American Water Works Association
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September 17, 2021

Ms. Radhika Fox
Assistant Administrator
Office of Water
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
SUBMITTED ELECTRONICALLY

RE: AWWA Comments on EPA's Drinking Water Contaminant Candidate List 5-Draft (Docket ID: EPA-HQ-OW-2018-0594)

Dear Ms. Fox,

The American Water Works Association (AWWA) appreciates the opportunity to provide comments on the Environmental Protection Agency's (EPA's) draft of the Drinking Water Contaminant Candidate List 5 (CCL 5). AWWA has a continuing interest in EPA's Safe Drinking Water Act (SDWA) program and has been an active participant in, and facilitator of, technical dialogues and stakeholder engagement around the drinking water regulatory process since its inception.

The CCL is the element of the nation's drinking water program that helps EPA identify contaminants that represent public health risks that can be reduced through drinking water treatment / control. As such it provides the starting point for identifying regulatory and research / information collection priorities for EPA, the federal government, and the sector. Consequently, it is important to recognize:

1. The work of the involved EPA staff and peer-reviewers on the CCL is vitally important and should be recognized by EPA management.
2. For the CCL to be an effective tool it must be a short, preferably prioritized, list. Given EPA's available resources, the draft CCL 5 is not yet sufficiently focused.
3. The final CCL 5 Federal Register notice will be a key opportunity to present research and information needs to advance EPA's drinking water regulatory program.
4. CCL 5 and subsequent CCLs should be used to inform coordination with other EPA programs (e.g., the Toxic Substances Control Act program [TSCA]) in order to prevent contamination of the nation's water supply.
5. The draft CCL 5 technical support document suggests that there are significant gaps in data that should be available from the TSCA program and the Clean Water Act National Pollutant Discharge Elimination System. EPA should take steps now to address these gaps – action

may be needed by the TSCA and Office of Enforcement and Compliance program offices to facilitate development of future CCLs.

6. The CCL process should be an ongoing effort rather than the current prepare-pause-regenerate preparation model and that ongoing effort should be in concert with external expert input.

7. The Draft CCL 5 Federal Register notice and technical support documents should be supplemented to better communicate the effect of influential decisions in CCL preparatory process, especially the identification of named groups rather than individual contaminants.

8. The CCL is an important and underutilized tool in EPA's risk communication efforts. A clearly described and supported prioritized list of contaminants would provide a framework for EPA communication about its efforts to protect the public from contaminants in drinking water

AWWA hopes that the following comments will assist EPA to utilize this important element of SDWA effectively. If you have any questions regarding this correspondence, please contact me or Chris Moody at 202.326.6127 or cmoody@awwa.org.

FOR THE AMERICAN WATER WORKS ASSOCATION

G. Tracy Mehan, III
Executive Director – Government Affairs
American Water Works Association

Attachment (1)

cc: Michal Freedhoff, EPA/OCSPP
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Who is AWWA

The American Water Works Association (AWWA) is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes more than 4,500 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our 50,000-plus total membership represents the full spectrum of the water community: public water and wastewater systems, environmental advocates, scientists, academicians, and others who hold a genuine interest in water, our most important resource. AWWA unites the diverse water community to advance public health, safety, the economy, and the environment.

ATTACHMENT A

Comments prepared
by the

American Water Works Association

on the

U.S. Environmental Protection Agency's
Drinking Water Contaminant Candidate List 5-Draft

(86 Federal Register 37948,
Docket ID: EPA-HQ-OW-2018-0594)

Prepared
September 17, 2021

Contents

Comments
Prepared by the American Water Works Association on
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(86 Federal Register 37948, Docket ID: EPA-HQ-OW-2018-0594)

Introduction

AWWA has commented extensively on prior contaminant candidate lists (CCLs) and their development.[1,2] In its Draft CCL 5 Federal Register notice EPA solicited comments on the following:

1. Contaminants selected for the Draft CCL 5, including any supporting data that can be used in developing the Final CCL 5.
2. Data that EPA obtained and evaluated for developing the Draft CCL 5 may be found in the Chemical Technical Support Document and Microbial Technical Support Document located in the docket for this document.
3. The improvements EPA implemented in the CCL 5 process.

The following comments are focused on these areas.

AWWA appreciates that EPA's approach in developing the draft CCL 5 and implementing recommendations from the National Drinking Water Advisory Council (NDWAC), AWWA, and others. The process described in the proposal is thorough and provided for consideration of large universe of potential candidate contaminants. The Agency clearly recognizes that the development of the CCL should be a comprehensive and methodical process. The CCL process is an important component of the Agency's Safe Drinking Water Act (SDWA) work plan and is essential to moving beyond regulating the "contaminant du jour". A well-crafted CCL is essential to informing future risk management actions that effectively utilize scarce resources to best protect public health.

Structuring a More Effective CCL 5

As described by the SDWA, the CCL is the first step of the regulatory process for drinking water contaminants and is intended to represent the contaminants that *"present the greatest public concern"*. To be an effective tool, the CCL must provide adequate focus to drinking water research needs. When effectively developed and structured, the CCL guides EPA and external stakeholders to conduct research important to addressing risks associated with drinking water risks, and thus informing action under SDWA when needed.

The CCL should also facilitate clear communication with consumers and engaged stakeholders on research gaps limiting further regulatory action, the scope of the necessary research projects (short-, mid-, and long-term), and the relative levels of priority that contaminants present as a public health risk. The CCL is revised on a five-year cycle so that the list reflects changes in available science and the relative risks presented by unregulated contaminants. For example, the national occurrence of a listed

[1] AWWA, 2009, Comment submitted on Drinking Water Contaminant Candidate List 3 – Draft, EPA-HQ-OW-2007-1189-0100.
[2] AWWA, 2012. AWWA Response to Contaminant Candidate list 4 Request for Nominations, Docket ID No. EPA-HQ-OW-2012-0217.https://www.regulations.gov/comment/EPA-HQ-OW-2012-0217-0059

contaminant may decrease due to management efforts under the Toxic Substances Control Act (TSCA), state regulatory actions, or changes in manufacturing and use trends. Alternatively, contaminants not previously on the CCL due to a limited availability of data may be added to the CCL due to new data that show the contaminant presents a greater public concern.

AWWA offers the following recommendations for EPA to consider as the CCL 5 is finalized and in the development of future CCLs.

Short, Manageable List is Needed

The EPA Science Advisory Board observed that CCL 3, which included 116 contaminants was a list too large to *"achieve the stated objectives of the CCL process."*[3] As proposed, the Draft CCL 5 is comprised of more than 1,400 individual contaminants. It is difficult, if not impossible, for stakeholders and consumers to effectively understand the EPA's priorities moving forward with such an extensive CCL. AWWA and other stakeholders have previously emphasized the need for a short, manageable CCL to facilitate the efficient advancement of research activities and to clearly communicate potential contaminants that present opportunities for meaningful public health protection. EPA should consider reducing the size of the CCL 5 such that only drinking water contaminants presenting the "greatest public concern" are included on the list and that the list's scope is commensurate with the funding available for EPA to deploy to advance SDWA decision-making processes. Moreover, it's completely infeasible to meaningfully consider regulation for 1,400+ contaminants. This dilutes the impact of the CCL and suggests that listing doesn't truly have any substantive significance to EPA's regulatory decision-making.

If one were to focus exclusively on the 176 contaminants that were reviewed by chemical evaluators for inclusion in the Draft CCL 5. The scoring process retained 38% of the contaminants that were subjected to a full evaluation. Alternatively, if one were to look at the total list of provisional contaminant candidate list (PCCL) chemicals that were listed on the Draft CCL 5 as individual contaminants, the Draft CCL 5 chemical list would total 114 chemicals (a 44% retention rate). EPA should consider whether the current scoring process is providing enough discrimination of high priority contaminants or alternatively if the challenge EPA faces in refining the CCL to an actionable length is institutional.

Communicate Priorities Within CCL.

The development process for the CCL is complex and the CCL itself is the product of an extensive review of available data. EPA should consider presenting the Final CCL 5, and future CCLs, as an organized list that illustrates relative levels of potential risk and the gaps in information needed to craft risk management decisions. Such an approach would accomplish the following benefits:

1. Help EPA prioritize research needs internally
2. Inform stakeholders on research goals (both short-term and long-term).
3. Clearly indicate to consumers what priorities the Agency has identified and the potential level of concern that they present

Organizing the CCL so that it clearly communicates the strength of available information and the Agency's concern based on that data would also clarify inclusion of contaminants as part of a group in the CCL. The Draft CCL 5 also includes groups of contaminants for which there is a wide variety of available information

[3] SAB. 2009. SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL3).

with respect to individual chemicals in the group (e.g., levels of toxicity, occurrence (or a risk of occurrence)). For example, the Draft CCL 5 includes more than 1,350 per- and polyfluoroalkyl substances (PFAS) and notes that listing all PFAS individually would be both "difficult and challenging." Rather than choosing between the extremes (e.g., listing all PFAS as a group or listing 1,000's of PFAS) the Agency could reflect groups of PFAS compounds based on the relevant and applicable data at hand. This approach is not dissimilar to the implied prioritization of certain groups of DBPs in the Draft CCL 5 Federal Register notice, though the docket underlying the notice regarding DBPs is lacking.[4]

Lack of Information Characterizing Wastewater Discharges.

A cursory review of the information data sheets illustrates that the Agency has a limited pool of datasets to characterize pollutant levels in wastewater discharges. The CCL 5 factsheets rely almost exclusively on two very limited research papers.[5,6] Currently, permittees in the Clean Water Act (CWA) National Pollutant Discharge Elimination System (NPDES) submit compliance monitoring data that provides discharge location, analyte concentration, and discharge flow information. That data is submitted electronically and should be readily available to inform the CCL process. Analytes for which monitoring is required have specified analytical methods of known resolution and robustness. EPA's CWA analytical methods include a number of contaminants included in the CCL 5 PCCL and it is possible that the use of this occurrence data could inform the list of contaminants for which EPA seeks out health effects information.[7] Utilizing data available through the CWA would be consistent with the NDWAC Report on the CCL Classification Process and the National Research Council report that preceded the NDWAC recommendations.[8,9]

Using CCL to Advance Source Water Protection

The CCL should inform risk management efforts beyond the scope of SDWA. This is especially important for contaminants like PFAS, where the source of the contamination is beyond the authorities of SDWA. In developing and presenting the CCL, EPA should consider how it can leverage this information to inform discussion about chemicals that may pose a risk to the nation's drinking water supply. For example, PFAS are a group of contaminants most appropriately addressed through the Toxic Substances Control Act, CWA, and Resource Conservation and Recovery Act. There are opportunities for federal agencies other than EPA to fund relevant research, employ policies and procedures that reduce the use of PFAS substances (e.g., Department of Defense, General Services Administration, etc.).

For other contaminants, other federal agencies may be most relevant to exposure reduction (e.g., Food and Drug Administration, U.S. Department of Agriculture, etc.). In order for EPA to effectively leverage CCL 5 to reduce contaminant occurrence, the final Federal Register notice must provide a sense of

[4] 86 FR 37954

[5] Scott, T. M., Phillips, P. J., Kolpin, D. W., Colella, K. M., Furlong, E. T., Foreman, W. T., & Gray, J. L. (2018). Pharmaceutical manufacturing facility discharges can substantially increase the pharmaceutical load to US wastewaters. Science of the Total Environment, 636, 69-79.

[6] Kostich MS, et al. 2014 Concentrations of prioritized pharmaceuticals in effluents from 50 large wastewater treatment plants in the US and implications for risk estimation. Environ Pollut. 2014 Jan;184:354-9. doi: 10.1016/j.envpol.2013.09.013. Epub 2013 Oct 3. PMID: 24095705.

[7] EPA, Accessed August 31, 2021. Approved CWA Chemical Test Methods.

[8] NDWAC. 2004. National Drinking Water Advisory Council Report on the CCL Classification Process.

[9] NRC. 2001. Classifying Drinking Water Contaminants for Regulatory Consideration.

priority for (1) which contaminants appear to pose the greatest priority for action and (2) research and data development needs to inform decision-making.

The CCL development process occurs over a five-year cycle. There are frequently stated concerns that the SDWA regulatory process is too slow. The CCL is an opportunity for EPA to step beyond that critique and move instead to timely initiation of action not only to inform risk in drinking water but contamination of the nation's waters.

CCL Development Process

There are aspects to the Draft CCL5 that EPA should address in preparing the Final CCL 5 and in preparation of future CCLs.

Coordination with Other SDWA Processes

The Draft CCL 5 includes many microbial pathogens and disinfection byproducts (M/DBPs). Some of these contaminants, like *Legionella pneumophila* and brominated haloacetic acids, are currently the focus of EPA's effort to consider potential revisions of M/DBP rules.[10] EPA presentations as part of the ongoing stakeholder process have raised the possibility of including a wider range of pathogens and DBPs.[11] The ongoing regulatory development process for M/DBPs is occurring on a short, fixed schedule to comply with a legal settlement (i.e., the same lawsuit that set a schedule for finalizing the CCL 5).[12]

Despite the parallel timing of the Draft CCL 5 Federal notice with the M/DBP process, EPA has not provided any information regarding how the inclusion of pathogens and DBPs on the CCL 5 will impact the potential revisions, or vice versa. The Final CCL 5 Federal Register notice should address how these two processes will interplay with respect to M/DBPs.

External Peer-Review

EPA engaged in an extensive process to develop CCL 5, particularly in comparison to CCLs 1, 2, and 4. However, EPA prepared the Draft CCL 5 Federal Register notice without seeking external expert review as was recommended by NDWAC and has been past practice (e.g., CCLs 1 and 3). AWWA appreciates that the draft CCL 5 will be reviewed by the Science Advisory Board but recommends that future CCLs be reviewed by an external expert panel in advance of the proposal. As is demonstrated by the two technical support documents that underpin the Draft CCL 5, it is challenging to develop the CCL process algorithm without resolving a lengthy series of individual questions of process and data quality. Without an external review, it is difficult to evaluate one's own work as to whether the completely assembled product works as it should. The technical support documents do not describe any internal process control measures, making the role of an independent third-party review even more important. The use of multiple chemical evaluator teams only serves as an internal check on one step in preparation of the CCL.

Contaminant Information Sheets

The EPA Technical support document, "Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Contaminant Information Sheets," represents a substantial body of background

[10] EPA, 2021. Potential Revisions of Microbial and Disinfection Byproducts Rules. Accessed August 24, 2021.
[11] Ibid
[12] 2020. Waterkeeper Alliance, Inc. et al. v. US. EPA and Andrew Wheeler. (19 Civ.899 (LJL), U.S. District Court Southern District of New York).

research. This document is, in many ways, central to EPA's efforts to assure that the CCL process is transparent to the public and interested stakeholders. AWWA commends the Agency for continuing to include these information sheets in the CCL docket and on its efforts to improve on previous CCL contaminant information sheets.[13, 14, 15] The improvements to the formatting of the sheets for CCL 5 facilitate stakeholder review of EPA's use of available data.

The information sheets also set the stage for EPA to elevate the influential aspects of the SDWA decision-making processes in the CCL preamble more clearly:

1. The role of changing assumptions in setting health reference levels
2. Influential data gaps in the CCL process

Transparency

EPA has a duty to transparently present the evidentiary basis for its decision-making not only as a matter of sound government but also in order to comply with Executive Orders and statutory requirements.[16, 17] This duty applies to influential documents, like the CCL, as well as formal rulemakings.

The Draft CCL 5 Federal Register notice docket is much more concise and focused than many EPA dockets (in large part due to the organization provided by the chemical information sheets). That the CCL 5 universe is more than three times larger than the CCL 3 universe dataset illustrates the growing need for of a concise summary.[18] Even so, there are more than 1,300 pages of technical support documentation for the public to review and evaluate within a 60-day comment period. It is not clear from the contaminants listed and the information provided in the Draft CCL 5 Federal Register notice and technical support documents that EPA fully explained how it created the Draft CCL 5. This is not a new challenge. In reviewing the draft CCL 3, the Science Advisory Board observed that the Agency made judgements within the CCL 3 process that were not readily apparent in CCL process documentation.[19]

It is important to note that EPA did identify some issues that warranted more detailed explanation of its methodology and its impact. An example is the treatment of cancelled pesticides, where there is an obvious concern that, while older data may indicate occurrence and there would be available health information, drinking water is much less likely to represent an ongoing source of exposure for a cancelled pesticide. EPA's summary illustrates how available data is and can be used to identify those cancelled

[13] EPA. 2008. Contaminant Information Sheets for the PCCL Chemicals Considered for CCL 3. EPA-HQ-OW-2007-1189-0043.
[14] EPA. 2015. Contaminant Information Sheets (CISs) for the Draft Fourth Preliminary Contaminant Candidate List (PCCL 4) Nominated Contaminants. EPA 815-R-15-003.
[15] EPA. 2016. Contaminant Information Sheets (CISs) for the Final Fourth Contaminant Candidate List (CCL 4). EPA 815-R-16-003.
[16] Presidential Memorandum. 2021. Memorandum on Restoring Trust in Government Through Scientific Integrity and Evidence-Based Policymaking.
[17] OMB. 2002. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies; Republication.
[18] EPA. 2008. Contaminant Candidate List 3 Chemicals: Identifying the Universe. EPA 815-R-08-002. EPA-HQ-OW-2007-1189-0037.
[19] SAB. 2009. SAB Advisory on EPA's Draft Third Drinking Water Contaminant Candidate List (CCL3).

pesticides that might pose a continuing risk. A more routine practice of reflecting on the impact of methodological decisions would help the public and facilitate improvement of the CCL process over time.

It is also not clear what effect significant methodological changes over past practice have had on the composition of CCL 5. The public would benefit from a fuller explanation of the CCL 5 process and insight into the influential decisions made in the construction of the CCL 5.

In reviewing the CCL 5 process as described by the Agency, AWWA found:

1. The Science Advisory Board review of CCL 4 led EPA to modify Criterion 9 in its screening of microbial contaminants to no longer exclude pathogens for which the only drinking water-related infections were nosocomial epidemiology.[20] This is a substantial and important change to the CCL process as nosocomial infections occur under a unique combination of exposure scenarios and involve individuals that are very susceptible to infection. Nosocomial infections often involve individuals or exposure scenarios that require a completely sterile environment. This change was important to the inclusion of *Mycobacterium abcessus* and *Pseudomonas aerugionosa* in CCL 5, but neither the Draft CCL 5 Federal Register Notice nor the "Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) - Microbial Contaminants" describe the weight-of-evidence approach used when applying the revised Criterion 9. If EPA finalizes CCL 5 retaining the incorporation of this modified criterion, it must more clearly describe its approach to implementing the revised criterion.

2. With the ongoing M/DBP effort, it is not clear why EPA was not able to include information on the health effects and occurrence of DBPs in the Draft CCL 5 Federal Register notice support documents. EPA must have information not otherwise included in the support documents to justify selecting 23 DBPs from the hundreds of known DBPs. At present, EPA cites the inclusion of 23 DBPs in the CCL 5 solely on the basis that it is contemplating revising existing M/DBP regulations.[21] In finalizing CCL 5, EPA should present the supporting data for including DBPs as a group in the CCL, since EPA is aware that there are marked differences in both DBP occurrence and health effects. AWWA agrees with EPA's stated intent of evaluating DBPs in a cohesive manner while assuring adequate disinfection.

3. In constructing the CCL Universe, EPA combined the health effects data from multiple forms of some chemical contaminants.[22] This approach is described in the docket, and there are compounds for which this would be a sound approach. Unfortunately, the Draft CCL 5 documentation only provides a handful of examples. The docket does not summarize the list of CCL or PCCL chemicals for which this approach was influenced by the availability of data. Consequently, the public does not have a clear notion of which contaminants are, in fact, included in the CCL based on data regarding the health-effects posed by contaminants likely to be present in water.

[20] SAB. 2016. Review of the EPA's Draft Fourth Contaminant Candidate List (CCL4).
[21] EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.
[22] EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.

4. EPA describes, in limited detail, a new presumption of contaminant occurrence used during CCL 5 screening.[23] Specifically, EPA occurrence metrics were calculated where non-detects were set equal to one-half the method detection level when data sources provided a method detection level (MDL). EPA does not describe how this presumption impacts the composition of the CCL 5 list in comparison with alternative valid approaches (e.g., setting non-detects equal to "0" or the MDL). Occurrence is a critical data element in the CCL development process. No doubt EPA analyzed such a substantial change on CCL contaminant scores. While this assumption of occurrence should generally be avoided for analyses such as construction of the CCL, by failing to show its work the Agency prevents commenters from understanding how influential this assumption is in the CCL 5 process. EPA makes similar assumptions elsewhere (e.g., chemical production data). Taken individually such assumptions can be influential; when applied regularly to multiple data elements, the compounding conservatism can distort the occurrence data elements that underpin the CCL process.

5. In describing how EPA prepared the Draft CCL 5, the technical support document indicates the Agency utilized existing health effects assessments to the degree possible. In reviewing the health reference levels listed in the Contaminant Information Sheets for pesticides listed on the Draft CCL 5, it appears that EPA made different assumptions in setting the health reference levels used in CCL 5 than in the Human Health Benchmarks for Pesticide update, which were published in parallel.[24] In part this difference appears to be the result from choosing different sensitive subpopulations. While it may be sound practice for EPA to utilize different assumptions compared to FIFRA assessments that are several years old, it is not clear why 16 of 24 contemporaneous health reference levels prepared by the Office of Water would differ with 14 citing different sensitive subpopulations.

6. EPA notes the use of FIFRA modelled pesticide concentrations to estimate exposure in developing the Draft CCL 5. The FIFRA drinking water exposure models are deliberately conservative, which generate exposure estimates that are typically substantially higher than observed occurrence. The chemical information sheets for three Draft CCL 5 contaminants (i.e., Bensulide, Propanil, and Thiamethoxam) include the modelled estimates. It is not clear from the docket how influential the FIFRA pesticide modelling estimates are as part of the CCL 5 decision-making process. FIFRA risk assessments did not emphasize drinking water risks for Propanil or Thiamethoxam.

7. The Draft CCL 5 is inconsistent in its treatment of pesticide degradates. CCL 5 considered risk analysis of individual pesticides conducted under the Federal Insecticide Fungicide Rodenticide Act. CCL 5 Contaminant Information Sheets reference at least 12 FIFRA re-registration dockets that note the role of pesticide degradates including degradates created during drinking water treatment in estimating associated risks. Yet, the Draft CCL5 includes four triazine degradates without explanation of why these four degradates

[23] EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.
[24] EPA. 2021. Human Health Benchmarks for Pesticides (HHBPs). Accessed 9/8/2021 at https://ordspub.epa.gov/ords/pesticides/f?p=HHBP:home.

warrant specific inclusion and the degradates of other pesticides in the Draft CCL 5 do not. The relative accessibility of information from available sources is not a rational explanation for this inconsistency given the extensive referencing of FIFRA work products in the Draft CCL 5 Federal Register notice docket.

8. The Draft CCL 5 includes three groups of contaminants (i.e., cyanotoxins, disinfection byproducts, and per- and polyfluoroalkyl substances). These groups contain contaminants that do not share known common mechanisms of toxicity and are known to occur in water under different conditions and timescales. Conversely, the Draft CCL 5 includes groups of pesticides that are already managed under FIFRA because such similarities exist, yet the docket does not address what distinguishes one "group" from another in the CCL decision-making process (i.e., why are some contaminants listed as individuals and others in groups). The description of EPA's area-under-the-curve receiver operating characteristics model is the only point in the docket that the Agency notes that orthophosphate pesticides (OPs) are highly selected by the Draft CCL 5 process when 12 of the Draft CCL contaminants are OPs.[25]

9. There are more than 1,300 pesticide constituents regulated under FIFRA and 86,000 chemicals in the TSCA inventory. The Draft CCL 5 includes 39 pesticides and 5 pesticide degradates. Pesticide-related contaminants make up over half of the individually named chemical contaminants in the Draft CCL. FIFRA maintains an active and thorough registration / re-registration process providing data in public-facing documents that do not exist for the thousands of industrial chemicals managed under TSCA. Both FIFRA and TSCA regulated chemicals are in the CCL 5 Universe. It is not clear from the docket whether the Draft CCL 5 process is being biased by the data-rich and transparent implementation of FIFRA re-registration practice. It appears that the FIFRA program is more capable of informing the CCL 5 process compared to the much less transparent TSCA process. In finalizing CCL 5, EPA should evaluate the impact of data accessibility and completeness between these two programs and for their potential to influence the CCL process. Such an analysis could inform not only EPA's SDWA processes but those implemented under TSCA.

10. The FIFRA program evaluations of pesticide chemistry, actual use, and conservative modelling of use patterns indicate that aggregate dietary exposure including drinking water exposure is unlikely to reach a level of concern for roughly half of the pesticides listed in the Draft CCL 5. For several pesticides, drinking water exposure was a significant, if not dominant, route of exposure in FIFRA exposure assessments, but only in a few instances were levels of concern exceeded under modelled high-risk pesticide use conditions. Even after review of FIFRA dockets (updated since the end of data collection for the Draft CCL docket), it is not apparent how EPA is reconciling inclusion of all listed pesticides in the Draft CCL 5 with available information from FIFRA. In finalizing Draft CCL 5 EPA should clearly describe how this evaluation, which is largely reliant on the same data as available

[25] EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.

to the FIFRA pesticide re-registration, is reaching different conclusions regarding the potential risk to drinking water and why this is appropriate.

Specific CCL 5 Contaminants

Appropriately Define PFAS

The Draft CCL 5 includes PFAS as a group of chemical contaminants. EPA describes the structural definition as, intended to be, inclusive of all PFAS compounds. Specifically the EPA has defined PFAS as chemicals with the chemical structure R-(CF_2)-C(F)(R')R" where the CF_2 and CF moieties are saturated carbons and none of the R groups can be hydrogen. This definition is based on the definition of PFAS included in a recently proposed TSCA Rule.[26] Under that rule, EPA indicated that approximately 1,346 PFAS meet this definition. This definition does not include all PFAS. The accepted definition of PFAS broadly is those substances containing at least one fluorinated carbon moiety.[27, 28, 29] According to the EPA CompTox PFAS Master List there are approximately 9,252 known PFAS chemicals, a much larger universe of PFAS compounds than what is included by the definition in the Draft CCL 5.

The Draft CCL 5 definition for PFAS excludes certain PFAS that have been found in drinking water and their sources from the proposed reporting requirements. For example, perfluoro-2-methoxyacetic acid (PFMOAA) does not meet the structural definition since this compound does not have a fluorinated two-carbon chain. However, PFMOAA is a perfluoro-ether carboxylic acid that has been found in the North Carolina Cape Fear River and nearby drinking water supplies.[30, 31] PFMOAA is an example of a replacement PFAS being used as legacy PFAS compounds (e.g., PFOA and PFOS) are phased out. If EPA anticipates using an all-inclusive structural definition of PFAS, then the appropriate chemical structure would be R-CF(R')(R"), where R, R', and R" are not hydrogen.

If EPA includes PFAS as a group in the final CCL 5, then it should be intentional and transparent in its inclusion and the chemical structures it is including. The framing of the CCL is as important as the list itself. As EPA notes, the current inclusion of 1,346 PFAS compounds assumes a common level of toxicity that is not substantiated in the docket and a premise that would be even less credible if applied to 9,252 PFAS compounds. This is an instance where, if EPA were to more clearly communicate the relative levels

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[26] EPA, 2021. TSCA Section 8(a)(7) Reporting and Recordkeeping Requirements for Perfluoroalkyl and Polyfluoroalkyl Substances.

[27] Buck et al, 2011. Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins. Integrated Environmental Assessment and Management. Doi: 10.1002/ieam.258.

[28] Organization for Economic Co-operation and Development, 2018. Toward a New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating The OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs). https://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=ENV-JM-MONO(2018)7&doclanguage=en

[29] EPA, 2020. EPA: PFAS Structures in DSSTox (Update August 2020). https://comptox.epa.gov/dashboard/chemical_lists/PFASSTRUCTV3

[30] North Carolina PFAS Testing Network, 2019. NC PFAST Quantitative Screening Results for Raw Drinking Water. https://www.brunswickcountync.gov/wp-content/uploads/2019/08/NC-PFAST-Quantitative-Screening-Results-for-Raw-Drinking-Water-Brunswick-County-Drinking-Water-System.pdf

[31] Hopkins et al., 2018. Recently Detected Drinking Water Contaminants: GenX and other Per- and Polyfluoroalkyl Ether Acids. Journal AWWA. https://doi.org/10.1002/awwa.1073

of potential risk and gaps in information needed to craft risk management decisions, it could more readily incorporate a group (or groups) of PFAS on the Final CCL 5.

Inclusion of *Mycobacterium avium* and *M. abscessus*

AWWA supports the inclusion of *Mycobacterium avium* and *M. abscessus* on CCL 5. AWWA has previously recommended the inclusion of *M. avium* for inclusion in the CCL.[32, 33] *M. avium* and *M. intracellulare,* which are very similar genetically, are responsible for the greatest majority of recognized pulmonary nontuberculous mycobacterial disease in the United States, but the number of cases of *M. abscessus* is growing rapidly.[34, 35] CDC does not identify drinking water as a key exposure for *M. abscessus* but case studies of nosocomial infections have involved on-site uses of potable water.[36]

For simplicity, researchers and clinicians will refer to "non-tuberculosis *Mycobacterium"* (e.g., a group of 190 non-tuberculosis *Mycobacterium*) (NTM).[37] The NTM nomenclature was initially a product of available analytical tools (i.e., phenotypic criteria based on colony morphology and biochemical metabolism) and an international focus on addressing tuberculosis.[38] Only nine NTM are generally associated with disease.[39, 40] At present, with our understanding of the *Mycobacterium* species that represent a significant health threat, NTM is not an appropriate grouping to include in the CCL.

Cyanotoxins

Cyanotoxins are a group of toxins naturally produced and released by some specifies of cyanobacteria. Several cyanotoxins were listed on the Third and Fourth CCL as part of a group. AWWA has recommended their inclusion in both the CCL and as part of the Unregulated Contaminant Monitoring Rule sampling. UCMR 4 included several Microcystins: nodularin, cylindrospermopsin, and anatoxin-a. As EPA summarizes, the UCMR is a nationally representative dataset providing sufficient data to support rulemaking decisions. In EPA's most recent data summary from UCMR 4 (July 2021) microcystins were only detected in finished water sample points at 0.2% of all participating systems and cylindrospermopsin was only detected in less than 0.4% of participating systems. Despite the extremely low occurrence of these cyanotoxins, the Draft CCL 5 includes these contaminants.

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[32] AWWA, 2009, Comment submitted on Drinking Water Contaminant Candidate List 3 – Draft, EPA-HQ-OW-2007-1189-0100.

[33] AWWA.2015. Comment submitted on Drinking Water Contaminant Candidate List 4 – Draft, EPA-HQ-OW-2012-0217-0059.

[34] Kasperbauer, Shannon H. 2017. Nontuberculous Mycobacteria (NTM) Overview. National Jewish Hospital. Accessed 9/2/2021 at https://www.nationaljewish.org/conditions/ntm-nontuberculous-mycobacteria/ntm-nontuberculous-mycobacteria-overview

[35] Johansen, M.D., Herrmann, JL. & Kremer, L. Non-tuberculous mycobacteria and the rise of *Mycobacterium abscessus*. Nat Rev Microbiol 18, 392–407 (2020). https://doi.org/10.1038/s41579-020-0331-1

[36] CDC. Mycobacterium abscessus in Healthcare Settings. Accessed 9/3/2021 at https://www.cdc.gov/hai/organisms/mycobacterium.html.

[37] Clinical Infectious Diseases, Volume 71, Issue 4, 15 August 2020, Pages e1–e36, https://doi.org/10.1093/cid/ciaa241

[38] Runyon EH: Typical mycobacteria: their classification. Am Rev Respir Dis. 1965;91:288–9.

[39] Kasperbauer, Shannon H. 2017. Nontuberculous Mycobacteria (NTM) Overview. National Jewish Hospital. Accessed 9/2/2021 at https://www.nationaljewish.org/conditions/ntm-nontuberculous-mycobacteria/ntm-nontuberculous-mycobacteria-overview

[40] Note mycobacteria avium complex is defined as a group of 10 mycobacteria species.

The role of CCL is to identify priority contaminants for potential drinking water regulation. Contaminants listed in the CCL should represent contaminants that present a public health risk and an opportunity for effective risk-reduction based on a chemical's occurrence and toxicity and its removal through drinking water treatment. Given that several cyanotoxins (e.g., total microcystins and cylindrospermopsin) were generally not detected in drinking water as part of the UCMR 4 monitoring program, it is unclear why these contaminants are included in the Draft CCL 5. The substantiation provided by the Agency in the docket to-date, is that inclusion is consistent with a risk assessment and plan created in 2015 that has not been subsequently updated.[41,42] If retained in the final CCL 5 Federal Register notice, EPA must provide additional information to demonstrate the value and objectives in retaining the several cyanotoxins for which EPA has occurrence data from UCMR 4. At present, EPA summarizes its bases for inclusion of the cyanotoxins as:

1. Not based on an assessment of data availability for individual cyanotoxin occurrence or health effects data
2. Reflecting model cyanotoxin health effects and the presumption that all cyanotoxins will have similar effects
3. Based on an assumption that since some cyanotoxins are present, occurrence of all in the group are likely and present at a level of concern[43]

The UCMR 4 data should give EPA pause, and the Agency should reconsider whether its assumptions regarding inclusion of this group are sound. If retained in the Final CCL 5, EPA should more clearly articulate a rationale for the cyanotoxins included.

Conclusion

AWWA greatly appreciates the Agency's efforts to bring the best available information to bear on identifying contaminants of concern in drinking water. The staff involved in developing the Draft CCL 5 should be commended.

EPA is often criticized for not regulating drinking water contaminants quickly. Managing the CCL as an ongoing component of the Agency's SDWA program rather than a cyclical statutory duty and aligning research and communication priorities, based on prioritized needs tied to the CCL, would be an important step toward addressing such critics. A more focused and prioritized CCL would great improve the Agency's success in advancing a clear and consistent regulatory agenda, which would benefit public health, the Agency's day-to-day work, and the sector more broadly.

[41] EPA. 2015. Algal Toxin Risk Assessment and Management Strategic Plan for Drinking Water.
[42] EPA. 2021. Technical Support Document for the Draft Fifth Contaminant Candidate List (CCL 5) Chemical Contaminants. EPA 815-R-21-005.
[43] 86 FR 37970