American Water Works Association

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December 30, 2021

Ms. Ashley Greene
Standards and Risk Management Division
Office of Ground Water and Drinking Water
Environmental Protection Agency
Mail Code: 4607M
1200 Pennsylvania Avenue, NW
Washington, DC 20460

SUBMITTED ELECTRONICALLY

RE: AWWA Comments on Stakeholder Meetings on Potential Revisions to Microbials and Disinfection Byproducts (M/DBPs) (Docket ID: EPA-HQ-OW-2020-0486)

Dear Ms. Greene,

The American Water Works Association (AWWA) appreciates the efforts by the U.S. Environmental Protection Agency (EPA) to engage stakeholders to inform the potential revision of drinking water standards regulating microbials and disinfectant byproducts (M/DBPs). AWWA has a continuing interest in EPA's drinking water program and remains an active participant in technical dialogues and stakeholder engagement, with more than 28 years of engagement on M/DBP regulatory requirements.

As EPA observed in its comments to the stakeholder webinar in October 2020, stakeholder dialogue played a critical role in the development of the current M/DBP drinking water regulations. These rules involve complex and interconnected risk-balancing considerations where many of the potential risks are not fully characterized, and the benefits of different risk management options do not accrue consistently to the same beneficiaries.

A number of stakeholders, including AWWA, called on EPA to organize a negotiated rulemaking process rather than the anticipated NDWAC working group. Key aspects of a dedicated process are (1) a shared understanding of what risk mitigation measures are defensible based on the available science and (2) a commitment from EPA to a specific regulatory framework. Many commenters have noted that development of EPA regulations requires seven years to craft, finalize and complete initial implementation. Without a clear and consistent commitment from EPA to a particular policy solution, drinking water systems and state regulators are stymied from taking decisive actions in advance of the final rule. In effect, lack of Agency transparency and lack of policy continuity create reluctance to make significant investments targeted toward rule requirements.

To develop an effective and durable risk management framework, EPA must (1) effectively engage in focused discussions with stakeholders on the knowns and unknowns surrounding this rulemaking, (2) describe a cohesive strategy for enhancing public health protection under the Safe Drinking Water Act, (3) identify non-regulatory mechanisms EPA and the water profession can use to advance risk reduction beyond the bounds of SDWA, and (4) establish a path toward developing a research plan to identify and inform additional risk management where warranted. To meet EPA's consent agreement obligations, the Agency must begin immediately to facilitate a robust, transparent, and science-driven stakeholder process.

EPA has requested stakeholder input on a broad array of topics. The attached comments reflect an initial review of the materials provided and the questions posed. If you have any questions regarding this correspondence or if we can be of assistance in some other way, please contact Chris Moody (386.628.6892, cmoody@awwa.org).

Best regards,

FOR THE AMERICAN WATER WORKS ASSOCIATION

G. Tracy Mehan, III
Executive Director – Government Affairs
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cc: Jennifer McLain, EPA/OW/OGWDW
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Attachment (1)

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.

COMMENTS ON
STAKEHOLDER MEETINGS ON POTENTIAL REVISIONS TO MICROBIALS AND DISINFECTION BYPRODUCTS

(Docket ID: EPA-HQ-OW-2020-0486)

Prepared by:
American Water Works Association
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December 30, 2021

CONTENTS

AWWA COMMENTS ON
STAKEHOLDER MEETINGS ON POTENTIAL REVISIONS TO MICROBIALS AND DISINFECTION BYPRODUCTS (Docket ID: EPA-HQ-OW-2020-0486)

The microbial and disinfection byproduct (MDBP) rules set regulatory requirements on treatment and operation of water systems that are central to how water systems manage drinking water and the water quality provided to consumers. These rules involve complex and interconnected risk balancing considerations where many of the potential risks are not fully characterized, and the benefits of different risk management options do not accrue consistently to the same beneficiaries.

Many commenters have noted that development of EPA regulations require seven years to craft, finalize and complete initial implementation. Without a clear and consistent commitment from EPA to a particular policy solution, drinking water systems and state regulators are stymied from taking decisive actions in advance of the final rule. In effect, lack of Agency transparency and lack of policy continuity creates reluctance to make significant investments targeted toward rule requirements.

To develop an effective and durable risk management framework EPA must (1) effectively engage in focused discussions with stakeholders on the knowns and unknowns surrounding this rulemaking, (2) describe a cohesive strategy for enhancing public health protection under the Safe Drinking Water Act, (3) identify non-regulatory mechanisms EPA and the water profession can use to advance risk reduction beyond the bounds of SDWA, and (4) establish a path toward developing a research plan to identify and inform additional risk management where warranted. To meet EPA's consent agreement obligations, the Agency must begin immediately to facilitate a robust, transparent, and science-driven stakeholder process.

OPPORTUNISTIC PATHOGENS

EPA's webinar series introduced a number of M/DBP topics in the context of managing opportunistic pathogens. In particular, EPA drew attention to the management of opportunistic pathogens that survive primary treatment at very low levels, but then subsequently proliferate when conditions allow.

Potential revisions for opportunistic pathogens should be limited to *Legionella pneumophila*

EPA has requested stakeholder input on "*what actions or tools should be considered as part of a comprehensive risk management framework for Legionella and other biofilm pathogens*". In this round of potential revisions, EPA should focus on *Legionella pneumophila* as opposed to a broader group of pathogens. The data available to incorporate risk management for other *Legionella* species, *Mycobacteria avium*, and *Naegleria fowleri* is much less robust.

EPA should prioritize risk management opportunities based on several factors including available data, actionable opportunities for public health protection, and managing unintended consequences. Of the 61 known species of *Legionella,* the majority have not been associated with disease and *L. pneumophila* accounts for more than 80 to 90% of Legionnaires' Disease cases and most drinking water outbreaks.[1, 2] Legionnaires' Disease is estimated to cause the death of 995 people in the U.S. annually as a result of exposure to *Legionella pneumophila* in drinking water sources.[3 4] In addition, the control of *L. pneumophila* (*Legionella* is already a listed pathogen under the Surface Water Treatment Rule) will likely result in the control of other *Legionella* spp. that would be of concern. Since *L. pneumophila* can be readily monitored with technology that is available today, it is only reasonable to focus risk management actions on *L. pneumophila*.

At present, the Centers for Disease Control and Prevention (CDC) reports that *N. fowleri* has very rarely caused deaths associated with drinking water sources.[5] While data on *Legionella* in distribution systems and drinking water is limited (e.g., occurrence levels, factors contributing to biofilm growth and detachment, factors affecting viability, and the relationship between occurrence and disinfectant residual levels), there is considerably less data to characterize *M. avium* and *N. fowleri* in drinking water distribution systems. Managing and controlling *L. pneumophila* is expected to require a significant level of effort and coordination by public water systems, states, and building water managers. Consequently, it deserves a timely focused effort. *L. pneumophila* presents an actionable opportunity to protect public health based on data that are either currently available or may be reasonably collected within the timeline of these revisions.

EPA should pursue an Information Collection Request in coordination with a targeted research program

EPA, AWWA, and other stakeholders have, on several occasions, discussed the need for more data to support certain opportunities for public health protection under these revisions. The collection of additional data, through a rulemaking process, will also extend EPA's legal deadline to propose potential revisions. AWWA recommends that EPA pursue a process for additional data collection and perform such a request in coordination with a targeted research program to support the current round of revisions and to address research gaps. Data collection and research is particularly critical for addressing opportunistic pathogens, including *Legionella pneumophila*, but is relevant to DBP formation and health risk as well.

EPA should coordinate with AWWA and other stakeholders to identify critical areas of research and data gaps for both short-term and long-term management of opportunistic pathogens. The drinking water

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[1] National Academies of Sciences, Engineering, and Medicine, 2020. Management of Legionella in Water Systems. https://www.nationalacademies.org/our-work/management-of-legionella-in-water-systems

[2] Benedict, K. M.; Reses, H.; Vigar, M.; Roth, D. M.; Roberts, V. A.; Mattioli, M.; Colley, L.A. et al. 2017. Surveillance for waterborne disease outbreaks associated with drinking water—United States, 2013–2014. Morbidity and Mortality Weekly Report, 66:44:1216. https://doi.org/10.15585/mmwr.mm6644a3

[3] Centers for Disease Control and Prevention, 2021. Waterborne Disease in the United States – Findings. https://www.cdc.gov/healthywater/surveillance/burden/findings.html.

[4] According to EPA, 90% of people exposed to *Legionella* get Pontiac Fever and only 5% get Legionnaires' Disease. This characterization is based on a case study of a *Legionella* outbreak from 1978. The EPA's consideration of such a limited data set, dating back 43 years, is inappropriate. A much broader history of documented *Legionella* outbreaks should be considered and evaluated as part of these revisions. This is critical given that outbreaks of Legionnaires' Disease have increased about 10-fold since 2000 while Pontiac Fever is still rare and sporadic. While Pontiac Fever may be under-diagnosed, the same is true for Legionnaires' Disease and the increase should be commensurate.

[5] Centers for Disease Control and Prevention, 2017. Parasites — Naegleria fowleri — Primary Amebic Meningoencephalitis (PAM) — Amebic Encephalitis. https://www.cdc.gov/parasites/naegleria/index.html.

community has been supporting research efforts through The Water Research Foundation which has ongoing research projects relevant to management of risks posed by *Legionella*. As a starting point:

- Research and information collection should reflect the shared responsibility of managing opportunistic pathogens, involving public water systems collecting data on distribution systems and building managers collecting data on premise plumbing. EPA's engagement in the development of research and data collection efforts along with building management groups and regulatory agencies, such as the Department of Labor, is critical to fostering a shared-responsibility approach to reduce the risks associated with opportunistic pathogens.

- Short-term research should be focused on supporting potential regulatory revisions to address *L. pneumophila.* Long-term research efforts should focus on developing tools, such as analytical methods, and data to support improving risk management strategies for *M. avium* and *N. fowleri* as part of future efforts.

- Specific research objectives should include, but not be limited to:

    - <u>Developing a clear understanding of how varying levels of *L. pneumophila* may impact human health</u>– As recognized by the National Academy of Sciences, Engineering, and Medicine (NASEM), some level of *Legionella* is common in drinking water without causing an outbreak, but high levels are associated with transmission into the lungs.[6] Levels of *L. pneumophila* are expected to vary significantly based on the type of system and sampling location (public water system, premise plumbing, cooling tower, etc). Developing a more thorough understanding of how the varying levels of *L. pneumophila* may result in human health effects will guide both building managers and public water systems. The CDC has released guidance regarding *Legionella* occurrence in buildings that should trigger action within building water safety plans.[7]

    - <u>Characterizing the relationship between key water quality parameters and the levels of opportunistic pathogens</u>– EPA has a stated interest in revising the disinfectant residual level requirement to manage opportunistic pathogens like *L. pneumophila.* To do this, EPA must be able to demonstrate that potential disinfectant residual levels can effectively contribute to the control of *Legionella* proliferation. While disinfectant residuals play a role in controlling *L. pneumophila* proliferation in buildings, other premise plumbing water quality factors play a critical role, as well.[6] EPA should also characterize how other water supply quality conditions (e.g., pH, temperature, and nutrient levels) influence the proliferation of plumbing-associated pathogens. Researchers have documented *Legionellae* being shielded inside

[6] National Academy of Sciences, Engineering and Medicine. 2019. Management of *Legionella* in Water Systems. https://www.nationalacademies.org/our-work/management-of-legionella-in-water-systems.
[7] CDC. 2021. Toolkit for Controlling *Legionella* in Common Sources of Exposure (*Legionella* Control Toolkit) Version 1.1. https://www.cdc.gov/legionella/wmp/control-toolkit/index.html.

of amoeba. *Legionella*'s occurrence as an intracellular pathogen may result in unexpected relationships between residuals and concentrations of *Legionellae* in water[8]. The implications of intracellular *Legionella* in biofilms in water systems is not well understood and requires further investigation.

- Identifying key building management and premise-plumbing practices that may mitigate pathogen proliferation– It is impractical to expect public drinking water supplies to be sterile. Water quality within a building requires management from the point of entry to the point of use by the building manager, using a multiple barrier concept (premise plumbing design, water quality management practices, and remediation strategies). It is likely that actions from both the public water system and building manager will facilitate optimum control of pathogen proliferation, but we do not know what these factors are and how they interact. Research is needed to understand how building management practices can control the proliferation in comparison to water system actions and to develop an adequate toolkit for building managers. This research will also assist water suppliers and building plumbing system engineers to look at the issue together. Recent CDC guidance on building water management plans suggests that 10 to 100 –fold increases in *Legionella* colony counts indicate a need for additional control measures within a building.[9] CDC also notes that the lack of a building water management plan and a failure to adequately follow plans that are in place are likely causal factors in outbreaks.[10]

- Evaluating occurrence and driving factors of sporadic cases of Legionellosis– Outbreaks of *L. pneumophila* have been a central focus of research historically. However, this only captures a portion of cases, and deaths, associated with legionellosis. According to NASEM, for every case of Legionnaire's Disease associated with an outbreak, there are nine sporadic cases.[6] EPA should advance research efforts understanding the occurrence and underlying factors contributing to sporadic cases of legionellosis throughout the water distribution system. For example, research is needed to determine if cases are due to public water supply quality or property-specific factors.

- Addressing Legionella Monitoring Challenges – There are challenges associated with monitoring *Legionella* in drinking water systems (distribution systems and premise plumbing). For example, polymerase chain reaction (qPCR) data detects nucleic acids, but a positive PCR signal does not mean that infective *L. pneumophila* are present in the sample. A positive signal may

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[8] Kilvington, S., & Price, J. 1990. Survival of *Legionella pneumophila* within cysts of *Acanthamoeba polyphaga* following chlorine exposure. The Journal of Applied Bacteriology, 68, 519–525.
[9] CDC. 2021. Toolkit for Controlling *Legionella* in Common Sources of Exposure (*Legionella* Control Toolkit). https://www.cdc.gov/legionella/downloads/Control-Toolkit-All-Modules.pdf
[10] CDC. 2021. Water Management Gaps and Legionnaires' Disease Outbreaks. https://www.cdc.gov/nceh/ehs/activities/water-mgt-gaps-ld-outbreaks.html.

reflect the presence of viable or non-viable bacteria. This is a particular concern in distribution systems where organisms' genetic material may be present but may represent dead, or non-viable, organisms. Culture methods that recover and enumerate *L. pneumophila* as colony-forming units (CFU) or most probable number (MPN) are still needed for regulatory or risk assessment purposes. The application of available analytical tools requires identifying monitoring locations and monitoring frequencies appropriate to the purpose of the sampling. The time required for sampling and sample analysis bears on monitoring plan elements and subsequent risk communication associated with observations.

MANAGING WATER QUALITY IN DISTRIBUTION SYSTEM

EPA began discussion regarding a number of topics that will require deeper technical discussion in order to craft sound risk management recommendations. Some topics that will need additional analysis include:

- *Disinfectant Residual Monitoring Issues* – The analysis and monitoring of disinfectant residuals will play a critical role in the potential revisions for disinfectant residual levels. For example, quality assurance and quality control requirements have increased over the past two decades along with the frequency and extent of monitoring for distribution systems. Potential revisions for disinfectant residual requirements will need to consider (1) improvements in data quality over time, (2) what the available disinfectant residual data represents, (3) the representativeness of the available data, (4) the bearing of disinfectant residual conditions on distribution system water quality management success, and (5) implications of changing monitoring station selection criteria. Available data will need to be evaluated and new regulatory requirements must be considered with the following in mind:
    - Data quality objectives, the purpose(s) for monitoring disinfectant residual, the level of quality assurance and control appropriate for the objectives, and a review of the data reliability generated by the available measurement technology. All total, there are more than 100 SDWA approved analytical methods for free chlorine, total chlorine, combined chlorine, and chlorine dioxide, and many have specific performance characteristics that must be taken into account when (1) interpreting available data and (2) when developing recommendations for primary and secondary disinfectant practice.[11, 12]

[11] EPA. 2019. Analytical Methods Approved for Drinking Water Compliance Monitoring under the Disinfection Byproduct Rules. EPA 815-B-19-001.
[12] Engelhardt, Terry and V. Malkov. 2013. Chlorination, Chloramination and Chlorine Measurement. HACH. (Updated in 2015).

- Adequacy of available secondary disinfectant residual data to inform analyses required under SDWA for developing primary standards. [13]

- Considering practicality of implementing the recently published EPA Method 127 for monochloramines under field conditions when selecting regulatory application(s) and associated data objectives.

- Considerations when integrating on-line monitoring stations for secondary disinfectant residual. Use of on-line analyzers will need to weigh logistics of maintenance, quality control, critical control point considerations, and managing multiple regulatory / water quality objectives. [14, 15, 16]

Finished Water Storage Tanks

Assuring adequate state oversight of finished water storage was an element of the Interim Enhanced Surface Water Treatment Rule (IESWTR), Ground Water Rule (GWR), and Revised Total Coliform Rule (RTCR).[17, 18, 19] Together these rules apply to all PWSs and provide for identification of problematic finished water storage tank inspection and maintenance practice through both proactive and remedial corrective action. There is authority under these regulations for states to require corrective action if warranted. Despite these existing SDWA regulatory oversight mechanisms there are instances like was discussed during EPA's webinars this summer, where individual states have found it necessary to craft state-specific regulations for (1) regular finished water storage inspection and (2) required maintenance of storage facilities. AWWA has previously commented to EPA in support of a clear federal requirement for finished water storage inspection and maintenance but completing this action will entail communicating the incremental benefit of a regulatory action with a factual basis.[20]

"Significant deficiencies" and "sanitary defects" are tracked as enforcement codes within SDWIS.[21] Will it be possible for EPA to extract a record of the frequency, nature, and resolution of significant deficiencies and sanitary defects associated with finished water storage to support analysis of additional regulatory requirements? This information would be useful and may help EPA overcome the likely data gap with respect to the frequency with which sanitary surveys currently identify and lead to correction of flaws in finished water storage.

Current state practice, including the presentations made in EPA's webinar series, refer to AWWA's finished water storage standards as the premise for (1) the substance of storage facility inspection and (2)

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[13] Seidel, Chad and C. Samson. 2021. Preliminary Analysis of Disinfectant Residual and Disinfection Byproducts Occurrence Data. Presented at Water Quality Technology Conference. AWWA. Tacoma, Washington. November 9, 2021.
[14] ANSI/AWWA. 2021. C670-20, Standard for Online Chlorine Analyzer Operation and Maintenance.
[15] EPA. 2009. Method 334.0: Determination of Residual Chlorine in Drinking Water Using an On-line chlorine Analyzer. EPA 815-B-09-013.
[16] EPA. 2018. Online Water Quality Monitoring Resources. https://www.epa.gov/waterqualitysurveillance.
[17] EPA. 1999. Guidance Manual, Conducting Sanitary Surveys of Public Water Systems-Surface Water and GWUDI. EPA 815=R-99-016. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=200022MT.txt.
[18] EPA. 2008. Sanitary Survey Guidance Manual for Ground Water Systems. EPA 815-R-08-015.
[19] EPA. 2020. The Revised Total Coliform Rule (RTCR) State Implementation Guidance—Final. EPA 816-R-20-003.
[20] AWWA. 2015. Correspondence to Peter Grevatt Re: Finished Water Storage Tanks Inspection Plans.
[21] EPA. Undated. SDWA Data Download Summary and Data Element Dictionary. https://echo.epa.gov/tools/data-downloads/sdwa-download-summary.

the frequency of such inspections. If it would be helpful, AWWA would be glad to provide a summary of existing finished water storage management practice standards. If AWWA were to organize such a summary presentation, it may also be helpful if AWWA brought individual member utilities and experts with relevant experience to a discussion with EPA to illustrate how the facets of current best practice are implemented.

EPA is just now completing data collection for the most recent EPA Needs Survey, but it has not completed the Community Water System Survey (CWSS) since the 2006 CWSS. The 2006 CWSS is reflective of that calendar year.[22, 23] At present, the 2006 CWSS is the only national dataset available from which to estimate the number, size, and types of finished water storage that must be accounted for in understanding the impact of a finished water storage inspection and maintenance requirement on systems and states. A discussion of how to best extrapolate from the 2006 CWSS may be warranted, as it is now fifteen years later and in the interim period water systems have been responding to a number of external and internal factors affecting finished water storage. Would states be able to query their data systems to compile a more complete estimate of the number of finished water storage facilities and their characteristics? Similarly, understanding the data collected with respect to finished water storage in the sixth and now ongoing seventh Needs Surveys may be informative. Summary statistics from the sixth Needs Survey indicate that 10.1% of the national drinking water infrastructure project costs over the next 20 years was associated with finished water storage.

Unintended Consequences

Common strategies to reduce the risk posed by pathogens can create risk trade-offs including higher disinfection byproduct (DBP) formation. In order to understand the degree to which treatment options and operational strategies are feasible, EPA and stakeholders need to be aware of and consider operational constraints. Such constraints also have a direct impact on the economic analysis EPA must prepare to support the rulemaking.

EPA is already considering the impact of DBP formation associated with elevating disinfectant residual levels. The presentation offered on Louisiana's experience illustrated roughly a 37 percent increase in TTHM violations over a 6-year period.[24] And, that presentation did not capture the efforts taken by water systems to remain in compliance. There is an existing body of research to draw upon to understand disinfectant residual increases and DBP formation. In addition to fundamental DBP formation research Roth and Cornwell looked specifically at this issue.[25] EPA has discussed updating the Water Treatment Plant Model, but the Agency did not provide any insight into the status of the WTP Model during the stakeholder process. The model was a useful tool in the earlier Stage 1 and 2 FAC processes but substantial work was needed in order for it to be a useful analytical tool in the upcoming rulemaking. Improvements include:

1. Inclusion of new DBP formation models, particularly for relevant HAAs

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[22] 85 FR 52340.

[23] EPA. 2009. 2006 Community Water System Survey. https://www.epa.gov/sdwa/community-water-system-survey.

[24] Kihlken, J. 2021. Disinfection Rule. EPA-HQ-OW-2020-0486-0029

[25] Roth, D. D. Cornwell. 2018. DBP Impacts from increasing Chlorine Residual Requirements. Journal AWWA 110:2: 13-28. https://doi.org/10.5942/jawwa.2018.110.0004.

2. Adaptation of the model to represent formation in distribution systems, ideally over extended timeframes and at relevant disinfect residual concentrations

3. Adaptation to the inclusion of newer treatment technologies

EPA will want to incorporate the lessons learned from Water Research Foundation (WaterRF) Project #5085.[26]

Corrosion Control: In 2021 EPA finalized the Lead and Copper Rule Revisions (LCRR).[27] There is a large emphasis on optimizing corrosion control and specific provisions targeting distribution system water quality control to support corrosion control efficacy.[28] Secondary disinfectant residual, pH, water age, distribution system maintenance practices will be considerations both with respect to LCR compliance and M/DBP risk management.[29,30,31] Balancing PWS responsibilities between these two rules' objectives, particularly with respect to EPA's interest in consecutive systems will require thoughtful consideration drawing on practical water system experience.

Safety Considerations: Steps to elevate and maintain disinfectant residual levels may create risks beyond microbial-DBP risk balancing. For example, disinfectant booster stations entail placing chemicals that pose an off-site hazard if accidentally released at locations distant from water system personnel. While remote operation of such facilities is a regular practice, it does introduce another operational complexity and risk. There are also strategies to address water system sustainability and other challenges that are unrelated to M/DBP risks, such as consecutive system consolidation that can in turn lead to unintended consequences, including water quality issues such as retention of an adequate disinfection residual, elevated DBP concentrations, and conditions conducive to biofilm growth (e.g., nitrification). Dialogue with water system professionals is especially important where implications for sustainable system operation require considerations beyond basic simultaneous regulatory compliance implications.

AWIA Section 2010, Additional Considerations for Compliance: America's Water Infrastructure Act (AWIA) of 2018 required EPA to promulgate a rule to facilitate consolidation.[32] EPA has not met this statutory deadline. The AWIA Section 2010 requirement, the existing Drinking Water State Revolving Loan Fund Rule, reports by EPA's Environmental Finance Advisory Board, and work of EPA's "Partnership Program" illustrate the importance of physical consolidation as a tool to assure sustainable water service.[33, 34, 35, 36]

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[26] WaterRF. 2020. Impact of a Haloacetic Acid MCL Revision on DBP Exposure and Health Risk Reduction. https://www.waterrf.org/research/projects/impact-haloacetic-acid-mcl-revision-dbp-exposure-and-health-risk-reduction.
[27] 86 FR 71574.
[28] EPA. 2021. 86 FR 4198.
[29] AWWA. 2017. M58 Internal Corrosion Control in Water Distribution Systems, Second Edition.
[30] AWWA. 2017. M68 Water Quality in Distribution Systems.
[31] Water Research Foundation. 2017. Optimization of Phosphorus-Based Corrosion Control Chemicals Using a Comprehensive Perspective of Water Quality.
[32] Public Law 115-270. https://www.congress.gov/bill/115th-congress/senate-bill/3021/text.
[33] 63 FR 59844.
[34] 65 FR 48286.
[35] EPA. 2020. Water System Partnership Handbook. https://www.epa.gov/dwcapacity/water-system-partnership-handbook.
[36] EFAB. 2019. Funding Strategies to Promote System Regionalization. https://www.epa.gov/sites/default/files/2019-12/documents/funding_strategies_to_promote_system_regionalization_april_25_2019.pdf.

EPA would be ill-advised to take steps in the current M/DBP process that discourage the wholesale delivery of water to consecutive systems or outright consolidation that would afford regional coordination to deliver improved water service. As EPA is aware, water service is multi-faceted (e.g., adequate technical, managerial, and financial (TMF) capacity, dependable water supply, reliable water pressure, consistent highly water quality, etc.) rather than solely a matter of complying with a subset of regulatory parameters.

Compliance with Risk Management Requirements Under Other Statutes: Water system complying with SDWA primary standards and AWIA must also comply with pesticide label requirements set by EPA under the Federal Insecticide Fungicide and Rodenticide Act (FIFRA).[37, 38] As well as Clean Air Act regulatory requirements and Occupational Safety and Health Administration (OSHA) standards for personnel safety and off-site consequences of chemical storage (e.g., chlorine, ammonia).[39, 40] While there are currently existing requirements for Risk Management Plans and Process Safety Management EPA and OSHA are actively reviewing those requirements and a rulemaking process is anticipated concurrent with the development of EPA's M/DBP proposal.[41]

AWIA Section 2013, Risk Management Requirement Compliance: In order to comply with AWIA, all water systems serving more than 3,300 persons are required to prepare an initial risk and resiliency assessment and response plan.[42] These assessments and response plans will be reviewed and updated as necessary every five years.[43] Water system assessments and response plans must include risk and resiliency considerations associated with the entirety of the system's facilities and operations, including storage and distribution facilities. EPA guidance specifies considerations relevant to resiliency to malevolent acts and natural hazards.[44] The implications for disinfectant addition and controls on distribution system facilities (physical and electronic) are relevant within the AWIA compliance framework.[45]

CONSECUTIVE SYSTEMS

Addressing the issues EPA raised during this year's webinar series with respect to consecutive systems will require considering more than simply the M/DBP regulations.

Current Regulatory Framework

The EPA white paper on Consideration of Consecutive Systems mistakes the special primacy condition in 40 CFR 142.16 as a granting of authority to alter DBPR monitoring locations across the wholesaler – purchasing system boundary. Rather, it is a special primacy requirement that a primacy agency that anticipates allowing water systems to collaborate in monitoring, must do so in manner that EPA approves

[37] EPA. 2020. Chlorine Gas Interim Registration Review Decision Case Number 4022. EPA-HQ-OPP-2010-0242-0028.
[38] EPA. 2018. Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite Interim Registration Review Decision Case Numbers 0029 and 5076. EPA-HQ-OPP-2012-0004-0032.
[39] 40 CFR 68.
[40] 29 CFR 1910.119.
[41] EPA.2021. Accidental Release Prevention Requirements: Risk Management Program Under the Clean Air Act; Retrospection. RIN: 2050-AH22.
[42] Public Law 115-270. https://www.congress.gov/bill/115th-congress/senate-bill/3021/text.
[43] Ibid.
[44] EPA. 2020. Guidance for Small Community Water Systems on Risk and Resilience Assessments under America's Water Infrastructure Act. https://www.epa.gov/waterresilience/small-system-risk-and-resilience-assessment-checklist.
[45] ANSI/AWWA. 2021. J100-21 Standard for Risk and Resilience Management of Water and Wastewater Systems.

will safeguard the intended function of the federal rule construct with adequate coverage in all of the systems monitored. This view is confirmed by the Six-Year Review docket.[46] The recognition that monitoring might be consolidated across systems is found in 40 CFR 141.29 and was intended as a tool to allow collaboration and efficiency in monitoring. It predates the Stage 1 and 2 DBPRs. Direct incorporation in the Stage 1 DBPR reflects both the rule structure, that each water system must comply and a desire for efficient implementation.[47] There were in 1998 and continue to be today, water systems that collaborate in their monitoring on this basis. It is also worthwhile to note that 40 CFR 141.29 is not specific to DBP monitoring and the stakeholder process this year included discussion of both disinfectant byproduct and disinfectant residual concentrations.

Regulatory Framework vs Monitoring for Exposure

The white paper also notes that EPA is concerned that "Monitoring in some combined distribution systems may be insufficient to adequately characterize DBP exposure" referencing its Six-Year Review notice. That 2017 notice states that "Some large, hydraulically complex combined water distribution systems may be conducting monitoring that is not adequate to characterize exposure throughout the distribution system."[48] The Stage 1 and 2 DBPR regulatory frameworks deliberately transitioned the DBP monitoring framework toward monitoring extremes in DBP formation potential. DBPR monitoring does not represent population-level exposure. The important analysis to focus on is whether DBP monitoring site selection is an adequate check on DBP formation control measures. It may be that some sample plans do not provide a check on DBP control measures (1) in a significant portion of distribution system or (2) a consecutive system such that the adequacy of control measures is under-estimated. If this is a systemic flaw in current practice, then it warrants evaluation. EPA is currently reviewing and approving approaches that states are using when they allow combined monitoring strategies. Would the Agency be able to provide a summary of the flaws in current primacy agency practice that are recuring?

Regulatory Monitoring Construct for Consecutive Systems

The current discussion as presented by EPA and speakers in the Agency's webinar series is much different from the current regulatory framework. The policy question being posed is, "Should the rule structure include a mechanism to prompt action based on water quality at the interconnect between two systems? And perhaps allocate the burden for action between the two systems."

EPA has highlighted compliance of consecutive systems in the Agency's In-Depth Analysis. The following are some take-aways from that analysis:

1. Most systems in violation of the Stage 2 Disinfection Byproducts Rule (Stage 2 DBPR) are community water systems (CWSs)
2. The overall violation rate (for all rules) of consecutive and nonconsecutive CWSs in the analysis are similar (7.2 and 6.9%, respectively)
3. The number of consecutive and the number of non-consecutive systems experiencing health-based Stage 2 DBPR violations reported nationally were roughly equal (515

[46] EPA. 2016. Six-Year Review 3 Technical Support Document for Disinfectants/Disinfection Byproducts Rules.
[47] 63 FR 69390.
[48] 82 FR 3537

nonconsecutive systems, 659 consecutive systems, total regulated systems in analysis 50.259)

4. A few states account for much of the Stage 2 DBPR noncompliant systems in the analysis and the percent of consecutive systems that are noncompliant varies significantly by state

Ten States in EPA's In-Depth DBPR 2 Analysis with Most Health-Based Stage 2 DBPR Noncompliant CWSs

State	CWS Stage 2 DBPR Health-Based Noncompliant System Count (2017)		
	All	Consecutive	Consecutive CWS as % of All Noncompliant CWS
TX	202	120	59%
OK	188	137	73%
LA	103	42	41%
KY	67	52	78%
MO	45	35	78%
KS	43	33	77%
CA	41	14	34%
NC	38	32	84%
WV	34	21	62%
NY	32	12	38%

Source: Extracted from EPA Stage 2 DBPR and Consecutive System In-Depth Analysis

Given that we are now five years past the 2017 data window in this analysis and three years post report, it would be useful to:

1. Compile a more current summary of efforts taken and cumulative success for the states where the greatest non-compliance associated with consecutive systems exists.

2. Determine if it is possible to compile simple summary statistics by state with respect to disinfectant residual performance of consecutive systems.

3. If there are states that continue to have elevated levels of consecutive system noncompliance then characterize those states with respect to:
   a. Specific systems in noncompliance
   b. Underlying issues in the noncompliant systems
   c. Efforts taken to-date / relative success
   d. Relevant state regulations and guidance

With respect to the disinfectant residual data it may require a special effort by state staff to compile data to support consecutive system option analysis. AWWA sponsored efforts to compile useful secondary disinfectant residual data from data readily available from state data systems have run into a number of challenges.

Existing EPA Guidance to Consecutive Systems: In promulgating the Stage 2 DBPR EPA published guidance for consecutive systems to assist them to reliably comply with the more challenging Stage 2 DBPR location running annual average requirements and operational evaluations required by the rule.[49] While this guidance is referenced in EPA's recent review of Stage 2DBPR compliance, the retrospective did not revisit the guidance document recommendations directly.[50] Would EPA be able to review the case studies captured in the recent review and evaluate the recognized challenges and solutions relative to the 2010 guidance?

Consecutive System Models

In order to have a policy conversation around consecutive systems the Agency will want to consider more than the simple, single wholesaler – single small customer system model. Not having given more consideration to the variety of water system supply models is currently impacting oversight of the LCR.

Model wholesale-consecutive systems include:

1. Single wholesaler – to one or many customer water systems through one or many direct interconnects between the respective systems
2. Single wholesaler – to one or many customer water systems through one or many direct interconnects between systems in series (e.g., one or several daisy-chained systems)
3. Multiple wholesalers servicing one or more of the same customer systems through one or many interconnects or indirectly through interconnections
4. There are also combinations like the above, where the customer system also has wells or water treatment plants under their control
5. Some systems have interconnects with other systems as a temporary back-up supply and are only "consecutive" systems when an emergency or planned construction activity requires reliance on the alternative supply

Would state be able to query their data systems to compile a more complete characterization of consecutive system connections details (location, buyer-seller, flow rate, utilization, etc.) to inform this discussion? While the plumbing of interconnects and the passage of water through a series of entities (PWSIDs) can be complicated, management of water quality is not simple either.[51] Where there are multiple supplies in use, any one wholesale connection may account for a small or a large part of the consecutive systems water supply over time and space. It is also possible that where there are multiple supplies, or that portions of the purchasing water system(s) is (are) physically or hydraulically isolated service areas or pressure districts. The influence any one source of supply has on compliance is a function of:

1. The characteristics of the supplied water

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[49] EPA. 2010. Stage 2 Disinfectants and Disinfection Byproducts Rule Consecutive Systems Guidance Manual. EPA 815-R-09-017. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1006MAZ.txt.

[50] EPA. 2019. Stage 2 Disinfectants and Disinfection Byproducts Rule (DBPR) and Consecutive System In-Depth Analysis. EPA 815-R-19-001. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P100X0T6.txt.

[51] Note that some community water systems operate under multiple PWSIDs due to system consolidation over time.

2. Timing of when a particular transfer occurs
3. The degree to which that transferred volume is blended with another supply
4. The time that the transferred water is in transit and the conditions under which it resides over that hydraulic residence time.

Importantly, the above factors must be taken into account in response to (1) seasonal and diurnal changes in demand, (2) opportunities to access particular supplies due to source specific factors, (3) relative cost of available water supplies, and (4) long-term sustainability objectives. Developing a regulatory mechanism that fits within this complex network of considerations must (1) provide a clear benefit, (2) be simple to implement, (3) trigger specific actions, and (4) not create perverse incentives. While the current dialogue is focused on assisting a small number of small systems, the regulatory structure, if proposed and finalized, would have implications for virtually all CWSs of all sizes.

Learning from Stage 2 DBPR Implementation

One of the critical elements of the Stage 2 DBPR was the Initial Distribution System Evaluation. That required exercise was intended not only to fill the nominal need of selecting Stage 2 DBPR sample sites, it was also intended to foster investment in data collection, hydraulic modelling, and water quality modelling.[52] During Stage 2 DBPR implementation, for the sake of simplicity, cost savings, and ease of compliance many smaller systems were advised to use the monitoring-driven IDSE options. This often occurred at the direction of states in order to simplify the regulatory process for the very numerous small systems that were being managed. As with the IDSE monitoring options used for Stage 2 DBPR compliance, it may be worthwhile to make sure that the regulatory incentives included in federal rule will indeed be implementable.

DISINFECTION BYPRODUCTS

EPA has raised a number of issues with respect to DBP control that will require a robust analysis (see comments regarding available data sets and related questions). A topic that received limited attention in the webinars held this year is nitrosamines.

Nitrosamines

In its white paper EPA requested information on nitrosamine occurrence and health effects. While not reflected in the white paper, EPA has participated in research planning and project oversight of research efforts at the Water Research Foundation with respect to disinfection and byproducts, including nitrosamines. WaterRF has a substantial body of research relevant to the precursors for, occurrence of, control options for, unintended consequences of managing, and analytical tools associated with nitrosamines control. The body of work is substantial and informative to the questions posed by EPA. If the Agency is not familiar with work funded through WaterRF AWWA would be glad to connect you to the relevant researchers or current staff at WaterRF most familiar with the research that was conducted.

[52] EPA. 2006. Initial Distribution System Evaluation Guidance Manual for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule. EPA-815-B-06-002. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=2000UD31.txt.

Similarly, EPA is aware of work that AWWA sponsored with respect to nitrosamine-related health effects. While the white paper notes that there are a number of exposures to nitrosamines, the relevance of endogenous formation is particularly important to health risk assessment.[53]

PRECURSOR REMOVAL

In organizing the August webinar EPA distributed a paper on "Potential Improvements to Organic Precursor Removal and Biological Stability." As reflected in the title, the paper's premise is that TOC removal provides additional risk reduction by making conditions less favorable for both DBP formation and proliferation of opportunistic pathogens like *L. pneumophila*.

EPA Six-Year Review TOC Removal Analysis

AWWA previously commented on EPA's 2017 Six-Year Review notice and the analysis of the TOC removal data in that docket.[54] The following is a brief, pertinent excerpt from those comments:

> "The M/DBP rules are an interconnected series of requirements that balance competing objectives. They also reflect the need for operational flexibility. Making changes to one element of the rules is very difficult to do without accounting for that change in other ways. The TOC-Alkalinity removal matrix is one such example. The Stage 1 DBPR rulemaking was based on analysis conducted by a stakeholder-EPA staff technical workgroup. In crafting the matrix, the technical workgroup incorporated a safety margin to assure reliable compliance with the matrix and MCLs, while allowing for operational flexibility.[55]
>
> **It is not surprising to find retrospectively that performance is on average better than must be achieved by the rule – this was planned into the rule's structure.** Modifying the matrix or eliminating alternative compliance criteria would significantly alter the compliance challenge and have impacts beyond those visible through a retrospective analysis of the Six-Year Review data call in. When the TOC removal requirements were developed for the 3x3 matrix, the intent was for 90 percent of systems to be able to comply with the requirements with a 15-percent safety margin. For example, the requirement in the box in the matrix for TOC >4.0-8.0 mg/L and alkalinity >60-120 mg/L is 35.0 percent. The thought was that PWSs would design the coagulation process to achieve a 40 percent removal (the requirement with a 15-percent safety margin). If some of the PWSs in this box were achieving 6-19 percent greater TOC removal than the requirement (i.e., 37.1-41.6 percent), they are removing not more, but exactly what was predicted, when taking into account use of a safety margin. **If the requirement in this box was to be increased to that currently being achieved by some (e.g., ~40 percent), then PWSs would need to design for 46 percent TOC removal (which includes a safety margin), which is beyond what was believed reasonably achievable for most systems in this box." [emphasis added]**

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[53] Hrudey, Steve E. et al. 2013. Drinking Water as a Proportion of Total Human Exposure to Volatile N-Nitrosamines. Risk Analysis, Vol. 33, No. 12. DOI: 10.1111/risa.12070.

[54] AWWA. 2017. Comments on National Primary Drinking Water Regulations; Announcement of the Results of EPA's Review of Existing Drinking Water Standards and Request for Public Comment and/or Information on Related Issues. EPA-HQ-OW-2016-0627-0265.

[55] EPA (2005) Economic Analysis for the Final Stage 2 Disinfectants and Disinfection Byproducts Rule. EPA 815-R-05-010. Page ES-16.

Previously Unconsidered Complication – Corrosion Control

Changing TOC levels also has impacts on the protective scales formed inside water pipes that are important to managing lead and copper release. Changing TOC removal requirements has implications for existing scales as well as the formation of new scales. In finalizing the LCR Revisions, EPA has created a challenging performance environment for water systems, consequently the implications of TOC control on corrosion control treatment strategies warrants consideration. This is not a consideration that was contemplated in EPA's LCR docket. In addition, enhanced coagulation is optimal at acidic (e.g., pH 6) levels. If the pH is not adequately readjusted, there can be corrosion issues. 40 CFR 141.82 and associated monitoring and reporting requirements as revised by the January 15, 2021, LCR Revisions would be triggered.

TOC as Technique to Reduce Pathogens of Concern

Managing TOC has multiple effects on the remaining microbial community that exists in drinking water system biofilters and distribution systems. Treated drinking water is already a nutrient limited environment. TOC removal will not significantly do too much to limit the trace levels of assimilable organic carbon (AOC) or biodegradable dissolved organic carbon (BDOC) that heterotrophic microbes use for growth. Enhanced coagulation removes high molecular weight humic substances, whereas biodegradable organic matter is low molecular weight and non-humic.[56, 57] Moreover, *Legionella* remains an issue in the Netherlands which already operates at AOC levels much lower than in the U.S. Removal of TOC will reduce disinfectant demand (and minimize DBP formation}, and the persistence of a residual will be impactful on the microbiology of drinking water. But TOC removal alone without accompanying biological treatment will not have a substantive impact on specific pathogens in distribution or building plumbing systems. A discussion of the equivocal role of organic carbon removal on the control of *Legionella* is in the NASEM report referenced by EPA in this current stakeholder process.[58] Optimizing conditions that are inhospitable to problematic species, is substantially more complicated than reducing TOC or elevating disinfectant residual. In reality, removal of TOC (and/or use of alternative disinfectants) needs to be optimized to control DBP formation, whereas other processes (e.g., biological filtration, increased residual) may need to be optimized to reduce pathogens of concern. Risk management actions initiated as a result of regulatory compliance should be well understood, based on science, and reliable.

Expanding Applicability of TOC Removal Requirement

EPA's white paper posits that TOC removal requirements applied to Subpart H water systems could be applied to direct filtration and groundwater systems. It is not clear what premise the Agency was working from in suggesting this option. At present when TTHM or HAA5 levels of any water system exceed the MCLs those systems are required to take steps to control DBP formation. Addition of TOC removal is the second option in the treatment option analysis underpinning the Stage 1 and 2 DBPRs (the first being moving earlier points of chlorination to later in the water treatment process).[59] To-date, EPA has been

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[56] Krasner, S.W. et al. 1994. Use of Some Simple NOM Characterization Techniques to Evaluate Enhanced Coagulation Treatability. AWWA Enhanced Coagulation Research Workshop, Charleston, S.C.

[57] Volk, C. et al. 2000. Impact of enhanced and optimized coagulation on removal of organic matter and its biodegradable fraction in drinking water. Water Research Volume 34, Issue 12. https://doi.org/10.1016/S0043-1354(00)00033-6.

[58] NASEM. 2019. Management of Legionella in Water Systems. https://www.nap.edu/read/25474/chapter/1.

[59] Malcolm Pirnie. 2000. Surface Water Analytical Tool (SWAT) Version 1.1 Program Description and Assumptions. https://www.epa.gov/sites/default/files/2017-03/documents/swat_manual_508.pdf.

reluctant to require small ground water CWSs and non-community water systems (NCWSs), which are very numerous in the United States, to install treatment that would require a level of sophistication beyond (1) reasonably anticipated technical, managerial, and financial capacity of those systems and (2) state primacy agency's capacity to oversee treatment practice and compliance. See the following table to illustrate the number additional systems that would be subject to this requirement if implemented. In comparison there are only 14,622 surface water systems. Given the substantial implementation burden for states a robust discussion of the likely benefit of such a provision will be necessary.

Summary of the Number of Groundwater Systems by System Size and PWS Type

Type of PWS	Population Served (number of persons)					
	≤500	501 – 3,300	3,301 – 10,000	10,001 – 100,000	>100,000	Total
CWS	26,949	13,337	5,016	3,988	448	**49,738**
NTNCWS	14,990	2,463	167	42	1	**17,663**
TNCWS	76,104	2,995	73	12		**79,184**
Grand Total	**118,043**	**18,795**	**5,256**	**4,042**	**449**	**146,585**

Source: EPA SDWIS, GPRA Inventory, 2021Q3, Active Only.
Abbreviations: CWS – community water system, NTNCWS – non-transient, non-community water system, and TNCWS – transient non-community water system
Note: All CWSs and NTNCWSs that add disinfectant other than UV light and TNCWSs that treat with chlorine dioxide are subject to DBP rules at present.[60]

Direct filtration plants cannot handle enhanced coagulation doses. During the Stage 1 Reg Neg federal advisory committee (FAC) process, it was noted that direct filtration plants tend to treat water of better quality than conventional plants. Nonetheless, an option that was not considered at the time is to add acid to the water. Operation at a lower pH level, while still using a low coagulation dose, may result in more TOC removal. If enhanced coagulation is extended to direct filtration plants, there need to be alternative performance criteria, as well as feasibility considerations (e.g., limits on acid feed). Groundwater typically is low in TOC (e.g., <2.0 mg/L) and is not treated with conventional coagulation (unless as a secondary source water at a surface water plant). The Stage 1 DBPR already requires groundwater under the influence of surface water (GWUDI) systems that comply with subpart H to do enhanced coagulation. The other groundwater type that may need some TOC removal is found at systems that treat colored groundwater. Some water treatment plants currently treating colored water use ozone, which transforms the TOC but does not remove it. Use of alternative disinfectants is another recognized treatment strategy for DBP control.

Organizing Data to Support Sound Policy Decisions

As a part of this stakeholder process, EPA posed the following question, "What relevant data or information, other than from the Six-Year Review information collection request (Six-Year ICR) and UCMR4 datasets, are available to inform and support changes to the existing TOC removal requirements?" The unfortunate answer to this question is that an uninformed analysis of the Six-Year

[60] EPA. 2010. Stage 1 Disinfectants and Disinfection Byproducts Rule: A Quick Reference Guide. EPA 816-F-10-080. https://www.epa.gov/dwreginfo/drinking-water-rule-quick-reference-guides#stage2qrg.

ICR and Fourth Unregulated Contaminant Monitoring Rule (UCMR4) datasets is very unlikely to inform the key questions important to the Agency. Data limitations include:

1. The UCMR4 data structure does not adequately link treatment characterization (particularly disinfection practice) and TOC data to observed disinfection practice.
2. The UCMR4 data and Six-Year ICR data must be combined in order to organize a cohesive dataset for all of the regulated and unregulated THM and HAA species.
3. The Six-Year ICR dataset may, but is unlikely, to contain a robust secondary disinfectant residual dataset.
4. Developing analyses that look at TOC reduction in the context of consecutive systems is further complicated by gaps in the organization of available data.

These challenges require careful assembly of subsets of the available information and developing informative model constructs rather than assuming trends in the bulk data are informative or that “big data” analyses will provide reliable analyses important for the policy discussion.

In Stage 1 and Stage 2 the FAC made policy decisions using less than ideal datasets, and even inferred impacts on the tails of probability distributions where the dataset was only robust in creating central tendency estimates. But the stakeholders and Agency participants in the negotiation fully understood the underlying analysis, why it was informative, and took the limitations into account when interpreting the results. There was no national database on enhanced coagulation. Thus, the technology workgroup assembled a database from studies conducted by university, consulting, and utility researchers. This database resulted in a set of enhanced coagulation requirements and alternative performance criteria based on sound science. At present the UCMR4 data are generally available to EPA staff and the water research community, but the Six-Year ICR data are as yet to be fully compiled and available for analysis. An analysis like that prepared to support the Stage 1 DBPR could be done again if a similar type of technology workgroup could be assembled.

Metrics to Supplement TOC Removal Requirements

As EPA is aware there are a suite of tools that are used to characterize TOC in order to inform treatment selection and to troubleshoot treatment efficacy. EPA correctly poses questions that will have to be resolved (Are there robust, accessible, affordable, demonstrated analytical tools?). It is important to pose the question with the actual application in mind, e.g., is there such a tool that would provide a:

1. Data stream that provides equivalent data that could substitute for current regulatory requirements (presumably more economically)
2. More reliable or useful data at an equivalent or lower cost
3. More informative data, that is sufficiently improved over the current approach that revision of the rule requirements are appropriate
4. A type of data that would be used in another context within the TOC removal construct

It is perhaps easier to answer the questions posed by the Agency with a particular task in mind (e.g., more frequently monitoring TOC removal, monitoring a particular fraction of TOC, monitoring performance of a unit operation in a different way, etc.). If EPA were intending to improve guidance for TOC removal, there would be an opportunity to revisit diagnostic approaches water systems could use to evaluate the DBP formation potential of the TOC that is removed by treatment. For example, as enhanced coagulation preferentially removes high molecular weight and humic substances, researcher have measured these parameters in raw and treated waters, including at intermediate coagulant doses. This type of information showed where TOC removal was optimal. When the residual TOC is low in molecular weight and in humic substances, additional coagulation will not have the appropriate type of TOC to remove.

CHLORITE AND CHLORATE

The UCMR3 data referenced in EPA's chlorate and chlorite white paper was collected in the 2013-2015. It is a robust national survey of analyte occurrence. Given the passage of time and the weighing of the sample toward larger water systems, additional work will be needed to understand the implications of that data today. There have been developments that have happened and are continuing that will impact observed chlorate levels that are not reflected in this data. Among those issues:

1. UCMR3 collected data during the later stages of Stage 2 DBPR / Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) implementation and the initial Revised Total Coliform Rule implementation, all of which led to changes in disinfectant selection and practice.

2. The UCMR3 sample does not support a robust characterization of small system disinfectant practice. Sodium hypochlorite use is a key contributor to chlorate levels; understanding actual hypochlorite use and practice in small systems, where it is used extensively, is important to regulatory development.

3. Since UCMR3 the FIFRA program has implemented new label requirements.[61] Those label requirements draw on resources developed through the Chlorine Institute and AWWA on the management of hypochlorite to reduce chlorate occurrence. [62, 63] FIFRA label requirements are enforceable.

4. Chemical supply constraints in the chlorine and caustic sector are increasingly impacting chlorine supply and delivery schedules. As access to sodium hypochlorite becomes less reliable PWSs have less ability to be selective about the chemical they receive, potentially needing to accept and use chemical that has not been maintained under appropriate conditions for protracted periods of time.

The FIFRA program undertook a significant effort to understand practice and coordinate within the Agency. Program staff used an accelerated action mechanism, an Interim Registration Review Decision, so as to ensure timely label updates. The SDWA program effort should take those efforts into account.

EPA staff from the Water Security Division are familiar with the chemical supply constraints relevant to chlorate formation. SDWA regulatory requirements must be feasible, consequently, it is important that the M/DBP discussion work from a reliable premise. While NSF 60 provides an important benchmark for

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[61] EPA. 2018. Sodium Hypochlorite, Calcium Hypochlorite, and Potassium Hypochlorite Interim Registration Review Decision Case Numbers 0029 and 5076. EPA-HQ-OPP-2012-0004-0032.

[62] Chlorine Institute. Undated. Sodium Hypochlorite. https://www.chlorineinstitute.org/stewardship/sodium-hypochlorite/.

[63] AWWA. 2011. Hypochlorite Assessment Model. Available at https://www.awwa.org/Resources-Tools/Toolbox.

the production of chemicals used in water treatment, expectations for the quality of hypochlorite that water systems can reasonably assume to be available to them after transportation is an important underlying consideration.[64]

AWWA would be glad work with EPA to provide practical insight into the constraints on hypochlorite management that are relevant to an SDWA policy discussion. For example, if the Agency contemplates elevating residual disinfectant levels and distributed booster disinfection becomes more extensive in response, there will be a growing reliance on hypochlorite addition at those locations. Which in turn will entail the construction and operation of facilities consistent with CI and AWWA good practice recommendations and the FIFRA label requirements. The effort required to accomplish those requirements varies across the nation due to temperature regimes, system areal extent, chemical distribution network, and other factors.

SANITARY SURVEY

Sanitary surveys were a sufficiently successful element of state programs prior to the IESWTR that the incorporation of surveys into the rule construct became a significant element of the rule. A decision that was then re-enforced through the GWR. The current stakeholder process does not explicitly include consideration of the GWR, yet this and other provisions being discussed would likely require revision of that rule as well. Where there are policy recommendations that have implications beyond the current effort's scope, the data and analysis to support decision-making should encompass the full impact of possible actions.

EPA summarized the definition of sanitary surveys and the associated value proposition as part of the Agency's perspective presentation.[65, 66] The role of sanitary survey and their scope has changed over time, beginning with the Total Coliform Rule (TCR), then IESWTR, and subsequently, the GWR.[67] Over the course of those rulemakings, the nature of the sanitary survey has changed. Sanitary survey practice is currently also a function of state program design, funding, and operational priorities. Consequently, sanitary surveys today tend to be:

1. Often conducted by personnel with limited training
2. Based on templates with defined content that are not based on the challenges particular to individual water systems
3. No longer framed as mentorship but rather as compliance fault identification and resolution
4. Organized for efficient use of state personnel's time

At present water systems do not have a clear understanding of Agency priorities in sanitary survey execution. The relevant regulatory requirements were last updated following the Ground Water Rule in 2007. Publicly available EPA guidance on the substance of sanitary surveys date back to 1999 and

[64] NSF/ANSI/CAN 60. 2020. Drinking Water Treatment Chemicals – Health Effects.
[65] 40 CFR §142
[66] EPA. Undated. Sanitary Surveys. https://www.epa.gov/dwreginfo/sanitary-surveys
[67] 40 CFR 142.16

2008.[68,69] Since then, EPA has conducted training for states and regional staff, modified data systems, developed templates for states to use. A multi-year effort between EPA and states produced training on the basics of Sanitary Surveys.[70] It would be helpful for stakeholders to understand the substance EPA's current direction to states regarding sanitary surveys so that there is a common understanding of the setting for any new recommendations.

If the sanitary survey is going to play a larger role in the management of microbial and disinfection byproduct risk reduction, then EPA and states will need to revisit their approach to implementing sanitary surveys. In an environment where most of the state supervisory burden is focused on small simple systems, a reasonably limited pattern can be followed by state sanitary survey personnel. As the task becomes more complex {e.g., balancing corrosion control and secondary disinfectant retention, coordinating relationships between wholesale providers and customer systems, evaluating systems in the context of water safety plans, etc.) then the current implementation model warrants discussion.

The incorporation of a greater reliance on sanitary surveys and or water safety plans is one aspect of a larger discussion. While there is a robust discussion around the technical, managerial, and financial capacity of water systems, the need for adequate support to state primacy agencies to accomplish the regulatory construct being pursued seldom receives adequate attention. Often when there is engagement, as in consideration of the information collection request that supports a rulemaking, there is little consideration given beyond basic paperwork tasks – as opposed to professional dialogue and engagement with regulated entities. Given the risk-risk tradeoffs associated with modifying practice for disinfection, the stakeholder process should include a discussion of the practical constraints on rule options posed by state program TMF capacity.

Comprehensive Performance Evaluation

The IESWTR and Long-Term 1 ESWTR (LT1ESWTR) draw on a framework for water treatment plant evaluation developed through the Partnership for Safe Water, the comprehensive performance evaluation (CPE).[71] While the concept of CPEs is neither new or unique to drinking water, the concept of a focused review on "*a facility's design capabilities and associated administrative, operational, and maintenance practices as they relate to achieving optimum performance*" is a hallmark of the Partnership.[72, 73] While CPEs in the Partnership are geared toward self-improvement, CPEs are triggered requirements in the IESWTR and LT1ESWTR as a path to identify and resolve shortcomings at facilities with recurring inadequate conventional treatment plant performance.[74, 75] Inclusion in the IESWTR were

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[68] EPA. 1999. Guidance Manual for Conducting Sanitary Surveys of Public Water Systems: Surface Water and Ground Water Under the Direct Influence (GWUDI). EPA-815-R-99-016. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=20002MT.txt.

[69] EPA. 2008. Sanitary Survey Guidance Manual for Ground Water Systems. EPA 815-R-08-015. https://www.epa.gov/sites/default/files/2016-12/documents/gwr_sanitary_survey_guidance.pdf.

[70] EPA. 2019. How to Conduct a Sanitary Survey of Drinking Water Systems, A Learner's Guide. EPA 816-R-17-001.

[71] AWWA. Undated. Partnership for Safe Water. https://www.awwa.org/Resources-Tools/Programs/Partnership-for-Safe-Water.

[72] EPA. 1998. Optimizing Water Treatment Plant Performance Using the Composite Correction Program. EPA/625/6-91-027.

[73] EPA. 2020. Guidance Manual for Compliance with the Interim Enhanced Surface Water Treatment Rule: Turbidity Provisions. EPA 815-R-20-004.

[74] 40 CFR 141.174.

[75] 40 CFR 141.563.

in large part a product of the Partnership program's success at the time the IESWTR was being formulated. The AWOP program and Partnership have drawn on the CPE concept as initially framed in the 1998 Handbook for Optimizing Water Treatment Plant Performance Using the Composite Correction Program.[76]

The CPE and CCP have historically been significantly different from "sanitary surveys." The Partnership and AWOP guidance utilize a combination of tools, including (1) recognized unit operation performance objectives in combination with process control practice, (2) self-testing and assessment, (3) expert peer-review, and (4) external recognition. In contrast, sanitary surveys have been conducted by state person with oversight responsibility for a system, making specific recommendations, typical through a formal report with expected corrections. As the Agency considers revision of the sanitary survey or contemplates incorporation of water safety plans, it would be useful to better understand the experience of the Partnership and AWOP programs: (1) key aspects of recognized successes, (2) recurring challenges, and (3) resource investment necessary to effectively pursue (participating system and program operator). Currently the AWOP methodology is not clearly summarized in a document for external review; it would be helpful if EPA or one of the AWOP partners could organize the program elements for review (see Partnership website for process and supporting documents).[77]

WATER SAFETY PLANS

Water Safety Plans (WSPs) have been a facet of drinking water risk management conversation in the United States since their initial inception. For a time in the early 2000s, EPA articulated the SDWA regulatory framework, with the example of the M/DBP regulations, through the lens of the hazard analysis critical control point (HAACP) framework.

EPA and stakeholders considered HAACP and WSPs explicitly during the revision of the TCR. There was strong support for the concept, recognizing its strengths:

1. Gains improved and common understanding of risks and risk management priorities
2. Incentivizes staff training, improved standard operating procedures, targeted capital, and operational investments
3. Facilitates communication with consumers regarding source-to-tap risk management.

The white paper released by EPA in support of the RTCR decision-making process summarizes strengths, models, and barriers to WSP implementation.[78] The Total Coliform Rule / Distribution System (TCRDS) Federal Advisory Committee Agreement in Principle did not adopt HAACP or WSPs per se but did attempt to shift the regulatory framework in that direction.[79] At that time, the barriers to implementation were viewed as too substantial:

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[76] EPA. 1998. Optimizing Water Treatment Plant Performance Using the Composite Correction Program. EPA/625/6-91-027.

[77] EPA. Undated. Optimization Program for Drinking Water Systems. https://www.epa.gov/sdwa/optimization-program-drinking-water-systems.

[78] EPA. 2006. Hazard Analysis Critical Control Point (HACCP) Strategies for Distribution System Monitoring, Hazard Assessment and Control. (available through NEPIS)

[79] Total Coliform Rule / Distribution System (TCRDS) Federal Advisory Committee.2008. Agreement in Principle.

2. Difficulty transitioning from uniform "bright line" standards to a process-based, system-specific risk management paradigm (e.g., institutional structures, risk communication)

These barriers have re-appeared in subsequent conversation within the sector (e.g., with respect to WaterRF #4310).[80] Implementation of the RTCR by state primacy agencies illustrates the challenges with moving to a WSP approach. While the RTCR deliberately attempted to create the operational mindset underpinning a WSP approach, in practice, implementation of the RTCR is as encumbered by the compliance data system, bright-line regulatory criteria, and sample site selection considerations as the previous rule. For the Agency to move forward to advance a WSP construction, EPA and stakeholders will need to understand why the RTCR revisions did not achieve their intended effect in practice.

The Partnership and the AWOP have both had tremendous benefits for participants. It is important not to mistake those programs for WSPs. The 2006 RTCR White Paper is a good reference point for the underpinning concepts for WSPs without actually having presentations from international practitioners. If the latter is needed to support discussion of this topic, AWWA would be glad to work with the Agency to identify some water systems that have experience operating in other nations that have embraced the WSP concept.

SOURCE WATER PROTECTION

Most water systems have limited control with respect to their source waters. Consequently, the Agency's requirements for credit in the LT2ESWTR Microbial Toolbox stymied momentum to foster PWS source water protection rather than accelerate measures to reduce *Cryptosporidium* loadings.[81] Similarly, the Microbial Toolbox guidance for receiving credit for riverbank filtration (RBF) slowed rather than accelerated application of RBF in the United States. RBF is a technology that improves water quality prior to entry into the water treatment plant. Evaluating source water protection in the context of a primary drinking water standard would require a significant change in the Agency's regulatory approach for this to be an effective activity.

Regulations Affecting Water Resource Management

The Agency is currently engaged in rulemakings and legal actions related to multiple statutes that bear on managing source water to reduce loadings to drinking water treatment plants. Water resource management requires identifying solutions that serve multiple objectives. Will EPA utilize the Stage 3 M/DBP process to better inform other program offices about how their actions relate to proactively managing water bodies to reduce influent hazards at water treatment plants?

Strategic Source Water Protection

AWWA and numerous other interested stakeholders have engaged EPA in an effort to encourage the Agency to utilize other statutory authorities to proactively curtail contamination of drinking water supplies. At present stakeholders are seeking federal action to:

[80] WaterRF. 2014. Identifying Meaningful Opportunities for Drinking Water Health Risk Reduction in the United States. WaterRF #4310. https://www.waterrf.org/research/projects/identifying-meaningful-opportunities-drinking-water-health-risk-reduction-united.
[81] EPA. 2010. Long Term 2 Enhanced Surface Water Treatment Rule: Toolbox Guidance Manual. EPA 815-R-09-016. https://www.epa.gov/dwreginfo/long-term-2-enhanced-surface-water-treatment-rule-documents.

1. Utilize the Toxic Substances Control Act to reduce the introduction of contaminants into drinking water supplies
2. Implement Clean Water Act (CWA) National Pollutant Discharge Elimination Permit System requirements on industries that are polluting drinking water supplies
3. Manage the unnecessary use / overuse of pesticides that endanger drinking water supplies through the Federal Insecticide, Fungicide and Rodenticide Act
4. Consider secondary consequences of air pollution control mechanisms, including impacts on drinking water supply

With passage of the Food Quality Protection Act the FIFRA program made dramatic changes to its pesticide review process that led to improved protection of drinking water supplies. It is not clear what programmatic coordination could be included as part of the current M/DBP implementation effort.

Other Federal Agencies Are Responding

Stakeholders have also engaged other federal agencies in efforts to protect source water on issues ranging from reduction of road salt loadings to improved management of agricultural lands that impact water supplies. In perhaps the best example of timely and effective response, the United States Department of Agriculture's Conservation Programs has have been able to rapidly direct more than $60 billion in on-farm improvements over the last 10 years. These funds are directed toward a variety of improvements including measures that reduce both chemical and microbial agricultural pollution.

Nutrient Impairment

Nutrient levels in lakes, rivers, and streams are a source of impairment that is a long-standing CWA concern[82] Nutrients are a frequent cause of impairment in waters across the country.[83] Indeed there are activities across the U.S. focused on regulatory action to effect nutrient control.[84] The latest assessment of state activity reflects systematic regulatory programs as of 2017, but a new summary is in development and should be available in 2022.[85]

In 2019 EPA finalized Recommended Human Health Recreational Ambient Water Quality Criteria or Swimming Advisories for Microcystins and Cylindrospermopsin.[86] With the development of active monitoring programs in ambient freshwater, EPA drinking water health advisories, and recent recreational water criteria, there is an increase in the incidence of recognized harmful algae bloom (HAB) events in U.S. surface water.[87] For example, in 2021 ambient water monitoring triggered advisory levels in at least 50 reaches during 8 months of 12 months that year. In comparison, during 2018 – 2020 UCMR4 monitoring did not observe many instances of cyanotoxin occurrence in finished drinking water. Over the three-year monitoring window UCMR4 cyanotoxin sampling captured a census of all PWSs

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[82] EPA. Undated. Impaired Waters and Nutrients. https://www.epa.gov/tmdl/impaired-waters-and-nutrients.
[83] EPA. Undated. National Summary of State information reported to EPA under Section 305(b) and 303(d) of the Clean Water Act. https://ofmpub.epa.gov/waters10/attains_nation_cy.control#causes.
[84] ACWA. 2018. Nutrient Reduction Progress Tracker Version 1.0-2017. https://www.acwa-us.org/wp-content/uploads/2018/03/Nutrient-Reduction-Progress-Tracker-Version-1.0-2017-Report.pdf
[85] AWWA. 2021. Personal communication with ACWA staff, December 20, 2021.
[86] 84 FR 26413.
[87] EPA. 2021. Freshwater HABs, Advisories and Closures Reported by States and Other Public Sources Since 2015. https://storymaps.arcgis.com/stories/d4a87e6cdfd44d6ea7b97477969cb1dd.

relying on surface water serving more than 10,000 persons and a statistically derived sample for smaller surface water systems. While timing of sampling was biased toward periods of the year when occurrence was likely, of 3,472 systems that sampled finished water: 7 had positive microcystin detections, 50 positive anatoxin-a samples, and 12 positive cylindrospermopsin samples.[88] Is EPA aware of, or has it compiled, a current, publicly available, national analysis that aligns CWA nutrient controls, active HAB response strategies, and drinking water intakes at risk of HABs. Such an analysis may be possible using data underlying EPA's ARCGIS Storymap website for HABs.

[88] EPA. 2021. The Fourth Unregulated Contaminant Monitoring Rule (UCMR 4): Data Summary. https://www.epa.gov/monitoring-unregulated-drinking-water-contaminants/data-summary-fourth-unregulated-contaminant.