and the underlying research to ask the most important question – does a national regulation provide a meaningful opportunity for health risk reduction? If EPA moves forward with both recommendations, then the proposed CCL5 would be 38 contaminants (109 [CCL4] minus 8 [preliminary Fourth Regulatory Determination] minus 63 [above recommendations]). This is a manageable number given EPA's flat funding for the past decade and increased SDWA implementation issues resulting from SDWA amendments in the Water Infrastructure Improvements for the Nation (WIIN) and the America's Water Infrastructure Act (AWIA).

Appendix A

Informing Regulatory Decisions Using National Occurrence Data

Roberson, J.A.

http://dx.doi.org/10.5942/jawwa.2012.104.0036

Roberson | http://dx.doi.org/10.5942/jawwa.2012.104.0036
Journal - American Water Works Association
PEER-REVIEWED

Informing regulatory decisions using national occurrence data

J. ALAN ROBERSON

AWWA, Washington, D.C.

As part of its regulatory development process, the US Environmental Protection Agency (USEPA) is charged with selecting the appropriate contaminants to regulate. The Safe Drinking Water Act (SDWA) lists three specific criteria for health effects, occurrence, and risk reduction that the USEPA must follow when identifying new contaminants for regulation. This article analyzes USEPA's past regulatory decisions and summarizes the underlying occurrence data used to support those decisions. This article also summarizes the occurrence data that will be used by USEPA in its third round of regulatory determinations scheduled to be proposed sometime in 2012.

KEYWORDS: *contaminants, occurrence, regulations, regulatory determinations*

The objective of the Safe Drinking Water Act (SDWA) is to ensure the provision of safe drinking water to customers served by public water systems. With an ever-increasing number of new chemicals being discovered and introduced into commerce, there is the potential to have a large number of national drinking water regulations for a large number of contaminants. The media regularly publishes stories about the "contaminant du jour" (NaturalNews, 2011). Some of these contaminants may be a legitimate public health concern, and some may be just media hype.

National drinking water regulations have to make sense from several points of view. Obviously, the US Environmental Protection Agency (USEPA) has to follow the law (the SDWA) in its regulatory development process. Oversight committees in Congress need to be re-assured that USEPA is doing its job in developing regulations for safe drinking water. New contaminants cannot exist only in a laboratory or be a problem only from the media's perspective. New contaminants have to occur in drinking water, and their removal has to provide increased public health protection. The challenge therefore is how to select the appropriate new contaminants for national drinking water regulations. In the end, drinking water utility ratepayers have to pay for any additional treatment to remove a specific contaminant, so the increased cost should make sense and be appropriately justified.

The 1996 SDWA Amendments (PL 104-182) mandated a new process for selecting new contaminants for potential regulation. The USEPA is required to publish a Contaminant Candidate List (CCL), a list of contaminants that might be a concern from the drinking water perspective, every five years. From the CCL, USEPA is required to make regulatory decisions, known as regulatory determinations, for at least five contaminants on a comparable cycle (every five years). These regulatory determinations are generally yes/no decisions to regulate/not regulate. But USEPA can also decide to issue a health advisory or other type of guidance or to determine that more research is needed for a specific contaminant.

If USEPA makes a positive regulatory determination for a specific contaminant (i.e., USEPA decides to move forward in the regulatory development process), the agency has 24 months after the final regulatory determination to propose a national drinking water regulation for that contaminant. USEPA has 18 months after the proposed regulation to promulgate a final one. If more time is needed, the deadline for the final regulation can be extended by nine months at the discretion of the USEPA administrator and with appropriate public notice.

The five-year cycles of CCLs and regulatory determinations are one of the four regulatory development processes used by USEPA. The second process is the six-year review in which USEPA reviews all existing drinking water regulations every six years. USEPA has completed two six-year reviews, and the policy implications of those reviews are compared with the regulatory determinations later in this article (USEPA, 2003a, 2010). The third process covers the "priority" regulations for which specific regulatory deadlines were set in the 1996 SDWA amendments (e.g., arsenic). The fourth process is an "out-of-cycle" regulatory determination. For example, if a contaminant rises to a high level of concern, USEPA can develop an "out-of-cycle" regulation, i.e., one that is separate from the five-year cycle for the CCL and regulatory determinations and from the six-year cycle for the six-year review. In February 2011, USEPA made an "out-of-cycle" regulatory determination for perchlorate (USEPA, 2011a).

REGULATORY HISTORY

USEPA has published three CCLs, has made two rounds of regulatory determinations, and has made one "out-of-cycle" determination (Table 1). The first CCL (CCL1) was published in 1998 and was developed using "expert judgment" (USEPA, 1998a). CCL1 contained 60 contaminants—50 chemicals and 10 microbial contaminants.

After CCL1 was published, USEPA asked the National Research Council (NRC) of the National Academies of Science for advice and recommendations to improve its initial CCL development process. The NRC recommended that USEPA develop a process that was more analytical in nature while still allowing for expert judgment to inform that process (NRC, 2001). To ensure input from a broad range of stakeholders, USEPA then asked the National Drinking Water Advisory Council (NDWAC) to form

a CCL workgroup to review the recommended NRC process and provide additional recommendations. The NDWAC CCL workgroup confirmed that the recommended NRC process was superior to the previous "expert judgment" process (NDWAC, 2004). The recommended process had three steps (Figure 1) and used screening and classification algorithms to narrow down the number of contaminants at each step of the process:

- Step 1—universe of contaminants,
- Step 2—preliminary CCL, and
- Step 3—CCL.

The NDWAC workgroup developed some implementation recommendations for each step of the process. The workgroup also recommended that a slightly different process be used for microbes versus chemicals because of the variances in available information. Finally, the NDWAC workgroup recommended that USEPA use a stepwise adaptive management approach to build on technological advances and to integrate the lessons learned in developing previous CCLs. This approach was not finalized in time to be applied to the second CCL (CCL2), but it was used for the third CCL (CCL3).

USEPA published the CCL2 in 2005 (USEPA, 2005). CCL2 contained the 51 "leftovers" (42 chemicals and nine microbial contaminants) from CCL1 after the first regulatory determinations were made for nine contaminants.

USEPA has made regulatory determinations for 20 contaminants, nine from CCL1 and 11 from CCL2, as shown in Table 2 (USEPA, 2003b, 2008a). For each of the 20 contaminants, USEPA made the determination not to regulate because the contaminant did not occur frequently in public water systems at levels of health concern and/or there was not a meaningful opportunity for health-risk reduction through a national regulation.

Using the three-step process recommended by NDWAC, USEPA published the CCL3 in 2009 (USEPA, 2009a). CCL3 contained 116 contaminants—104 chemicals and 12 microbial contaminants. As shown in Figure 1, USEPA started off with a universe of approximately 7,500 chemical and microbial contaminants and then used screening criteria to narrow this down to approximately 600 contaminants for the preliminary CCL. More detailed evaluation criteria and expert judgments were used to select the final 116 CCL3 contaminants. USEPA is scheduled to publish its preliminary third regulatory determination from CCL3 in 2012.

THE THREE CRITERIA FOR SELECTING NEW CONTAMINANTS

The 1996 SDWA amendments mandated a new process for selecting new contaminants for potential regulation. Section 1412(b)(1)(A) of the SDWA details the following three criteria that USEPA must follow in contaminant selection:

(1) The contaminant may have an adverse effect on the health of persons.

(2) 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.

(3) In the sole judgment of the administrator, regulation of such contaminant presents *a meaningful opportunity for health-risk reduction* (emphasis added) for persons served by public water systems.

A contaminant must meet each of the three criteria for a positive regulatory determination, i.e., to move forward in the regulatory development process toward a proposed/final drinking water regulation. It is not an either/or decision—all three criteria play a role in USEPA's decision-making process. USEPA is required to make regulatory determinations on at least five contaminants every five years.

One previous research approach on the first two criteria was the development of "risk indexes." These are graphs that showed both the relative health-effects and occurrence data and the data quality for each contaminant (Roberson et al, 2009). Initially, the researchers thought that this graphical approach might provide a simplistic approach (by comparing one graph with another) to placing potential contaminants into bins of "regulate," "don't regulate," or some "gray area" in between. But the variability in both the health effects and the occurrence data made this process more complex than initially anticipated, so this graphical approach was not pursued.

Although the focus of this article is on occurrence data (the second criterion), the other two criteria warrant some discussion. The first criterion (health effects) is extremely complex and subject to debate. In addition to the legitimate science and technical debates on the underlying science of human health effects associated with specific chemicals, many new chemicals with limited health-effects data are regularly created. The Chemical Abstracts Service lists more than 64 million chemicals—and a new one is added every 5 to 10 seconds (CAS, 2011). Adequate health-

TABLE 1 Regulatory history

Date	Reference	Regulatory Action	Outcome
Mar. 2,1998	USEPA, 1998a	CCL1	60 contaminants listed
July 18, 2003	USEPA, 2003b	RD1	Do not regulate nine
Feb. 24, 2005	USEPA, 2005	CCL2	51 contaminants listed
July 30, 2008	USEPA, 2008a	RD2	Do not regulate 11
Oct. 8, 2009	USEPA, 2009a	CCL3	116 contaminants listed
Feb. 11, 2011	USEPA, 2011a	"Out-of-cycle" RD for perchlorate	Regulate perchlorate

CCL—Contaminant Candidate List, CCL1—first CCL, CCL2—second CCL, CCL3—third CCL, RD—regulatory determination, RD1—first RD, RD2—second RD, USEPA—US Environmental Protection Agency

effects data do not yet exist for many potential drinking water contaminants, and because of resource constraints, they may never be obtainable.

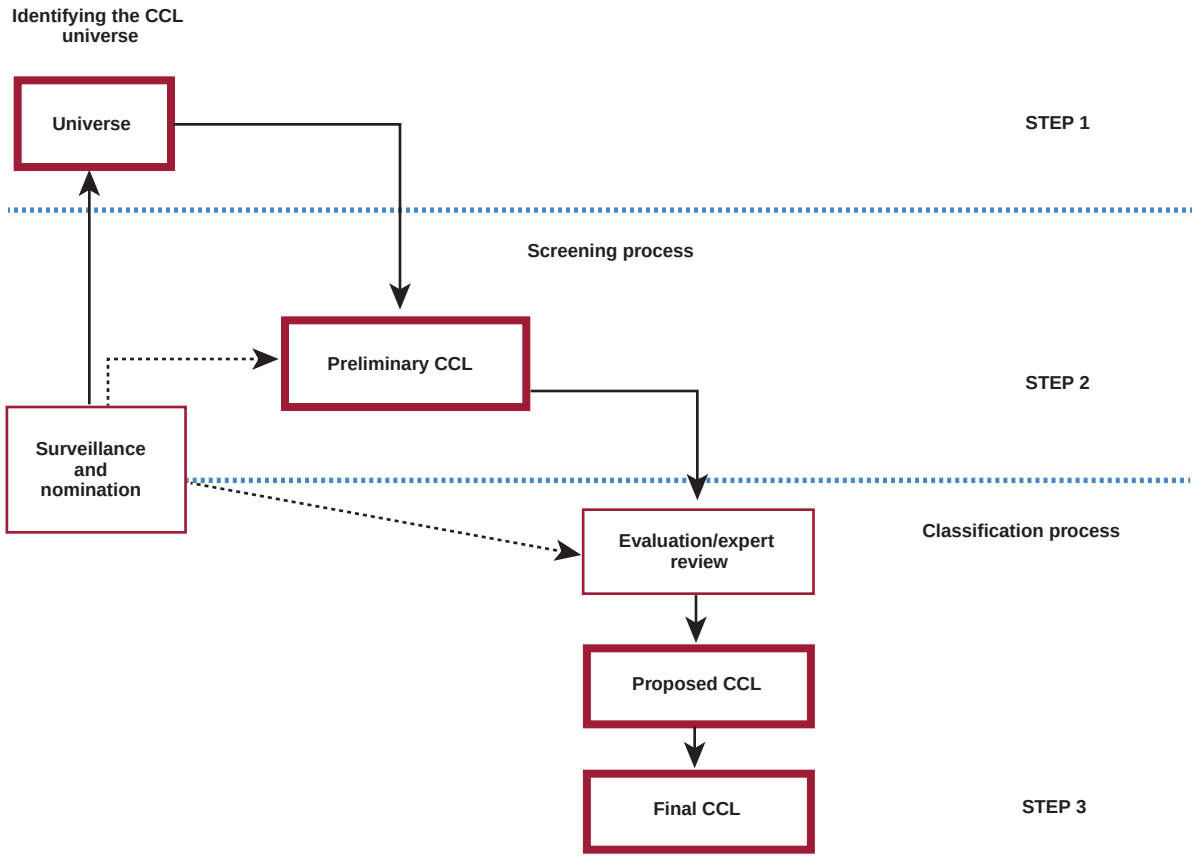
Exactly what constitutes "a meaningful opportunity for health risk reduction" is also open to debate. The logic behind the development of this language for the 1996 SDWA amendments was to provide the "best bang for the buck" and to not regulate contaminants simply to increase the number of contaminants being regulated (Curtis, 2011). Additionally, the phrase "sole judgment of the administrator" grants a lot of discretion to USEPA and clearly allows the administrator to make the final decision.

The number of systems or the population affected provides two potential benchmarks for meaningful opportunities for risk reduction. Meaningful opportunity also creates some debate for a whole host of underlying issues such as relative source contribution, i.e., the relative contribution of the risk from drinking water compared with other contributors to the total risk, such as food or air.

The criteria for evaluating meaningful opportunity also might vary depending on the potency of the specific contaminant. For example, USEPA might need to regulate a contaminant with a high-cancer-slope factor or a low reference dose compared with another contaminant with similar occurrence but with lower potency.

Finally, the cost for utilities to comply with a regulation for a potential contaminant is not a consideration when evaluating whether a contaminant should be regulated based on these three criteria. The tradeoff between treatment costs and health benefits is used later in the regulatory development process when USEPA conducts a benefit–cost analysis (called a health risk reduction and cost analysis in the SDWA) to evaluate different numerical standards. As part of its decision-making process, USEPA develops an estimate of the number of systems and the population potentially affected by a potential regulatory determination, and, ultimately, a rough estimate of the costs and financial impacts that might be borne by that affected population. Clearly, some

FIGURE 1 Overview of CCL Process Recommended by NDWAC Work Group



CCL—Contaminant Candidate List, NDWAC—National Drinking Water Advisory Council

consideration of both the costs and benefits by the USEPA administrator is part of the process of determining whether a regulation provides a "meaningful opportunity for health risk reduction." Therefore, developing some understanding of the relationship between the decision-making and the occurrence data is important from a policy perspective.

THE FIRST TWO REGULATORY DETERMINATIONS

USEPA uses a three-step process to evaluate both health effects and occurrence data for regulatory determinations that mirrors the three SDWA criteria:

(1) The health effects data are assessed to develop a health reference level (HRL).

(2) Data from nationally representative occurrence studies are analyzed and compared with the HRL (and half the HRL).

(3) The potential health risks above the HRL are evaluated to determine whether a national drinking water regulation provides . . . a meaningful opportunity for risk reduction.

The occurrence data used for the first two regulatory determinations are found in the *Federal Register* notices for the preliminary determinations (USEPA, 2002, 2007a). Tables 3 and 4 summarize the occurrence data provided in those two notices. With the exception of sodium and sulfate (both special cases), for the 20 contaminants included in these two determinations, USEPA decided that if the contaminant had detections above the minimum reporting levels (MRLs) in less than 50 systems, it did not warrant a national regulation because a national regulation would not provide a meaningful opportunity for risk reduction as mandated by the SDWA. In the case of sodium, USEPA determined that there is much higher exposure to sodium from food than from water. In the case of sulfate, USEPA determined that the health effects from sulfate are mild and self-limiting.

Detections above the HRL in fewer than 50 systems is not a "bright line" for determining whether a national regulation is warranted. As previously discussed, basing these decisions on the judgment of the USEPA administrator provides some discretion to the agency for its decision-making. The upper limit of that line is likely higher than 50 systems, but it is not clear at this time what that upper limit might be. It would be hard to argue that occurrence at levels of health concern in the range of 1,000-2,000 systems in several states did not warrant a national drinking water regulation. More than 50 systems and less than 1,000 systems might be more of a "gray area" rather than a specific number. The administrator would take into account some of the factors previously discussed, such as the population and number of systems affected, the geographic distribution of occurrence (occurs in five states versus 15 states), and the relative potency and source contribution of the contaminant.

THE THIRD CCL

The *Federal Register* notice for CCL3 contained a research needs table that summarized USEPA's assessment of the health effects, occurrence, and treatment research needs for each of the 116 contaminants (104 chemicals, 12 microbials) identified in the list. Although almost all contaminants had some research gaps, the table showed the relative lack of occurrence data for a large number of CCL3 contaminants. Twenty contaminants had substantial health-effects data gaps versus 65 contaminants that had no comprehensive drinking water occurrence data. The lack of occurrence data shows the need to develop appropriate new analytical methods and collect the occurrence data through future Unregulated Contaminant Monitoring Rules (UCMRs), i.e., to monitor for contaminants that appropriately fit the needs of the regulatory development process.

THE FIRST POSITIVE REGULATORY DETERMINATION

Perchlorate was listed on both the CCL1 and CCL2, but it was not addressed in either of the first two regulatory determinations. In 2008, outside of the standard five-year cycle, the Bush administration made a preliminary negative regulatory determination for perchlorate, i.e., perchlorate in drinking water should not be regulated because it ". . . would not represent a meaningful opportunity for health risk reduction . . . " (USEPA, 2008b). Under the Obama administration in 2009, USEPA published a "Supplemental Request for Comments on Regulating Perchlorate" (USEPA, 2009b).

One of the issues that USEPA requested comments on in this notice was whether it would be appropriate for USEPA to take occurrence data from one state, i.e., Massachusetts (which has a laboratory MRL of 1 µg/L), and apply these data using a Bayesian hierarchical model to estimate national occurrence based on the data from the first UCMR (UCMR1), which had an MRL of 4 µg/L. This modeling approach would be a new way to estimate low-level "national" occurrence data as opposed to using real monitoring data.

Actual national occurrence data through UCMR1 has been summarized elsewhere (Brandhuber et al, 2009). Based on the UCMR1 data, 9 systems (0.02%) had perchlorate levels greater than 20 µg/L, 41 (0.08%) had perchlorate levels greater than 10 µg/L, and 150 (0.3%) had perchlorate levels greater than 6 µg/L. Although these are relatively low numbers of systems from a

TABLE 2 Contaminants not regulated by first and second regulatory determinations

First Regulatory Determinations	Second Regulatory Determinations
Acanthamoeba	Fonofos
	Terbacil
	1,1,2,2-Tetrachloroethane
Aldrin	1,1-Dichloro-2,2-bis(p-chlorophenyl)ethylene
Dieldrin	1,3-Dichloropropene
Hexachlorobutadiene	2,6-Dinitrotoluene
Manganese	Boron
Metribuzin	2,4-Dinitrotoluene
Napthalene	*s*-Ethyl dipropylthiocarbamate
Sodium	Dacthal mono-acid degradate
Sulfate	Dacthal di-acid degradate

national perspective (particularly when compared with the first two regulatory determinations), an analysis of potentially lower levels of health concern would likely yield a larger number of affected systems.

In February 2011, USEPA Administrator Lisa Jackson subsequently announced at a hearing of the Senate Environment and Public Works Committee that USEPA had reversed its position and would be developing a national drinking water regulation for perchlorate. The final determination was published in the *Federal Register* a few weeks later (USEPA, 2011a). On the basis of the statutory deadlines published in the 1996 SDWA amendments, USEPA now has until February 2013 to propose a perchlorate regulation. What remains to be seen is whether this new approach for estimating national occurrence data for developing a drinking water regulation will be used, because it would be a significant shift from using actual national monitoring data.

Whether this new approach meets the second criteria listed in section 1412(b)(1)(A), ". . . known to occur or there is a *substantial likelihood* [emphasis added] that the contaminant will occur . . ." is, of course, debatable. USEPA does not have to prove national occurrence "beyond a reasonable doubt." The SDWA provides the agency with lots of "wiggle room" with the phrase "substantial likelihood"—actual national monitoring data may not be necessary to make a positive regulatory determination, now or in the future.

THE UPCOMING THIRD REGULATORY DETERMINATION

USEPA held a stakeholder meeting June 16, 2011, on the upcoming third regulatory determination (RD3) that is scheduled to be proposed in 2012 and finalized in 2013 (USEPA, 2011b). At this stakeholder meeting, USEPA provided background on the SDWA regulatory development process and the approach being used for RD3. USEPA also provided a summary of occurrence data from 32 of the 116 CCL3 contaminants for which health assessments could have been completed by 2011 and national occurrence data are available (or state-level occurrence data show some levels of potential health concern). Table 5 shows those 32 contaminants.

Tables 6 and 7 summarize the occurrence data presented at that stakeholder meeting. Most of the occurrence data came from UCMR1, UCMR2, and the National Inorganics and Radionuclide Survey, but USEPA also presented other occurrence data. USEPA does not rely solely on UCMR data in making regulatory determinations. Other "reliable" data can be used, such as the older UCM, monitoring data from the US Geologic Survey, and data from individual states.

Nitrosamines were detected more frequently than any other contaminant in UCMR2 (Table 6). As of Mar. 1, 2011, *N*-nitrosodimethylamine was detected in 324 of 1,198 (27.0%) systems at levels ranging from 2 to 630 ng/L. Additionally, *N*-nitrosodiethylamine was detected in 26 of 1,198 systems (2.2%), and *N*-nitrosopyrrolidine was found in 21 of 1,198 systems (1.8%). The other three nitrosamines had relatively low occurrence.

Table 7 summarizes the occurrence data for 10 CCL3 contaminants that were discussed at the June 2011 stakeholder meeting. Chlorate was the only other contaminant with relatively high occurrence data that was discussed at the meeting. On the basis of the limited monitoring data gathered under the Information Collection Rule (ICR) during 1997–98, 22/59 plants (37.3%) using hypochlorite had samples above the HRL (210 µg/L). For plants using chlorine dioxide, 15/29 (51.7%) had samples above the HRL (210 µg/L). Because of the lack of occurrence data, chlorate has been proposed to be included in the UCMR3. Six other CCL3 contaminants from Table 7 have also been proposed for inclusion in the UCMR3.

Table 8 lists nine contaminants with zero or near-zero occurrence data discussed at the stakeholder meeting. The chloroacetanilides and their degradates (an additional eight contaminants) also had zero or near-zero occurrence, but the occurrence data from the UCMR2 Screening Survey are more limited because these data were collected from a small subset of systems.

TABLE 3 Summary of first regulatory determination occurrence data

Contaminant	HRL µg/L	Data Source	Number of Systems With Detects (> ½ HRL)—%	Number of Systems With Detects (> HRL—%)	Population Affected (> HRL—%)	Population Affected (> HRL—%)
Aldrin	0.002	UCMRd2	2/12,165 (0.02)	2/12,165 (0.02)	8,700/47.7 M (0.02)	8,700/47.7 M (0.02)
Dieldrin	0.002	UCMRd2	11/11,788 (0.09)	11/11,788 (0.09)	32,200/45.8 M (0.07)	32,200/45.8 M (0.07)
Hexachlorobutadiene	0.9	UCMRd1	20/12,284 (0.16)	14/12,284 (0.11)	407,600/71.6 M (0.57)	262,500/71.6M (0.37)
		UCMRd2	18/22,736 (0.08)	4/22,736 (0.02)	1.6 M/67.1 M (2.3)	3,100/67.1 M (0.005)
Manganese	300	NIRS	60/989 (6.1)	32/989 (3.2)	68,100/1.5 M (4.6)	39,000/1.5 M (2.6)
Metribuzin	91	UCMRd2	0/13,512 (0)	0/13,512 (0)	0/50.6 M (0)	0/50.6 M (0)
Napthalene	140	UCMRd1	2/13,452 (0.01)	2/13,452 (0.01)	5,600/77.2 M (0.007)	5,600/77.2 M (0.007)
		UCMRd2	2/22,923 (0.01)	0/22, 293 (0)	1,700/67.5 M (0.002)	0/67.5 M (0)
Sodium	120,000	NIRS	224/989 (22.6)	131/989 (13.2)	274,300/1.5 M (18.5)	123,600/1.5 M (8.3)
Sulfate	500,000	UCMRd2	819/16,495 (4.97)	295/16,495 (1.8)	5.2 M/50.4 M (10.2)	446,200/50.4 M (0.9)

HRL—health reference level; M—million, UCMRd1—Unregulated Contaminant Monitoring, round 1; UCMRd2—UCM, round 2; NIRS—National Inorganics and Radionuclides Survey

USEPA faces some challenges in making regulatory decisions, given the limited detections previously discussed. Production and/or release/use data, such as the Toxic Release Inventory or the pesticide use data from the National Center for Food and Agricultural Policy could also be used as a surrogate for real national occurrence data. These data could be used to determine whether there is a "substantial likelihood" that a contaminant can occur in drinking water. However, any modeling or extrapolation from these types of data sources should be validated with the monitoring data from UCMR1 and UCMR2, using the contaminants with zero or near-zero detections. Whatever surrogates are used must be validated with the "real" monitoring data. Although the SDWA statutory language gives USEPA this option, shifting from actual national monitoring data to modeling to estimate "substantial likelihood" is a significant policy change for selecting new contaminants for regulation. Any modeling needs to be appropriately validated.

USEPA is continuing to work on the *Federal Register* notice for a preliminary RD3 that will be published in 2012. At this point, USEPA will likely issue some positive determinations for nitrosamines, given their relatively high occurrence percentage identified in the UCMR2. The biggest issues for nitrosamines are the small amount of risk they pose in drinking water compared with the risk in food and to what extent nitrosamines are generated inside the body (Fristachi & Rice, 2007). USEPA will be challenged to demonstrate that a nitrosamines regulation will provide a meaningful opportunity for risk reduction as mandated by the SDWA. If nitrosamines are to be regulated, appropriate potential risk management actions must still be addressed. USEPA will also likely issue some negative determinations for the contaminants listed in Table 8 with zero or near-zero occurrence such as (but not limited to) disulfoton, diuron, molinate, and RDX. A potential regulatory determination (either positive or negative) for chlorate is uncertain at this time given its limited ICR data and its inclusion in the proposed UCMR3.

REGULATORY DETERMINATIONS VERSUS SIX-YEAR REVIEWS

The policy differences between regulatory determinations (selecting a new contaminant for regulation) and six-year reviews (revising an existing regulation) warrant some discussion. A previous analysis of the supporting data for the first six-year review found an upper limit of 1,067 systems that could potentially be affected by lower maximum contaminant levels (MCLs), and USEPA decided not to lower the existing MCLs for these contaminants (Roberson, 2005). For most of the contaminants that USEPA considered for potentially lower MCLs, the number of systems affected was in the range of 10–200. According to USEPA's analysis, dichloromethane would affect the largest number of systems (1,067) by potentially lowering the MCL from 0.005 to 0.00025 mg/L. USEPA concluded that the administrative and transactional costs for lowering a handful of national drinking water regulations did not make sense for the resulting small reduction in risk.

Additionally, the resultant changes in exposure from these two regulatory processes warrant some discussion. With a new regulation for a new contaminant, systems with relatively high concentrations of that contaminant are now required to reduce its concentration to the new MCL. The highest values, or the

TABLE 4 Summary of second regulatory determination occurrence data

Contaminant	HRL *µg/L*	Data Source	Number of Systems With Detects (> ½ HRL—%)	Number of Systems With Detects (> HRL—%)	Population Affected (> ½ HRL—%)	Population Affected (> HRL—%)
Boron	1,400	NIRS	43/989 (4.3)	17/989 (1.7)	42,700/1.48 M (2.9)	6,400/1.48 M (0.4)
Dacthal di-acid degradates	70	UCMR1	2/3,868 (0.05)	1/3,868 (0.03)	739,000/225 M (0.33)	500/225 M (< 0.01)
Dachtal mono-acid degradates	70	UCMR1	2/3,868 (0.05)	1/3,868 (0.03)	739,000/225 M (0.33)	500/225 M (< 0.01)
1,1-Dichloro-2,2-bis(p-chlorophenyl) ethylene	0.2	UCMR1	NR	1/3,867 (0.03)	NR	18,000/226 M (0.01)
1,3-Dichloropropane	0.4	UCMRd1	15/9,164 (0.16)	15/9,614 (0.16)	436,000/51 M (0.86)	436,000/51 M (0.86)
		UCMRd2	50/16,787 (0.30)	38/16,787 (0.23)	193,000/46 M (0.42)	152,000/46 M (0.33)
		UCMR1	NR	0/796 (0)	NR	0/2.8 M (0)
2,4-Dinitrotoluene	0.05	UCMR1	NR	1/3,866 (0.03)	NR	38,000/226 M (0.02)
2,6-Dinitrotoluene	0.05	UCMR1	NR	0/3,866 (0)	NR	0/226 M (0)
EPTC	175	UCMR1	0/3,866 (0)	0/3,866 (0)	0/226 M (0)	0/226 M (0)
Fonofos	10	UCMR1	0/295 (0)	0/295 (0)	0/41 M (0)	0/41 M (0)
Terbacil	90	UCMR1	0/3,866 (0)	0/3,866 (0)	0/226 M (0)	0/226 M (0)
1,1,2,2-Tetrachloro-ethane	0.4	UCMRd1	44/20,407 (0.22)	41/20,407 (0.20)	1.6 M/95 M (1.69)	1.5 M/95 M (1.63)
		UCMRd2	18/24,800 (0.07)	17/24,800 (0.07)	362,000/71 M (0.51)	56,000/71 M (0.08)

HRL—health reference level; M—million; NIRS—National Inorganics and Radionuclides Survey; UCMR1—first Unregulated Contaminant Monitoring Rule; NR—not reported because method reporting limit > ½ HRL; UCMRd1—Unregulated Conaminant Monitoring, round 1; UCMRd2—UCM, round 2

"tails," of the national exposure to that contaminant are reduced substantially (to the new MCL) with a new regulation. With a potential revision to an existing regulation being considered as part of the six-year review, the current relatively low exposure (as a result of an existing MCL) is potentially lowered by a small increment.

Disinfection by-products (DBPs) provide an example of the differences in the calculated health outcomes and in the policy implications of promulgating a new regulation versus revising an existing one. DBPs were first regulated in 1979 under the Total Trihalomethanes Rule (TTHMR; USEPA, 1979). DBP regulations were later strengthened with the Stage 1 and Stage 2 of the Disinfectants/Disinfection Byproducts Rule (D/DBPR; USEPA, 1998b, 2006). The resultant changes in DBP exposure from these regulations provide some insights into both health outcomes and policy implications.

Data collected in finished drinking water between 1975 and 1976 (pre-TTHMR) show mean TTHM levels of 68 µg/L and a 90th percentile of 150 µg/L (AWWA & AwwaRF, 2002). Post-TTHMR, data gathered from finished water samples collected between 1997 and 1998 under the ICR show mean TTHM levels of 28 µg/L and a 90th percentile of 60 µg/L. These are significant reductions in both the means and 90th percentiles (150% reduction) resulting from the TTHMR. The Stage 1 and Stage 2 D/DBPR are more akin to revising an existing regulation (i.e., the TTHMR). In contrast, USEPA estimated a 24% reduction in the TTHM levels from the Stage 1 DBPR (USEPA, 1998b).

The preceding example compares the efficacy of developing a new regulation versus modifying an existing regulation. It is clear from these data that a new regulation is more effective at reducing high exposures. This cursory analysis does not address the policy issue of whether it is better to have a greater percentage of exposure reduction for a smaller number of systems with relatively high levels (for regulating a new contaminant) or to have a small percentage reduction for a larger number of systems when an existing regulation is revised. The answer is not as simple as multiplying the number of people affected by the resultant change in concentration of the specific contaminant, and this policy issue is worthy of a more substantive debate.

The transactional costs between these two regulatory development processes also warrant some discussion. When USEPA promulgates a regulation for a new contaminant, each state has to develop its own regulation that is at least as strict as the federal regulation to maintain primacy for their drinking water program. Additional transactional costs are necessary, and they cannot be avoided. When revising an existing regulation, USEPA and each individual state would have to go through its own process to incorporate these revisions into their own specific requirements. The transactional costs for both new and revised regulations are not inconsequential, especially given the current fiscal climate at both the national and state levels.

Community water systems are normally required to conduct an initial round of quarterly monitoring for any new contaminant that is being regulated, and that cost can be significant from a national perspective. Assuming a national average of two entry points to the distribution system for the 52,000 regulated community water systems (CWSs) and an analytical method that costs $125, the initial round of quarterly monitoring for a year for a new contaminant would cost $52 million. The cost for each CWS is only $1,000, but the total national cost is significant. The additional monitoring costs for revising a regulation (assuming the standard was lowered) are more difficult to quantify because existing monitoring waivers might not apply and a new initial round of monitoring might be required to ensure that the CWSs are well below the revised standard.

Additionally, the drinking water sector has spent a significant amount of time and resources for UCMR1 and UCMR2 (and more will be spent on UCMR3) as shown here:

TABLE 5 Thirty-two CCL3 contaminants discussed at June 16, 2011, stakeholder meeting

CCL3 Contaminants
Nitrosamines
N-nitrosodimethylamine (NDMA)
N-nitrosodiethylamine (NDEA)
N-nitrosodi-n-propylamine (NDPA)
N-nitrosopyrrolidine (NPYR)
N-nitrosodiphenylamine (NDPhA)
Chlorate
Molybdenum
Strontium
Vanadium
1,1,2-Tetrachloroethane
1,2,3-Trichloropropane (TCP)
1,3-Dinitrobenzene
1,4-Dioxane
Methyl *tert* butyl ether (MTBE)
Nitrobenzene
Perfluorooctane sulfonic acid (PFOS)
Perfluorooctanic acid (PFOA)
RDX (cyclotrimethylenetrinitramine)
Dimethoate
Disulfoton
Diuron
Molinate
Terbufos
Terbufos sulfone
Acetochlor
Acetochlor ethanesulfonic acid
Acetochlor oxanilic acid
Alachlor ethanesulfonic acid
Alachlor oxanilic acid
Metolachlor
Metolachlor ethanesulfonic acid
Metolachlor oxanilic acid

- UCMR1— $14.5 million (USEPA, 1999),
- UCMR2— $29 million (USEPA, 2007b), and
- Proposed UCMR3— $43.6 million (USEPA, 2011c).

The combined investment of $43.5 million in UCMR1 and UCMR2 is significant given the relatively large number of contaminants with zero and near-zero detects. No one can argue that nondetects are good from a public health perspective because zero detects in a UCMR conclusively demonstrates that contaminant "X" does not occur in drinking water. The question is whether we can better optimize the selection of the UCMR analytes to fill the occurrence data gaps of the contaminants with the greatest potential adverse health effects.

WHAT THE FUTURE HOLDS

USEPA faces significant challenges ahead in selecting new contaminants for regulation, and that situation is unlikely to change in the future. The number of new chemicals being developed every day is increasing. New and improved analytical methods continue to drive down detection limits, and the detection of new and emerging chemicals in drinking water raises concerns about potential adverse health effects. This is especially problematic if corresponding health effects data at low levels typically found in the environment are not yet available.

The Government Accountability Office (GAO) released a report in May 2011 recommending improvements to the process that USEPA uses to make decisions on regulating contaminants (GAO, 2011). Some of the GAO's recommendations advised that USEPA's Office of Water should:

- develop criteria and a process for identifying CCL contaminants that present the greatest public health concern,
- develop a coordinated process to obtain both health effects and occurrence data for the CCL contaminants, and
- use its full statutory authority under the SDWA to require UCMR testing for 30 contaminants and should require assessment monitoring (as opposed to screening) for most (or all) of the 30 contaminants.

Clearly, implementing all of GAO's recommendations would require a substantial investment of time and financial resources by USEPA. In addition, some of GAO's recommendations, such as the development of policies or guidance to interpret the broad statutory criteria, might limit the discretionary authority currently allowed the USEPA administrator under the SDWA.

USEPA is also under pressure from some in Congress and from some environmental advocates to "do something," i.e., regulate something new. The current fiscal climate probably will exacerbate these problems. USEPA's budget will likely be reduced in the future, resulting in fewer resources for both the regulatory development process and the supporting research. Water utilities are also experiencing revenue challenges that restrict their ability to support research.

In the future, the regulatory development process for new contaminants will be chasing smaller and smaller risks compared with those posed by the 91 contaminants currently regulated. Proving that regulating a new contaminant provides a meaningful opportunity for risk reduction as set forth in the SDWA will continue to be a challenge for USEPA. Although these challenges continue to grow for USEPA, water utilities need to be able to explain the risk reductions that are anticipated by the new regulations.

That does not, however, mean that the water sector should throw up its hands and declare that this policy question is too difficult to solve. One potential solution is a more collaborative process between USEPA, state regulators, water systems, environmental advocates, and other stakeholders on how to refine the process for identifying new contaminants for regulation. USEPA has done this in the past through the National Drinking Water Advisory Council and federal advisory committees in addition to using other available methods of collaboration.

The agency is also working on making the regulatory development process more efficient by regulating contaminants as a group rather than addressing them one at a time. USEPA has regulated groups in the past (e.g., DBPs and radionuclides). USEPA has identified carcinogenic volatile organic chemicals (cVOCs) as the first group to be regulated under this new approach (USEPA, 2011d). The cVOC Rule is scheduled to be proposed in 2013.

TABLE 6 Summary of UMCR2 nitrosamines occurrence data*

Nitrosamine	MRL *ng/L*	Number of Samples With Detects	Number of Systems With Detects	Approximate Population Affected by Detects
NDMA	2	1,787 (10%)	324 (27%)	94 M
NDEA	5	46 (0.3%)	26 (2.2%)	13 M
NPYR	2	41 (0.2%)	21 (1.8%)	9 M
NDBA	4	9 (0.05%)	5 (0.4%)	2 M
NMEA	3	3 (0.02%)	3 (0.3%)	0.2 M
NDPA	7	0	0	0

*As of Mar. 1, 2011, determined from approximately 17,900 samples collected from 1,200 public water systems

M—million, MRL—minimum reporting level, NDBA—*N*-nitrosodibutylamine, NDEA—*N*-nitrosodiethylamine, NDMA—*N*-nitrosodimethylamine, NDPA—*N*-nitrosodipropylamine, NMEA—*N*-nitrosomethylethylamine, NPYR—*N*-nitrosopyrrolidine, UCMR2—Unregulated Contaminant Monitoring Rule 2

More work is needed to refine the existing process for identifying new contaminants for regulation so that the public is assured that the drinking water is safe. At the same time, more outreach is needed so that the public understands that detection does not necessarily equate to risk. Addressing both of these needs will be a challenge for both USEPA and the drinking water community.

ACKNOWLEDGMENT

The author thanks Gary R. Lynch from Park Water Company for his reviews of early drafts of this article and for his suggestions to improve it.

ABOUT THE AUTHOR

J. Alan Roberson *is the director of federal relations for AWWA in the association's government affairs office at 1300 Eye St. NW, Suite 701W, Washington, DC 20005-3314. He can be reached at aroberson@awwa.org.*

PEER REVIEW

Date of submission: 12/05/2011
Date of acceptance: 02/10/2012

REFERENCES

AWWA and AwwaRF, 2002. Information Collection Rule Data Analysis (M.J. McGuire, J.L. McLain, and A. Obolensky, editors). Denver.

Brandhuber, P.; Clark, S.; & Morley, K., 2009 A Review of Perchlorate Occurrence in Public Drinking Water Systems. *Jour. AWWA*, 101:11:63.

CAS (Chemical Abstracts Service), 2011. www.cas.org/ (accessed Dec. 2, 2011).

Curtis, T., 2011. Personal communication.

Fristachi, A. & Rice, G., 2007. Estimation of the Total Daily Intake of NDMA Attributable to Drinking Water. *Jour. Water & Health*, 05:3:341.

GAO, 2011. Safe Drinking Water Act: EPA Should Improve Implementation of Requirements on Whether to Regulate Additional Contaminants. GAO-11-254. Washington.

National Research Council, 2001. *Classifying Drinking Water Contaminants for Regulatory Consideration.* National Academy Press, Washington.

NaturalNews, 2011. Sucralose Found in Drinking Water Supply for More Than 28 Million Americans. www.naturalnews.com/033661_sucralose_drinking_water.html (accessed Nov. 28, 2011).

TABLE 7 Summary of occurrence data for 10 CCL3 contaminants

Contaminant	HRL µg/L	Data Source	Systems (> HRL—%) or Samples With Detects	Maximum µg/L
Chlorate*	210	ICR hypochlorite	22/59 (37)	
		ICR chlorine dioxide	15/29 (52)	
Molybdenum	35	NIRS	6/989 (0.6)	
Strontium*	4,200	NIRS	23/989 (2.33)	
Vanadium*	21	NIRS	17/989 (1.7)	
1,1,1,2-Tetra-chloroethane	1	UCMRd1	9/17,000 (0.05)	
		UCMRd2	8/24,000 (0.03)	
		State of North Carolina	5/2,500 (0.2; samples)	
1,2,3-Trichloropropane (TCP)*	0.005	UCMRd1	44/17,000 (0.3)	
		UCMRd2	19/24,000 (0.1)	
		State of Califonia	157/400 (4; samples)	
1,4-Dioxine*	3	State of California	13/218 (6; samples)	
Methyl *tert* butyl ether (MTBE)	19.4	UCMR1A	5/4,000 (0.13)	
		State of California	19/4,000 (0.4; samples)	
Perfluorooctanic acid (PFOA)*	1.1	State of Alabama (from Tennessee River)	18/40 (45; samples)	0.598
		State of Minnesota	7/85 (8; samples)	0.9
		State of New Jersey	4/7 (57; samples)	0.55
		State of Ohio (from Little Hocking)	All detects in samples from the distribution system > HRL	7.2
Perfluooctane sulfonic acid (PFOS)*	0.2	State of Alabama (from Tennessee River)	40/40 (100; samples)	0.144
		State of Minnesota	6/85 (7; samples)	1.4
		State of New Jersey	2/7 (29; samples)	0.014

* Proposed for third Unregulated Contaminant Monitoring Rule (UCMR3)

CCL3—Contaminant Candidate List 3; HRL—health reference level; ICR—Information Collection Rule; NIRS—National Inorganics and Radionuclides Survey; UCMR1A—first Unregulated Contaminant Monitoring Rule assessment survey; UCMRd1—unregulated contaminant monitoring, round 1; UCMRd2—unregulated contaminant monitoring, round 2

TABLE 8 Potential RD3 negative determinations

Contaminant	UCMR1A Detects	UCMR1S Detects	UCMR2A Detects
1,3-Dinitrobenzene			0
Nitrobenzene	2	0	
RDX			3
Dimethoate			0
Disulfoton		0	
Diuron		1	
Molinate	1		
Terbufos		0	
Terbufos sulfone			1

RD3—third regulatory determination, UCMR1A—first Unregulated Contaminant Monitoring Rule assessment monitoring, UCMR1S—first Unregulated Contaminant Monitoring Rule screening monitoring, UCMR2A—second Unregulated Contaminant Monitoring Rule assessment monitoring

NDWAC (National Drinking Water Advisory Council), 2004. Report on the CCL Classification Process. www.epa.gov/safewater/ndwac/pdfs/report_ccl_ndwac_07-06-04.pdf (accessed Nov. 11, 2011).

Roberson, J.A.; Lueders, M.; Adams, C.; & Rosen, J.S., 2009. Risk Indexes for Draft CCL3 Chemicals. *Jour. AWWA,* 101:9:64.

Roberson, J.A., 2005. Triggers Behind the Regulatory Development Triad. *Jour. AWWA,* 97:3:66.

USEPA (US Environmental Protection Agency), 2011a. Drinking Water: Regulatory Determination on Perchlorate. *Fed. Reg.,* 76:29:7762.

USEPA, 2011b. Regulatory Determinations for the Third Drinking Water Contaminant Candidate List. http://water.epa.gov/scitech/drinkingwater/dws/ccl/upload/Preliminary-Regulatory-Determinations-3-June-16th-Public-Meeting-Slides.pdf (accessed Nov. 11, 2011).

USEPA, 2011c. Revisions to the Unregulated Contaminant Monitoring Rule (UCMR3) for Public Water Systems; Proposed Rule. *Fed. Reg.,* 76:42:11713.

USEPA, 2011d. Basic Questions and Answers for the Drinking Water Strategy Contaminant Groups Effort. http://water.epa.gov/lawsregs/rulesregs/sdwa/dwstrategy/upload/FactSheet_DrinkingWaterStrategy_VOCs.pdf (accessed Nov. 11, 2011).

USEPA, 2010. Announcement of Completion of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issue. *Fed. Reg.,* 75:59:15500.

USEPA, 2009a. Drinking Water Contaminant Candidate List 3 – Final. *Fed. Reg.,* 74:194:51850.

USEPA, 2009b. Drinking Water: Perchlorate Supplemental Request for Comments. *Fed. Reg.,* 74:159:41883.

USEPA, 2008a. Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List. *Fed. Reg.,* 73:147:44251.

USEPA, 2008b. Drinking Water: Preliminary Regulatory Determination on Perchlorate. *Fed. Reg.,* 73:198:60262.

USEPA, 2007a. Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List—Preliminary Determinations. *Fed. Reg.,* 72:83:24016.

USEPA, 2007b. Unregulated Contaminant Monitoring Rule (UCMR) for Public Water Systems Revisions. *Fed. Reg.,* 72:2:367.

USEPA, 2006. Stage 2 Disinfectants/Disinfection Byproducts Rule: Final Rule. *Fed. Reg.,* 71:2:387.

USEPA, 2005. Drinking Water Contaminant Candidate List 2: Final Notice. *Fed. Reg.,* 70:36:9071.

USEPA, 2003a. Announcement of Completion of EPA's Review of Existing Drinking Water Standards. *Fed. Reg,.* 68:138:42908.

USEPA, 2003b. Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List. *Fed. Reg,.* 68:138:42897.

USEPA, 2002. Announcement of Preliminary Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List. *Fed. Reg.*, 67:106:38222.

USEPA, 1999. Revisions to the Unregulated Contaminant Monitoring Rule Regulation for Public Water Systems. *Fed. Reg.,* 64:180:50555.

USEPA, 1998a. Announcement of the Drinking Water Contaminant Candidate List. *Fed. Reg.,* 63:40:10273.

USEPA, 1998b. Stage 1 Disinfectants/Disinfection Byproducts Rule: Final Rule. *Fed. Reg.,* 63:241:69389.

USEPA, 1979. Total Trihalomethanes Rule: Final Rule. *Fed. Reg.,* 44:231:68624.

Appendix B

Development of Recommendations for the Fourth Contaminant Candidate List

Roberson, J.A.; Adams, C.; Bench, R.; and Rosen, J.S.

http://dx.doi.org/10.5942/jawwa.2015.107.0127

Development of Recommendations for the Fourth Contaminant Candidate List

J. ALAN ROBERSON,[1] CRAIG ADAMS,[2] RYAN BENCH,[3] AND JEFFREY S. ROSEN[4]

[1]AWWA, Washington, D.C.
[2]Utah State University, Logan, Utah
[3]Carollo Engineers Inc., Salt Lake City, Utah
[4]Corona Environmental Consulting Inc., Rockland, Mass.

An independent set of recommendations for the Fourth Drinking Water Contaminant Candidate List (CCL4) was developed by prioritizing compounds with weightings based on data quality for occurrence and toxicity. This approach used key information including the number of studies used in the analysis and the associated spread and variability of the particular attributes between data sources, and resulted in four recommendation groups:

- Group 1: Top priority for inclusion on CCL4—seven compounds plus one "super group" of disinfection by-products
- Group 2: Include on CCL4 but insufficient information for a regulatory determination (need occurrence data)—11 compounds
- Group 3: Could be included on CCL4 only if a future negative regulatory determination will be made—32 compounds
- Group 4: No need to consider further in the CCL4 process—55 compounds

Having too many contaminants on the CCL results in a fragmented research agenda; conversely, some compounds might be missed on a CCL that is too small.

Keywords: *attribute, CCL, Contaminant Candidate List, regulatory*

The US Environmental Protection Agency (USEPA) is required by the Safe Drinking Water Act (SDWA) to publish the Drinking Water Contaminant Candidate List (CCL) every five years for regulatory consideration. The purpose of the CCL is to provide the requisite information needed for regulatory determinations and to identify data gaps for health effects, analytical methods, occurrence, and treatment if such research is needed. If a positive determination is made, that information will serve as the foundation for the regulatory impact analysis that USEPA must conduct to propose and promulgate a national primary drinking water regulation. The SDWA requires USEPA to publish a determination (i.e., a decision) on at least five contaminants from the most recent CCL every five years. The regulatory determinations are not necessarily a binary yes/no decision to regulate, as USEPA can also decide that more research, additional guidance, or a health advisory is needed instead. The regulatory development process also involves the Unregulated Contaminant Monitoring Rule (UCMR) to provide magnitude and frequency information for both the formulation of the CCL and the regulatory determinations for CCL contaminants. If a positive regulatory determination is made, a final regulation is developed approximately four years after the final positive determination. That final regulation is reviewed after six years for possible revision because of any new data on health effects, analytical methods, occurrence, or treatment.

Section 1412(b)(1)(B)(i) of the 1996 SDWA Amendments requires USEPA to publish a list of contaminants for consideration that

- are currently unregulated,
- are known or anticipated to occur in public water systems, and
- may require regulation under the SDWA.

Section 1412(b)(1)(A) of the SDWA specifies three criteria for USEPA to consider when identifying contaminants for potential regulation:

- The contaminant may have an adverse effect on the health of persons.
- The contaminant is known to (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.
- In the sole judgment of the USEPA Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

These three criteria are critical in the regulatory development process established in the 1996 SDWA Amendments. Note that words such as "may" or "substantial likelihood" could be interpreted differently by stakeholders. In the end, the ultimate decision on whether to regulate rests with the sole judgment of the USEPA Administrator.

The CCL development process has evolved since the 1996 SDWA Amendments. In March 1998, USEPA published the first CCL (CCL1), which contained 50 chemical and 10 microbial contaminants (63 FR 10274). CCL1 was developed with the expert opinion of technical experts using readily available data and information, which was a reasonable approach given the short time frame (two years) after the 1996 SDWA Amendments. Five years hence, in July 2003, USEPA published final determinations that no regulation was needed (that is, a "negative regulatory determination") for nine contaminants: acanthamoeba, aldrin, dieldrin, hexachlorobutadiene, manganese, metribuzin, naphthalene, sodium, and sulfate (68 FR 42898).

In February 2005, the second CCL (CCL2) was published by USEPA and included all of the 41 CCL1 compounds without the negative regulatory determinations and added 10 new contaminants (totaling 42 chemical contaminants and nine microbial contaminants) (70 FR 9071). In July 2008, the USEPA published negative regulatory determinations for 11 of the CCL2 contaminants: boron, dacthal mono-acid and di-acid degradates; 1,1-dichloro-2,2-bis (p-chlorophenyl)ethylene; 1,3-dichloropropene; 2,4-dinitrotoluene; 2,6-dinitrotoluene; S-ethyl di-*N*,*N*-propylthiocarbamate (EPTC); fonofos; terbacil; and 1,1,2,2-tetrachloroethane (73 FR 44251).

In October 2009, the third CCL (CCL3) was developed on the basis of a significantly modified process relative to CCL1 and CCL2. The CCL3 contaminant selection process started with a CCL3 "universe" of nominally 7,500 chemical and microbial compounds that were screened down to approximately 600 contaminants on the Preliminary CCL using specific criteria (74 FR 51850). Using detailed information and expert opinion, 116 contaminants were selected for the final CCL3 (including 104 chemical contaminants and 12 microbial contaminants). In June 2011, as part of a public stakeholder meeting, a CCL3 short list was published for 34 compounds being evaluated as potential regulatory determination candidates (USEPA 2011).

In May 2012, USEPA sought nominations for chemical and microbial contaminants for possible inclusion on the fourth CCL (CCL4). USEPA also requested supporting information that had become available since the development of CCL3, or existing information that was not considered for CCL3, showing that the nominated contaminant may have an adverse health effect on people and is known or anticipated to occur in public water systems (77 FR 27057). Nominations for the CCL4 closed June 22, 2012.

In February 2015, USEPA published the draft CCL4 (80 FR 6076), which listed 100 chemicals or chemical groups and 12 microbial contaminants. USEPA used a carryover approach for the draft CCL4 by carrying over all of the CCL3 contaminants, dropping six with preliminary or final regulatory determinations since CCL3, and then adding two of the nominated compounds—manganese and nonylphenol. The USEPA CCL4 process included compiling attribute data related to prevalence (Pr), magnitude (M), potency (P), and severity (S) for each carryover or nominated compound.

The number of contaminants listed on CCL4 and future CCLs is important in the regulatory development process. Too many contaminants being listed results in an extensive drinking water research agenda that cannot be actualized, while too small a list might result in some potentially important contaminants being missed. The amount of research that would need to be conducted to fill all of the data gaps is much greater than the USEPA drinking water research budget. For example, Seidel et al. (2009) found that even in cases where specific and defined research plans were developed for arsenic and disinfection byproducts (DBPs), less than half (33–35%) of arsenic research tasks were incorporated or partially incorporated into the final arsenic regulation. The Stage 2 Disinfectants and Disinfection Byproducts Rule (D/DBPR) had between 45 and 72% of the research tasks incorporated into the final rule.

The purpose of this contaminant identification research was to develop a set of CCL4 recommendations for USEPA on the basis of a modified approach and expanded data set as determined by the AWWA CCL Technical Advisory Workgroup (TAW). In the USEPA process, only the highest-priority attribute was used for a given compound on the basis of a specific hierarchy and well-defined criteria. USEPA commented on its hierarchical approach as follows: "The protocols and established hierarchies ensured that the data used at each step and were applied uniformly for all contaminants. The hierarchy also provides a transparent data driven approach that allows stakeholders and the public to uniformly understand the assumptions and processes that were applied in the selection of data for individual contaminants" (USEPA 2009a). In AWWA's modified approach, a wide range of toxicological and occurrence data was included in the analysis and prioritization of compounds with appropriate weightings based on data quality. The AWWA process included USEPA dossier data as well as data from a variety of other sources. This modified AWWA approach allowed for retention of multiple studies and key information, including the number of studies in the analysis and the associated spread and variability of particular attributes between data sources. The USEPA draft CCL4 and AWWA CCL4 recommendations have significant overlap, though the lists differ, with regard to compounds that are included or excluded.

RESEARCH OBJECTIVES

The specific objectives of the AWWA research were as follows:

- Develop a list of compounds that are of potential concern via drinking water related to the protection of public health.
- Develop a comprehensive database for the selected compounds for potency, magnitude, and prevalence relevant to the determination of risk.
- Provide the mechanism for an informed, data-driven response and a set of recommendations to the draft USEPA CCL4 once it was released.
- Provide relevant information for a CCL4 research plan.
- Provide additional useful information for USEPA in the regulatory determination process for both the CCL3 short list and CCL4.

In addition to providing recommendations for the CCL4, this research also provided some recommendations for the UCMR4, which is scheduled to be proposed in late 2015. The UCMR4 recommendations are for compounds with potency data suggesting toxicity for which insufficient prevalence and/or magnitude data exist. Putting these compounds on UCMR4 would provide a national occurrence distribution for any potential future regulatory determination.

APPROACH

This project built on previous CCL policy efforts by AWWA, including a similar process for CCL3 (Roberson et al. 2009). The approach used in the current CCL4 project is illustrated in Figure 1. First, a list of relevant chemicals from various sources was developed including the CCL3 short list, CCL4 nominated compounds, highest-priority compounds from the previous AWWA

CCL3 study (Roberson et al. 2009), and additional emerging contaminants selected by the AWWA CCL TAW. Next, the TAW developed criteria and weightings for potency, magnitude, and prevalence for each contaminant on the basis of USEPA's criteria to allow easy comparison and interpretation of the results. Potency, magnitude, and prevalence data were obtained from a wide range of published and unpublished sources including USEPA and other government sources, utility databases, academic studies, and other sources. The data were then compiled in a database and analyzed in several ways. First, space diagrams—the previous analysis tool reported in Rosen and Roberson (2007) and applied in Roberson et al. (2009)—were developed for each compound to visually present normalized potency, magnitude, and prevalence data. Algorithms were developed and applied that included the three attributes with different relative weightings and combinations. The AWWA CCL TAW used data sheets for each study compound including raw and processed data to develop groupings and prioritization on the basis of the TAW's collective expert opinion for recommendation to USEPA and the water industry.

SELECTION OF STUDY COMPOUNDS

The expert opinion of the AWWA CCL TAW members was used to select 119 compounds to be included in this project. The compounds came from four sources: nominated compounds reported by USEPA for CCL4, compounds on the USEPA CCL3 short list (79 FR 62715), compounds selected as "higher risk" in the previous AWWA CCL3 project (Roberson et al. 2009), and additional compounds selected by the CCL TAW as being of potential concern. These compounds were sorted and organized into one of seven groups (with subgroups) as follows:

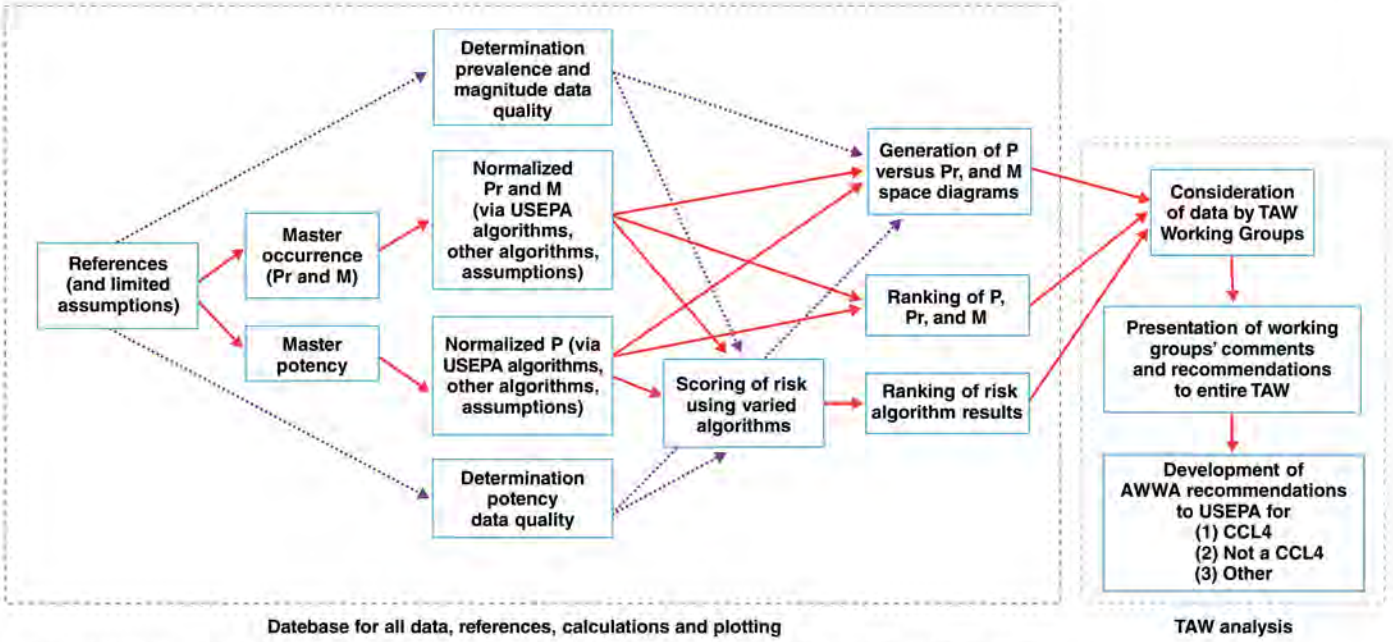
- Cyanotoxins, with subgroups microcystins and saxitoxins
- DBPs, with subgroups iodomethanes, halonitromethanes, and nitrosamines
- Industrial chemicals, with subgroups alkylphenols, alkylphenol ethoxylates, fluorosurfactants, and phthalates
- Inorganic chemicals
- Pesticides, with subgroups fungicides, herbicides, herbicide/acetochlor plus degradates, herbicide/alachlor plus degradates, herbicide/metolachlor plus degradates, insecticides, and herbicide/terbufos plus degradates
- Pharmaceuticals and personal care products (PPCPs), with subgroups antibiotics, antidepressants, herbicides, hormones, lipid regulators, nonsteroidal anti-inflammatory drugs (NSAIDs), and pain relievers (not NSAIDs)
- Volatile organic compounds (VOCs)

A single group was selected for each compound, even in cases for which several different groups could have been valid (e.g., chlorate was assigned as a DBP rather than as an inorganic compound). A summary of the study compounds and their source is provided in Table 1.

ATTRIBUTES

In this study, three categories of data (or attributes) were compiled for each study compound: potency, magnitude, and prevalence. These attributes were also used by USEPA in its

FIGURE 1 Process used by AWWA to develop CCL4 recommendations



CCL4—Contaminate Candidate List 4, M—magnitude, P—potency, Pr—prevalence, TAW—technical advisory workgroup, USEPA—US Environmental Protection Agency

process (USEPA 2009a). A fourth attribute, severity, also was used by USEPA, but it was not used in this project as it was considered too subjective and/or required information that does not exist or is not available to the AWWA CCL TAW. There were several reasons for using the same attributes as used by USEPA, including that this makes the results more easily comparable to USEPA results via the use of a previously published system (including input from the National Research Council) (USEPA 2009b).

Potency "is a value that indicates the power of a contaminant to cause adverse health effects" (USEPA 2009b). The highest-quality potency data were reference dose (RfD) or equivalent, no observed adverse effect level (NOAEL), lowest observed adverse effect level (LOAEL), rat oral median lethal dose (LD50), and cancer potency (concentration in water equivalent to a 10^{-4} cancer risk). All external potency data were obtained from USEPA dossiers (USEPA 2009a), the USEPA Integrated Risk Information System database, or related sources, and were assigned the highest

TABLE 1 Study compounds organized by major group and subgroups with original source

Group	Code/Subgroup	Total Count	USEPA CCL3 Shortlist	USEPA CCL4 Nominated	AWWA CCL3[a]	Emerging Contaminant
Cyanotoxins	**CYANO**	**9**	**x**	**x**	**x**	**9**
	anatoxin A	x	x	x	x	1
	cylindrospermopsin	x	x	x	x	1
	microcystins	x	x	x	x	5
	saxitoxins	x	x	x	x	2
Pesticides	**PEST**	**36**	**15**	**19**	**2**	**x**
	insecticide	x	2	13	2	x
	herbicide or herbicide degradates	x	13	5	x	x
	fungicide	x	x	1	x	x
Disinfection By-products	**DBP**	**16**	**6**	**1**	**x**	**9**
	iodomethanane	x	x	x	x	6
	halonitromethane	x		x	x	3
	nitrosamine	x	5	x	x	x
	mutagen X	x	x	1	x	x
	inorganic	x	1	x	x	x
Pharmaceuticals and Personal Care Products	**PPCPs**	**23**	**x**	**14**	**x**	**9**
	antibiotic	x	x	12	x	4
	antidepressant	x	x	x	x	1
	lipid regulator	x	x	x	x	1
	NSAID	x	x	x	x	2
	Pain reliever (non-NSAID)	x	x	x	x	1
	hormone	x	x	2	x	x
Industrial Compounds	**INDUST**	**21**	**4**	**12**	**5**	**x**
	phthalate	x	x	7	x	x
	alkylphenol	x	x	3	x	x
	alkylphenol ethoxylates	x	x	1	x	x
	fluoro surfactant	x	2	x	x	x
	other	x	2	1	5	x
Volatile Organic Compounds	**VOC**	**8**	**5**	**x**	**3**	**x**
	cVOC list	x	2	x	1	x
	other	x	3	x	2	x
Inorganics	**INORG**	**7**	**3**	**3**	**1**	**x**
	TOTAL	**120**	**33**	**49**	**11**	**27**

CCL—Contaminate Candidate List, cVOC—carcinogenic volatile organic compound, DBP—disinfection by-product, NSAID—nonsteroidal anti-inflammatory drug, PPCPs—pharmaceuticals and personal care products, USEPA—US Environmental Protection Agency, VOC—volatile organic compound

[a]Higher risk

quality ranking. For emerging contaminants not in the aforementioned databases, potency values were assigned on the basis of other sources, including the expert opinion of the AWWA CCL TAW (and were assigned a lower quality ranking). Potency attributes were normalized to a scale of 1 to 10 using equations from USEPA (2009a) and Roberson et al. (2015). Potency values based on assumptions made by the AWWA CCL TAW or sources outside of USEPA-based data were assigned a lower quality ranking (e.g., for emerging contaminants).

Two occurrence attributes were used consistent with the USEPA approach—magnitude and prevalence. Magnitude "is related to the quantity (e.g., concentration) of a contaminant that may be in the environment" (USEPA 2009b). Prevalence "provides a measure of how widespread the occurrence of the contaminant is in the environment" (USEPA 2009b). Pseudo-occurrence indicators such as mobility and persistence of a compound were not used in this study.

Magnitude attribute was based on the median, the 75th to 95th percentile detections, and the 99th percentile to maximum concentrations of detections in finished (treated) or ambient (raw) waters. Magnitude normalization on a scale of 1 to 10 of these three bins were based on the concentration ranges shown in Table 2.

Prevalence was based on the percent of finished (treated) or ambient (raw) water sites with detections of contaminants. Prevalence normalization on a scale of 1 to 10 was based on the percentage detections of ≤0.1, 0.11–0.16, 0.17–0.25, 0.26–0.44, 0.45–0.61, 0.62–1.00, 1.01–1.30, 1.31–2.50, 2.51–10.00, and >10.00, respectively.

DATA QUALITY

Visualization. Risk for a compound is related to its potency combined with magnitude and prevalence. For example, a compound with high potency that also has high magnitude and prevalence may be considered higher risk, whereas if its potency were low, then it may be considered lower risk.

In this project, a space diagram approach that visually combines potency, magnitude, and prevalence (Rosen & Roberson 2007) and that was applied for CCL3 compounds in previous work (Roberson et al. 2009) was used. For each compound, a space diagram was constructed in which all normalized potency values were plotted against all normalized magnitude and prevalence data (Figure 2) where

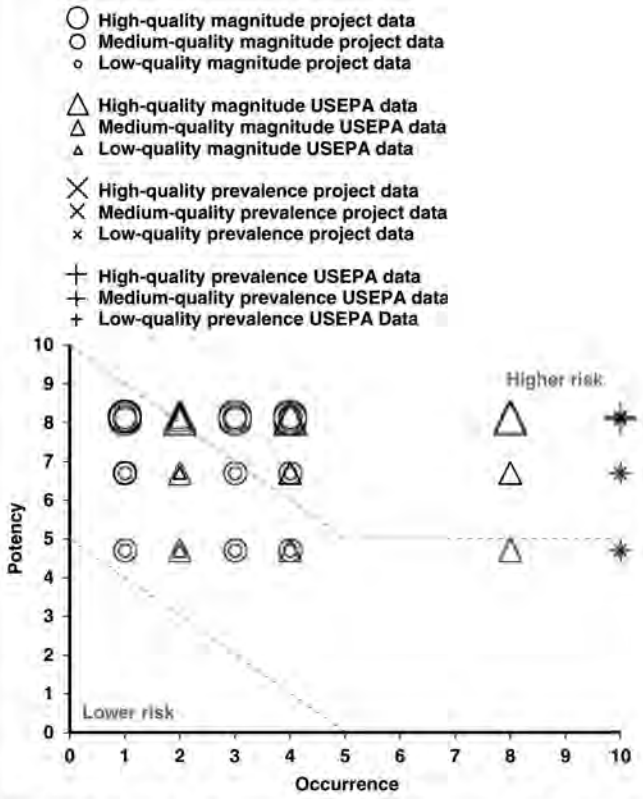
- open triangles (Δ) = magnitude data from USEPA plotted against potency,
- open circles (O) = magnitude data from the project (i.e., other than USEPA sources) plotted against potency
- multiplication symbols (×) = prevalence data from USEPA plotted against potency, and
- plusses (+) = prevalence data from the project (i.e., other than USEPA sources) plotted against potency.

TABLE 2 Magnitude normalization scale for finished and ambient water contaminant concentrations

Normalized Value	Concentration of Contaminant in Finished or Ambient Water Detections µg/L		
	Median of Detections	90th or 95th Percentile	Maximum
1	<0.003	<0.01	>0.01–0.03
2	>0.003–0.01	>0.01–0.03	>0.03–0.1
3	>0.01–0.03	>0.03–0.1	>0.1–0.3
4	>0.03–0.1	>0.1–0.3	>0.3–1
5	>0.1–0.3	>0.3–1	>1–3
6	>0.3–1	>1–3	>3–10
7	>1–3	>3–10	>10–30
8	>3–10	>10–30	>30
9	>10–30	>30	NA
10	>30	NA	NA

NA—not applicable

FIGURE 2 Example plot showing normalized magnitude and prevalence data for NDMA



NDMA—*N*-nitrosodimethylamine, USEPA—US Environmental Protection Agency

Normalized risk based on a scale from 1 to 10 using equations from the USEPA (2009a) and Roberson et al. (2015).

The open symbols ("×" and "+") correspond to prevalence data, and the closed symbols ("Δ" and "O") correspond to magnitude data. Higher-quality data are shown in larger symbols.

Closed symbols, therefore, correspond to magnitude data crossed with potency, and open symbols correspond to prevalence data crossed with potency.

Furthermore, the symbol size on the space diagrams was set on the basis of the quality of the data, with large symbols being used for higher quality and small symbols being used for lower-quality data sources or types. Specifically, symbol sizes were set by evaluating the importance (or relevance to human health protection) of the parameter used, combined with the credibility of the data source. For occurrence, finished water sources were of higher importance than raw water, which was higher than wastewater data (Roberson et al. 2015). For potency, the highest importance was assigned to RfD, NOAEL, and LOAEL, LD_{50}, 10^{-4} cancer risk (all from USEPA normalized equations), with lower importance assigned to oral slope factor (mg/kg-d), minimum risk level (mg/kg-d), supplemental no observable effect level (mg/kg-d), lowest oral chronic level (mg/kg-d), slope factors $(mg/kg\text{-}d)^{-1}$, tolerable daily intake (mg/kg-d), and maximum acceptable daily intake (mg/kg-d). With respect to the level of credibility of the data source, the ranking applied was government sources (e.g., USEPA, US Geological Survey) > peer-reviewed literature > lower quality peer-reviewed literature > other sources. Details of these assignments are presented in Roberson et al. (2015). Some alternative weightings could also be appropriate.

The upper-right quadrant and a region of lower occurrence but high potency were deemed higher risk by the AWWA CCL TAW. The reason for inclusion of the lower occurrence and higher potency region is that, although relatively few utilities might be affected, these high-potency compounds would be a particular concern to affected consumers. The lower-risk region is the lower potency and lower occurrence area of the diagram, and was determined by using reason (as opposed to any specific toxicological basis).

A compound that is potent with high magnitude and/or prevalence poses higher risk and appears toward the upper-right quadrant of the space diagram. Conversely, a compound that has low potency combined with low magnitude and/or prevalence appears toward the lower-left quadrant of the space diagram. Intermediate risk can arise from a variety of combinations of moderate potency, magnitude, and/or prevalence. The power of this visualization approach is that one can simultaneously view all of the data included, with symbols showing the source of the data (USEPA versus other), the quality of the data source (via symbol size), and differentiating magnitude and prevalence crossed with potency. For example, a space diagram can illustrate a compound that is potent and has high magnitude but a low prevalence. Such a compound may not affect a large number of people, but it would pose risk to populations that are exposed. Space diagrams for all study compounds are compiled in Roberson et al. (2015).

Space diagrams were also prepared for groups of compounds including cyanotoxins, DBPs, industrial chemicals, VOCs, pesticides, PPCPs, and inorganics by plotting the median potency against the median magnitude and prevalence (using triangle and circle symbols, respectively). Additionally, a space diagram for USEPA's currently regulated chemicals was developed so as to baseline the study compounds against regulated compounds (Roberson et al. 2015).

ALGORITHMS

Additional tools developed to help prioritize and group compounds and develop CCL4 recommendations were mathematical algorithms with different combinations and weightings for potency, magnitude, and prevalence. It was not the intent to develop a single toxicologically based and/or occurrence-based algorithm to assess and rank risk, but rather to develop a set of algorithms using different assumptions and then to analyze patterns and commonality within the rankings for each algorithm. The nine algorithms used are detailed in Roberson et al. (2015), and were each normalized to a 1–10 scale for risk.

PROCESS

In January 2014, an expert panel (composed of the AWWA CCL TAW and additional participants) was convened to consider the raw data and analyses for each compound to bin each compound relative to four different recommendations related to inclusion on the CCL4. The four groups were as follows:

- Recommendation Group 1: "Recommend as top priority for inclusion in CCL4"
- Recommendation Group 2: "Recommend inclusion on CCL4 but insufficient data currently for regulatory determination"
- Recommendation Group 3: "Recommend inclusion on CCL4 based on sufficient data for negative regulatory determination"
- Recommendation Group 4: "No need to consider further based on existing potency, prevalence, and/or magnitude data"

RESULTS

The data sheets for each compound included in Roberson et al. (2015) include space diagrams, mean attribute scores (for highest quality data only, all data, and USEPA data), the drinking water equivalent level (based on the USEPA RfD, 70 years exposure and 2 L/d consumed), algorithm results, and all data values used with references.

Comparison of approach. The USEPA approach was to use the highest hierarchal value for each attribute in its analysis, as contrasted with this study, which sought to retain all attribute values within the analysis. It was of interest to examine the correlation between the USEPA-determined attributes and the mean AWWA CCL4 project attributes. It was observed that while the correlations were significant at 95% (and 99%), only 39, 51, and 21% of the variability was explained by a linear model for potency, magnitude, and prevalence, respectively, on the basis of regression analysis (Roberson et al. 2015).

Group space diagrams. In addition to the study group of compounds, an additional space diagram for the USEPA-regulated compounds was prepared to benchmark the study results. The results showed that 47% of 59 regulated contaminants were in the higher risk region based on potency crossed with magnitude; and just 27% of 59 regulated chemicals fell into the higher risk region on the basis of potency crossed with prevalence (Roberson et al. 2015). Ten regulated chemicals were in the higher risk for

potency crossed with both magnitude and prevalence (Roberson et al. 2015):

- 1,2-dibromo-3-chloropropane (DBCP)
- 1,2-dichloroethane
- Benzene
- Carbon tetrachloride
- Cis-1,2-dichloroethylene
- Dichloromethane
- Selenium
- Tetrachloroethylene
- Trichloroethylene
- Uranium

Six chemicals were included in the higher-risk region because of prevalence but not magnitude, as they occur frequently but at relatively lower concentrations:

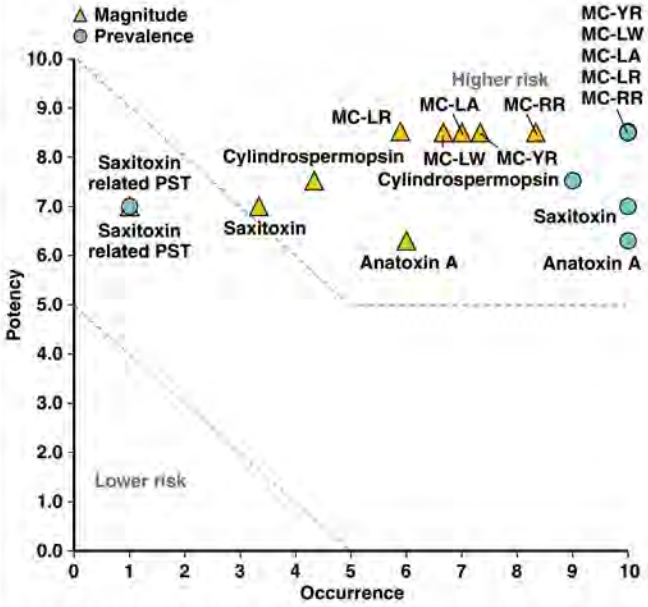
- Ethylene dibromide
- Antimony
- Arsenic
- Beryllium
- Cadmium
- Chromium

Conversely, 18 chemicals were included in the higher-risk region as a result of magnitude but not prevalence, as they occur at higher concentrations but relatively infrequently (Roberson et al. 2015):

- 1,1,2-trichloroethane
- 1,2,4-trichlorobenzene
- 1,2-dichloropropane
- 2,4,5-TP (silvex)
- 2,4-D
- Carbofuran
- Chlordane
- Dinoseb
- Diquat
- Endothall
- Endrin
- Heptachlor epoxide
- Hexachlorobenzene
- Hexachlorocyclopentadiene
- Methoxychlor
- Polychlorinated biphenyls (PCBs)
- Toxaphene
- Vinyl chloride

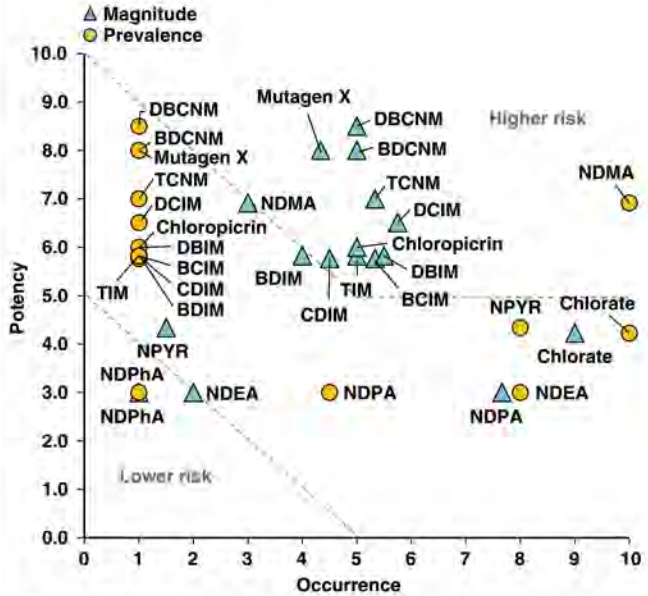
Group space diagrams for each group of study compounds are presented in Figures 3–9 to include cyanotoxins, DBPs, industrial chemicals, VOCs, pesticides, PPCPs, and inorganics, respectively. Results from the space diagrams are tabulated in Table 3 with respect to the percentage of the study compounds within each group in the higher-, medium-, or lower-risk regions on the basis of potency crossed with magnitude and prevalence. Notably, cyanotoxins were generally in the higher-risk region for both magnitude and prevalence (crossed with potency). DBPs were primarily in the higher-risk region on the basis of potency crossed with magnitude, but not with prevalence. All other groups were predominantly in the medium-risk region on the basis of potency crossed with magnitude and with prevalence (Table 3).

FIGURE 3 Risk comparison of occurrence (magnitude and prevalence) and potency for cyanotoxins



MC-LA, MC-LR, MC-LW, MC-RR, MC-YR—microcystin variants, PST—paralytic shellfish toxin

FIGURE 4 Risk comparison of occurrence (magnitude and prevalence) and potency for DBPs



BCIM—bromochloroiodomethane, BDIM—bromodiiodomethane, BDCNM—bromodichloronitromethane, CDIM—chlorodiiodomethane, DBCNM—dibromochloronitromethane, DBIM—dibromoiodomethane, DBPs—disinfection byproducts, DCIM—dichloroiodomethane, NDEA—*N*-nitrosodiethylamine, NDMA—*n*-nitrosodimethylamine, NDPA—*n*-nitrosodi-*n*-propylamine, NDPhA—*n*-nitrosodiphenylamine, NPYR—*n*-nitrosopyrrolidine, TCNM—tetranitromethane, TIM—triiodomethane

Study compounds relative to current CCL3. Of the 106 CCL3 compounds, only 47 were included in this study from the CCL3 short list (28 total), AWWA CCL3 project priority higher risk compounds (13 total), CCL4-nominated chemicals (three total), and emerging contaminants selected by the AWWA CCL TAW (three total). The five compounds for which USEPA recently made a preliminary regulatory determination were included in the study:

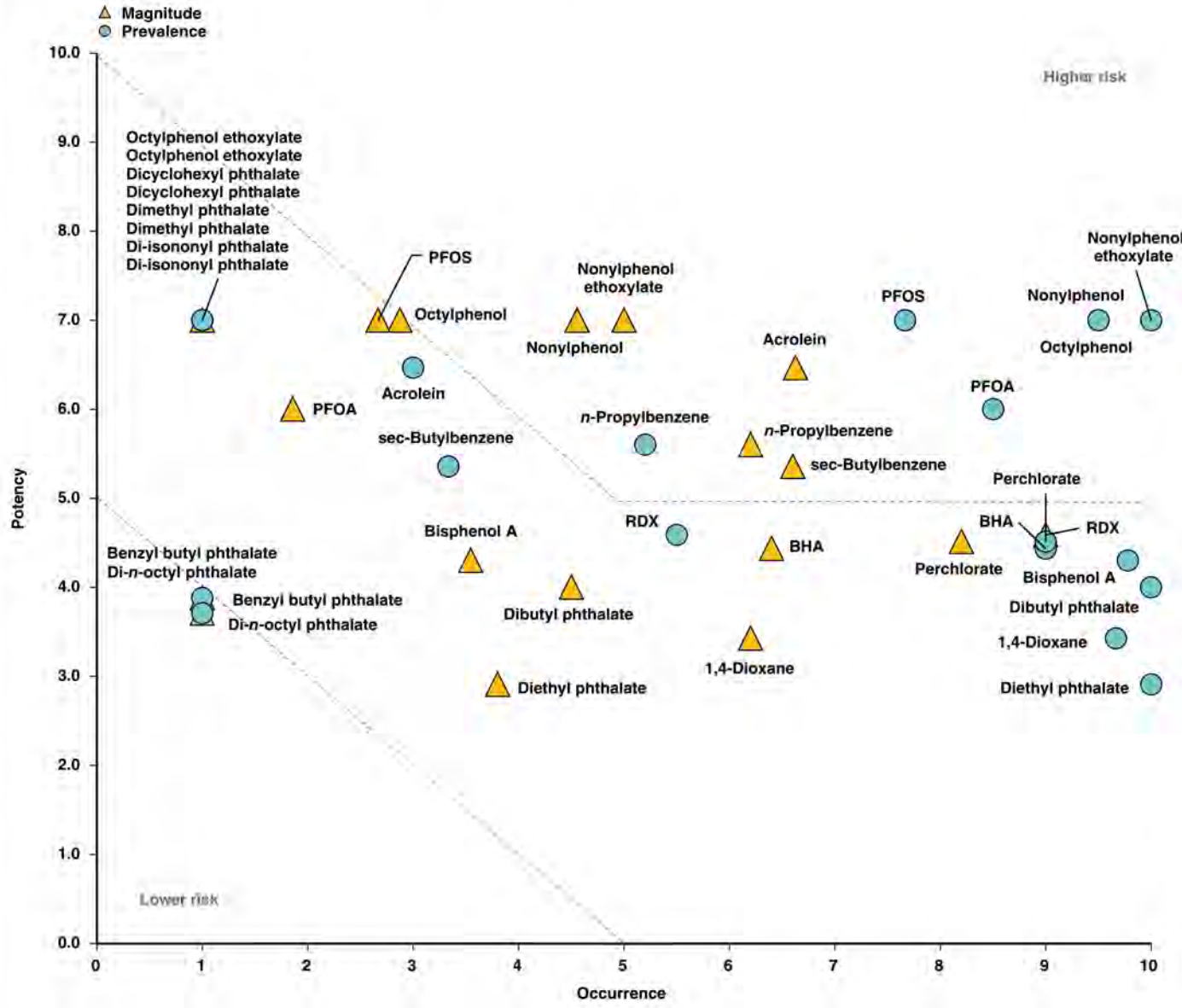
- Strontium
- 1,3-dinitrobenzene
- Dimethoate
- Terbufos
- Terbufos sulfone

The AWWA CCL TAW agrees with the USEPA preliminary negative regulatory determination for 1,3-dinitrobenzene, dimethoate, terbufos, and terbufos sulfone (as reflected in their Group 3—i.e., "Include in CCL4 due to sufficient data existing for negative regulatory determination") categorization.

For the 47 CCL3 compounds included in this study,

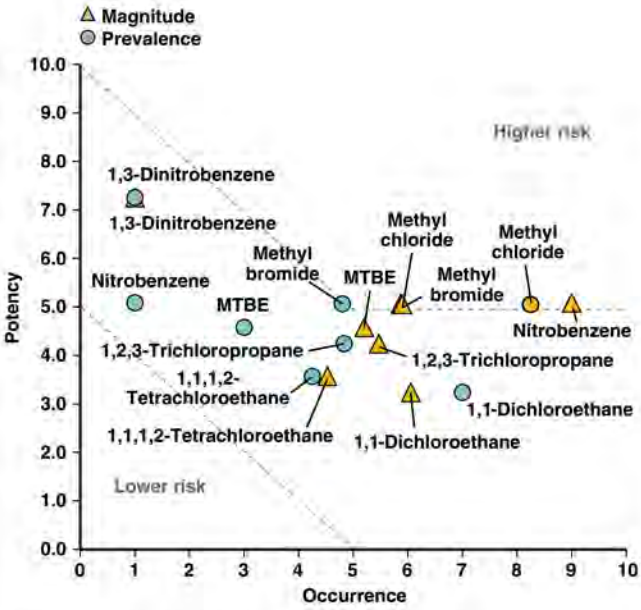
- 10 compounds were included in Group 1 as a top priority for inclusion:
  - nitrosamines,
  - 1,1-dichloroethane,
  - molybdenum,
  - chlorate,

FIGURE 5 Risk comparison of occurrence (magnitude and prevalence) and potency for industrial chemicals



BHA—butylated hydroxyanisole, PFOA—perfluorooctanoic acid, PFOS—perfluorooctanesulfonic acid, RDX—1,3,5-trinitroperhydro-1,3,5-triazine

FIGURE 6 Risk comparison of occurrence (magnitude and prevalence) and potency for VOCs



MTBE—methyl-tert-butyl-ether, VOC—volatile organic compound

- strontium, and
- 1,4-dioxane;

- three compounds were included in Group 2 as recommended for CCL4 but having insufficient data to make a determination, although high-quality studies do exist (e.g., Graham & Jones 2009, Graham et al. 2006):
  - 3-hydroxycarbofuran,
  - anatoxin-A, and
  - microcystin-LR;
- 25 of the CCL3 compounds were considered to have sufficient data for a negative regulatory determination; and
- nine others were determined to not need any further consideration.

In addition to the CCL3 compounds, the AWWA CCL TAW identified many compounds that also warranted consideration. Two pharmaceuticals (fluoxetine, gemfibrizol) as well as DBPs as a "super group" (e.g., nitro- and iodo-methanes) were included as top priority for inclusion in CCL4. Four other compounds (i.e., 3-hydroxycarbofuran, anatoxin-A, microcystin-LR, cylindrospermopsin) were recommended for the CCL4 with the note that insufficient information exists for regulatory determination. Additionally, while microcystin-LR is the only variant of the microcystins on CCL3, AWWA believes the other microcystin variants should also be included in CCL4, including -LA, -LW, -RR, and -YR (specifically) (Roberson et al. 2015). The AWWA study included other non-CCL3 compounds of which five were recommended for CCL4 with sufficient information for a negative regulatory determination (i.e., progesterone, testosterone, aldicarb, linuron, trichlosan), and 47 others were considered not requiring further consideration with respect to the regulatory process.

RECOMMENDATIONS

The AWWA CCL TAW grouped the 120 study compounds into four different recommendation groups on the basis of extensive discussion and collaborative expert opinion. The following recommendations, as well as the project report, were submitted to USEPA as part of the public comment record for the draft CCL4.

Group 1. Group 1 compounds were those with top priority for inclusion in CCL4. This group encompassed

- seven compounds plus a super group of DBPs,
- one VOC (1,1-dichloroethane),
- one additional industrial chemical (1,4-dioxane),
- one DBP (chlorate),
- two inorganic chemicals (molybdenum and strontium), and
- two pharmaceuticals (fluoxetine and gemfibrozil).

With respect to DBPs, the AWWA CCL TAW recognized that DBPs are formed in all drinking water treatment plants using chemical disinfection. Due in part to the sheer number of potential DBPs formed, the potency of many of the more common and emerging DBPs has often not been adequately studied and is currently unknown. The AWWA CCL TAW considered that DBPs are of top priority for inclusion in CCL4, including those included explicitly in this study as well as others not included (e.g., the four currently unregulated chloro- and bromo-haloacetic acids [HAAs], other HAAs [e.g., iodo-], dihalogenated nitromethanes, haloamides, haloacetonitriles, tribromopyrrole, aldehydes, and others) (Wagner et al. 2012; Plewa et al. 2008, 2004; Richardson et al. 2007). Thus, a super group of DBPs is of top priority and is included in Group 1.

Because of their relatively high prevalence combined with potency and/or magnitude, chlorate, molybdenum, and strontium were all considered top priority (Group 1). 1,1-Dichloroethane was included in Group 1 because of relatively high occurrence and moderate toxicity. 1,4-Dioxane was also considered of high priority and has the complications of persistence and difficult treatability via conventional water treatment processes.

For pharmaceuticals, relatively little data exist that suggest negative health effects for chronic exposure through drinking water at the concentrations at which they tend to occur. Nonetheless, pharmaceuticals are biologically active by design, and there is public concern regarding their occurrence in many or most drinking water supplies. The AWWA CCL TAW selected two of the higher-risk pharmaceuticals in this study as top-priority compounds (Group 1) in part to help establish a rational precedence for other pharmaceuticals that may be of lower potency, magnitude, and/or prevalence.

Group 2. Group 2 compounds were recommended for inclusion on CCL4, but it is noted that there are currently insufficient data for regulatory determination. This group included seven cyanotoxins and three pesticides. The cyanotoxins (i.e., five microcystins, anatoxin-A, cylindrospermopsin) are being detected with increasing frequency and often in severe cyanobacterial blooms in the United States and abroad. Cyanotoxins exhibit significant

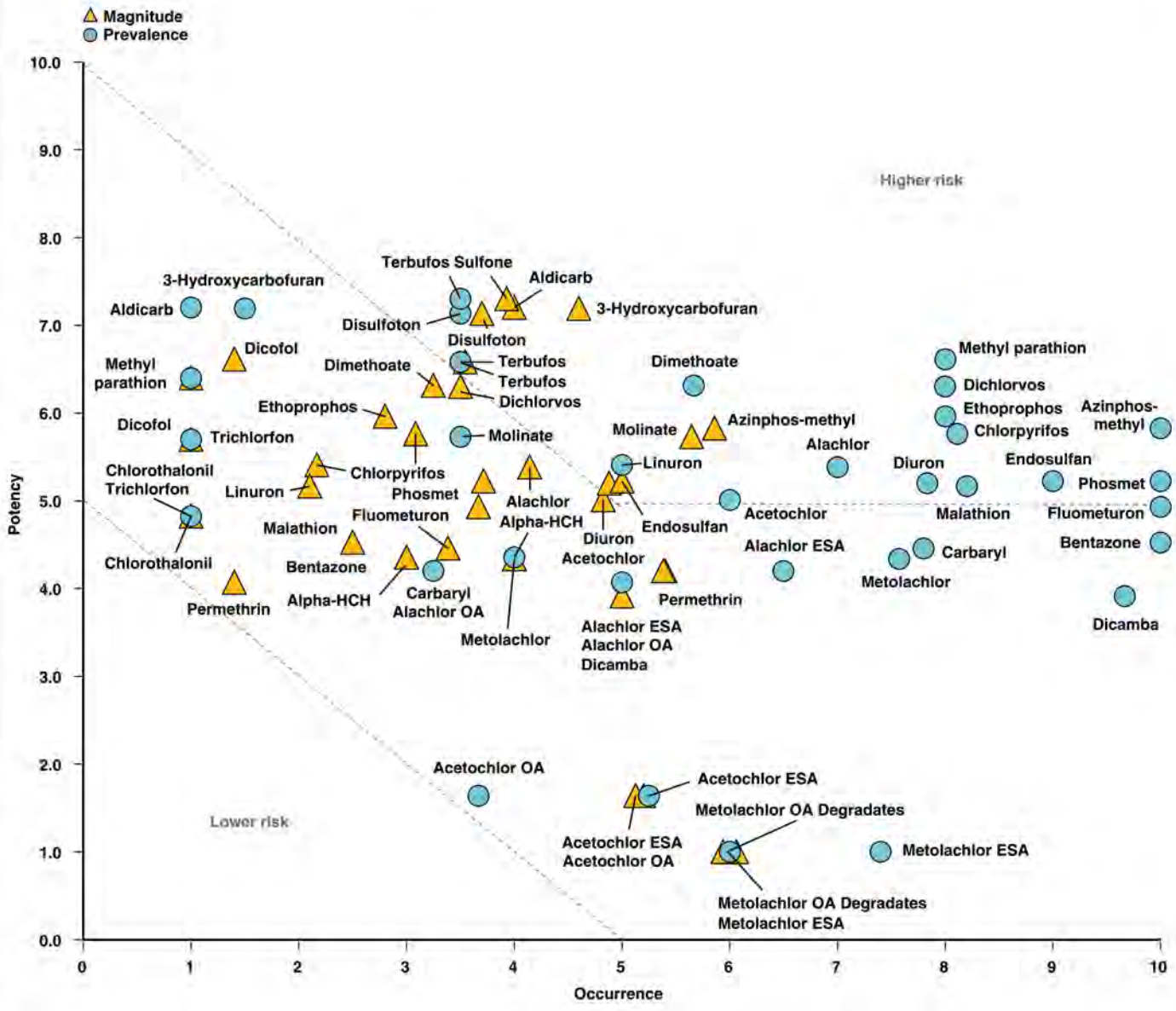
potency and, combined with their increasing magnitude and prevalence, the TAW advised their inclusion in CCL4. Of the 36 pesticides within the study, three (i.e., 3-hydroxycarbofuran, azinphos-methyl, chlorpyrifos) were considered of sufficient concern for inclusion in CCL4 so as to develop sufficient data for a regulatory determination.

As knowledge evolved for manganese in 2014 and early 2015, manganese was eventually shifted from Group 4 to Group 2 so that robust occurrence data could be collected through a future national monitoring program. New health-effects data showing potential adverse health effects were a factor in this shift. The level at which these effects occur compared with typical environmental levels is key to developing an understanding of whether manganese should move forward in the regulatory development process, noting that USEPA previously made a negative regulatory determination for manganese in 2003 (68 FR 42898).

Group 3. Thirty-two Group 3 compounds were recommended for inclusion on CCL4, only if—in the opinion of the AWWA CCL TAW—this listing would ultimately lead to a negative regulatory determination for each compound. These compounds included

- six VOCs:
  - 1,1,1,2-tetrachloroethane,
  - 1,2,3-trichloropropane,
  - methyl bromide,

FIGURE 7 Risk comparison of occurrence (magnitude and prevalence) and potency for pesticides

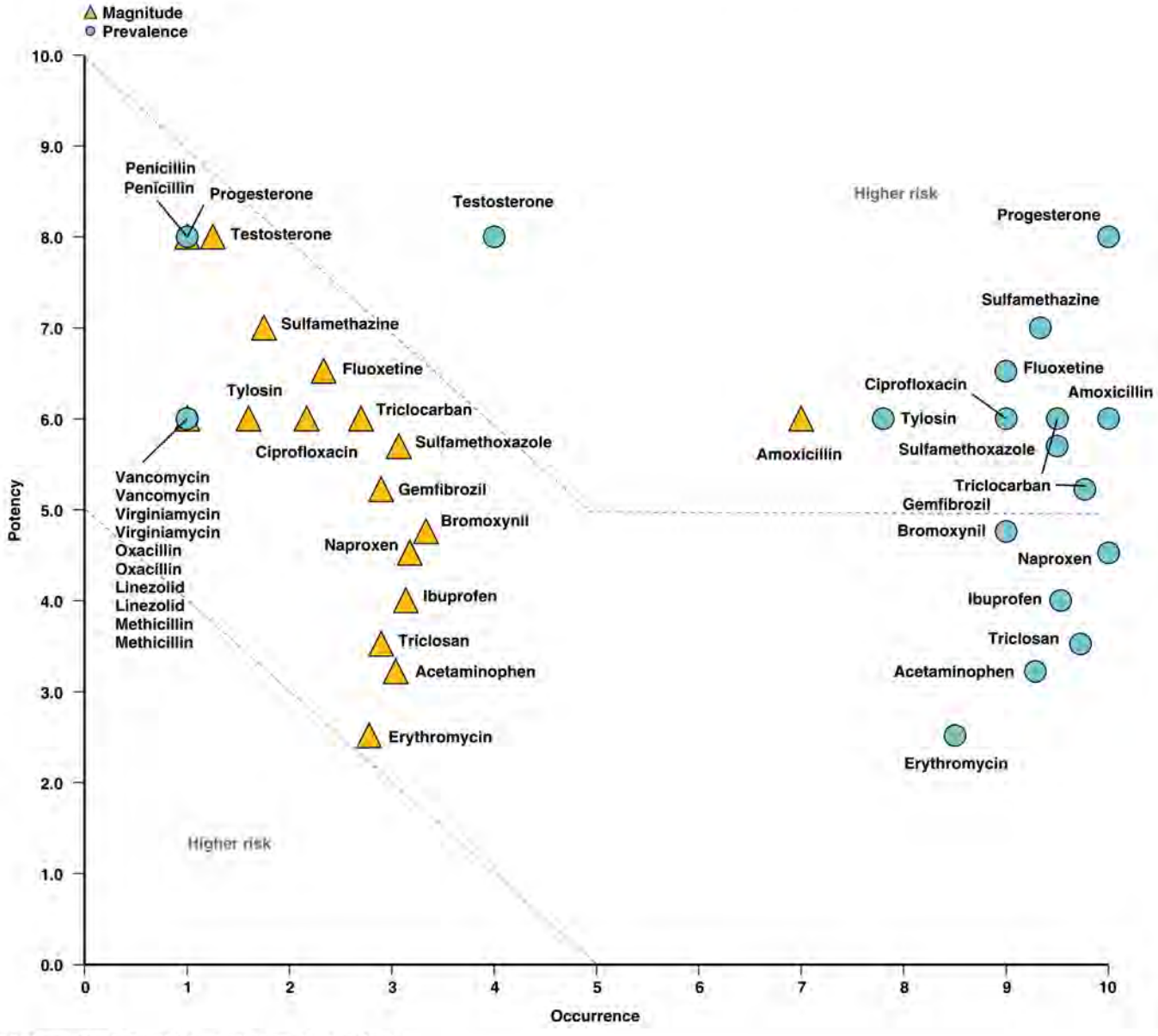


ESA—ethane sulfonate, HCH—hexachlorocyclohexane, OA—oxanilic acid

- methyl chloride,
- methyl-*tert*-butyl ether, and
- 1,3-dinitrobenzene;

- four additional industrial chemicals:
  - acrolein,
  - perfluorooctanoic acid,
  - perfluorooctanesulfonic acid, and
  - RDX (1,3,5-trinitroperhydro-1,3,5-triazine);
- 17 pesticides or degradates:
  - acetochlor and two degradates,
  - two alachlor degradates,
  - metolachlor and two degradates,
  - terbufos and one degradate,
  - aldicarb,
  - alpha-hexachlorocyclohexane,
  - dimethoate,
  - disulfoton,
  - diuron,
  - linuron, and
  - molinate; and
- five pharmaceuticals or hormones:
  - erythromycin,
  - progesterone,
  - sulfamethoxazole,

FIGURE 8 Risk comparison of occurrence (magnitude and prevalence) and potency for PPCPs



PPCPs—pharmaceuticals and personal care products

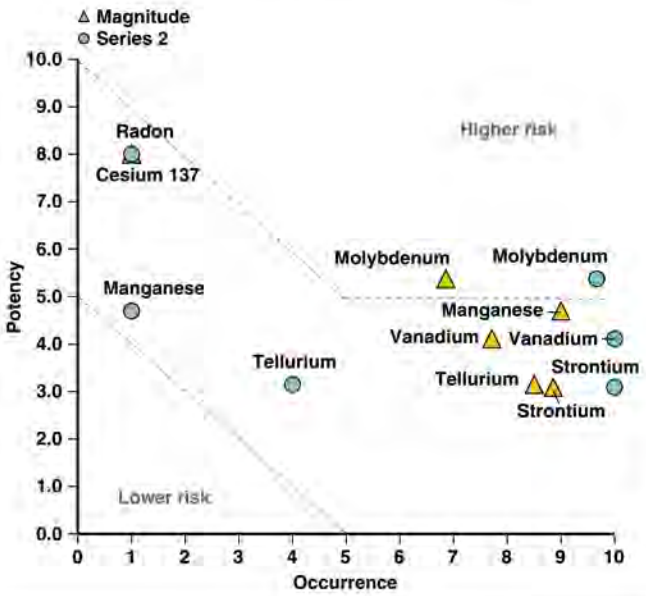
- testosterone, and
- triclosan.

Data on prevalence and magnitude, for example, are available for most of these compounds from UCMR1, UCMR2, and/or UCMR3 and have been used by USEPA to support negative regulatory determinations.

Group 4. Fifty-five Group 4 compounds were recommended for not including on CCL4, as these compounds had sufficient information such that a "no need to consider further" designation is warranted. These Group 4 compounds include

- one VOC (1,3-dinitrobenzene);
- 16 industrial chemicals:
  - seven phthalates (benzyl butyl, dibutyl, dicyclohexyl, diethyl, diisononyl, dimethyl, di-*n*-octyl),
  - two alkylphenols (octyl and nonyl),
  - two alkylphenol ethoxylates (octyl and nonyl),
  - bisphenol A,
  - butylated hydroxyanisole,
  - *n*-propylbenzene,
  - perchlorate, and
  - sec-Butylbenzene;
- four inorganics:
- cesium 137,
  - radon,
  - tellurium,
  - vanadium; and
- 16 pharmaceuticals:
  - three pain relievers (acetaminophen, ibuprofen, naproxen),
  - 13 antibiotics (amoxicillin, bacitracin, ciprofloxacin, linezolid, methicillin, oxacillin, penicillin, spiramycin, sulfamethazine, triclocarban, tylosin, vancomycin, virginiamycin); and
  - 15 pesticides (bentazone, carbaryl, chlorothalonil, dicamba, dichlorvos, dicofol, endosulfan, ethoprophos, fluometuron, malathion, methyl parathion, permethrin, phosmet, bromoxynil, trichlorfon).

FIGURE 9 Risk comparison of occurrence (magnitude and prevalence) and potency for inorganics



DISCUSSION

The AWWA CCL TAW recommends that Group 1 and Group 2 be included in the final CCL4 to reflect highest priority based on known data and the need for more detailed information, respectively. Group 3 compounds should be included only on the final CCL4 if USEPA is willing to make negative determinations for all of them. In the latest round of regulatory determinations,

TABLE 3 Study compounds in each group in "higher-risk," "medium-risk," or "lower-risk" regions of space diagrams from Figures 3–9 for potency crossed with magnitude or prevalence

Risk	Potency crossed with Magnitude %	Potency crossed with Prevalence %
Cyanotoxins		
Higher	89	89
Medium	11	11
Lower	0	0
DBPs		
Higher	59	6
Medium	29	88
Lower	12	6
Industrial chemicals		
Higher	24	25
Medium	67	56
Lower	10	10
VOCs		
Higher	38	13
Medium	63	88
Lower	0	0
Pesticides		
Higher	26	46
Medium	74	54
Lower	0	0
PPCPs		
Higher	5	45
Medium	95	55
Lower	0	0
Inorganics		
Higher	20	20
Medium	80	80
Lower	0	0

DBPs—disinfection by-products, PPCPs—pharmaceuticals and personal care products, VOCs—volatile organic compounds

USEPA made the absolute minimum number of decisions (five), so it is unlikely that the agency would make such a large number of negative regulatory determinations. It is the authors' opinion that further consideration of Group 4 (as well as Group 3) compounds for potential regulation diverts critically needed resources that should be applied to more meaningful opportunities for protection of public health.

The AWWA CCL TAW recommends that USEPA develop a CCL4 research plan for Group 1 and Group 2 compounds to fill in research gaps related to health effects, analytical methods, concentrations, and prevalence. The research plan should be designed to result in prioritization of contaminants to advance the regulatory development process.

Additionally, the AWWA CCL TAW strongly supports the CCL nomination process as a viable means by which to solicit public input on contaminants of potential concern. The nominations process provides a mechanism to solicit a broad range of stakeholders for contaminants of potential concern, keeping in mind the overall principle of shorter CCLs in the future.

The fundamental CCL/UCMR/regulatory determination process for identifying new contaminants for potential regulation from the 1996 SDWA Amendments is fundamentally sound, but some tweaking is needed to optimize this process for future CCLs and regulatory determinations. The number of contaminants on future CCLs is critical, and shorter is better. The optimal number of contaminants is unclear, but anything over 100 is too many.

USEPA needs to use a more collaborative process for developing future CCLs. USEPA resources across all of its program offices are being reduced, so a new collaborative approach, inclusive of a broad range of stakeholders, is needed in the future to consider the following questions:

- Can the drinking water community leverage other USEPA program efforts, such as the Office of Pesticide Programs?
- Can we leverage international efforts?
- Can we leverage university research not in the peer-review literature (i.e., the "gray" literature)?
- Can we use new technologies and tools to speed up the analyses needed to scan a potential "universe" of contaminants?

Since the CCL is the start of the regulatory development process, it's important to get it right. At the same time, all stakeholders in the drinking water community need to be cognizant of decreasing USEPA resources and to think about what should be done to ensure that future CCLs result in a well-defined research agenda that can be adequately completed to make the necessary regulatory determinations.

ACKNOWLEDGMENT

The authors acknowledge the volunteer contributions from the members of the AWWA Contaminant Candidate List Technical Advisory Workgroup and the other experts who attended the January 2014 workshop and assisted in the development of the April 2015 report. This project was funded through the Water Industry Technical Action Fund (WITAF) (Project #419). WITAF is administered by AWWA and is funded through AWWA organizational members' dues. WITAF funds information collection and analysis and other activities in support of sound and effective legislation and regulations.

ABOUT THE AUTHORS

J. Alan Roberson *(to whom correspondence may be addressed) is director of federal relations at AWWA, 1300 Eye St. NW #701W, Washington, DC 20005 USA; aroberson@awwa.org. He has a bachelor's degree in engineering from Georgia Institute of Technology in Atlanta and a master's degree in civil engineering from the Virginia Polytechnic Institute and State University in Blacksburg. A recipient of the Archie Becher Award, which recognizes exemplary AWWA staff, Roberson has worked at AWWA for over 24 years, with 12 years of consulting before that, and he has served on the Fairfax Water board of directors for over six years. He is also the recipient of two AWWA Division Best Paper Awards.* ***Craig Adams*** *is professor of civil and environmental engineering at Utah State University in Logan.* ***Ryan Bench*** *is a project engineer with Carollo Engineers Inc. in Salt Lake City, Utah.* ***Jeffrey S. Rosen*** *is president of Corona Environmental Consulting Inc. in Salt Lake City, Utah.*

PEER REVIEW

Date of submission: 05/22/2015
Date of acceptance: 06/03/2015

REFERENCES

63 FR 10274, 1998. Announcement of the Drinking Water Containment Candidate List. https://federalregister.gov/a/98-5313 (accessed Aug. 21, 2015).

68 FR 42898, 2003. Announcement of Regulatory Determinations for Priority Contaminants on the Drinking Water Contaminant Candidate List. https://federalregister.gov/a/03-18151 (accessed Aug. 21, 2015).

70 FR 9071, 2005. Drinking Water Contaminant Candidate List 2; Final Notice. https://federalregister.gov/a/05-3527 (accessed Aug. 21, 2015).

73 FR 44251, 2008. Drinking Water: Regulatory Determinations Regarding Contaminants on the Second Drinking Water Contaminant Candidate List. https://federalregister.gov/a/E8-17463 (accessed Aug. 21, 2015).

74 FR 51850, 2009. Drinking Water Contaminant Candidate List 3-Final. https://federalregister.gov/a/E9-24287 (accessed Aug. 21, 2015).

77 FR 27057, 2012. Request for Nominations of Drinking Water Contaminants for the Fourth Contaminant Candidate List. https://federalregister.gov/a/2012-11048 (accessed Aug. 21, 2015).

79 FR 62715, 2014. Announcement of Preliminary Regulatory Determinations for Contaminants on the Third Drinking Water Contaminant Candidate List; Proposed Rule. https://federalregister.gov/a/2014-24582 (accessed Aug. 21, 2015).

80 FR 6076, 2015. Drinking Water Contaminant Candidate List 4—Draft. https://federalregister.gov/a/2015-02210 (accessed Aug. 21, 2015).

Graham, J.L. & Jones, J.R., 2009. Microcystin in Missouri Reservoirs. *Lake and Reservoir Management,* 25:3:253. http://dx.doi.org/10.1080/07438140903143239.

Graham, J.L.; Jones, J.R.; & Jones, S.B., 2006. Microcystin in Midwestern Lakes. *Lakeline,* Summer 2006:32. http://ks.water.usgs.gov/static_pages/studies/water_quality/cyanobacteria/GrahamJonesJones-LakeLine2006.pdf (accesed July 10, 2015).

Plewa, M.J.; Muellner, M.G.; Richardson, S.D.; Fasano, F.; Buettner, K.M.; Woo, Y-T.; McKague, A.B.; & Wagner, E.D., 2008. Occurrence, Synthesis, and Mammalian Cell Cytotoxicity and Genotoxicity of Haloacetamides: An Emerging Class of Nitrogenous Drinking Water Disinfection Byproducts. *Environmental Science & Technology,* 42:3:995. http://dx.doi.org/10.1021/es071754h.

Plewa, M.J.; Wagner, E.D.; & Jazwierska, P., 2004. Halonitromethane Drinking Water Disinfection Byproducts: Chemical Characterization and Mammalian Cell Cytotoxicity and Genotoxicity. *Environmental Science & Technology,* 38:1:62. https:/dx.doi.org/10.1021/es030477l.

Richardson, S.D.; Plewa, M.J.; Wagner, E.D.; Schoeny, R.; & DeMarini, D.M., 2007. Occurrence, Genotoxicity, and Carcinogenicity of Regulated and Emerging Disinfection By-products in Drinking Water: A Review and Roadmap for Research. *Mutation Research,* 636:1–3:178. http://dx.doi.org/10.1016/j.mrrev.2007.09.001.

Roberson, J.A.; Adams, C.; Bench, R.; & Rosen, J.S., 2015. AWWA Recommendations for Contaminant Candidate List 4 (CCL4), Water Industry Technical Action Fund (WITAF) Project #419. AWWA, Denver, CO. www.awwa.org/Portals/0/files/legreg/documents/2015CCLAWWAReport.pdf (accessed May 22, 2015).

Roberson, J.A.; Lueders, M.; Adams, C.; & Rosen, J.S., 2009. Risk Indices for Draft CCL3 Chemicals. *Journal AWWA,* 101:9:64.

Rosen, J.S. & Roberson, J.A., 2007. A Simplified Approach to Developing Future Contaminant Candidate Lists. *Journal AWWA,* 99:3:66.

Seidel, C.; Roberson, J.A.; Summers, R.S.; Zearley, T.; & Tang, G., 2009. Incorporation of Research Plan Results Into Regulatory Policy. *Journal AWWA,* 101:12:42.

USEPA, 2011. Regulatory Determinations for the Third Drinking Water Contaminant Candidate List. www2.epa.gov/sites/production/files/2014-09/documents/preliminary-regulatory-determinations-3-june-16th-public-meeting-slides.pdf (accessed May 22, 2015).

USEPA, 2009a. Contaminant Information Sheets for the Final CCL3 Chemicals. EPA 815-R-09-012. http://water.epa.gov/scitech/drinkingwater/dws/ccl/upload/Final-CCL-3-Contaminant-Information-Sheets.pdf (accessed July 10, 2015).

USEPA, 2009b. Final CCL3 Chemicals: Classification of the PCCL to CCL. EPA 815-R-09-008. www.epa.gov/ogwdw/ccl/pdfs/ccl3_docs/CCL3_PCCLtoCCL_08-31-09_508.pdf (accessed July 10, 2015).

Wagner, E.D.; Hsu, K-M.; Lagunas, A.; Mitch, W.A.; & Plewa, M.J., 2012. Comparative Genotoxicity of Nitrosamine Drinking Water Disinfection Byproducts in *Salmonella* and Mammalian Cells. *Mutation Research,* 741:1-2:109.