American Water Works Association
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May 15, 2017

Sarah Rees, Director
Office of Regulatory Policy and Management
Office of Policy
US Environmental Protection Agency
Mail Code 1803A
1200 Pennsylvania Avenue NW.
Washington, DC 20460

RE: Evaluation of Existing Regulations (Docket ID No. EPA-HQ-OA-2017-0190)

Dear Ms. Rees,

The American Water Works Association appreciates the opportunity to respond to the U.S. Environmental Protection Agency's request for comment as the Agency evaluates existing regulations. The following comments highlight opportunities for refinement, clarification, and improvement to the overall efficiencies and effectiveness of the rules and guidance described below. These comments reflect water utility implementation experiences and/or interpretations of existing guidance impacting utility operations.

AWWA is committed to protecting public health through safe and reliable drinking water and therefore advocates for cost-effective regulations based on sound science. AWWA supports the regulatory principles and processes established in the 1996 Amendments to the Safe Drinking Water Act (SDWA). The current review presents an opportunity to improve the effectiveness of our regulatory system and should not be used to eliminate important public health protections under SDWA or other statutes. AWWA's review focused on opportunities for cost-savings, streamlining and efficiencies that reduce burden without adversely impacting public health. Indeed, AWWA is hopeful that more efficient implementation of existing regulations allows for more funds to be applied locally on actions that have public health benefits and help keep the cost of water service affordable for all Americans.

The Safe Drinking Water Act provides for a regular review of individual primary standards, called the "Six-Year Review." Each review focuses on the opportunities for additional risk reduction. In the past, the Six-Year Review process has identified opportunities to improve rule implementation, e.g., the Revised Total Coliform rule. The Six-Year Review process also provides a substantial body of information and analysis for EPA to use in its current evaluation

of SDWA regulations. Unfortunately, program offices that operate under other statutes do not always have the same level of analysis readily available. With some exceptions, individual rule development seldom involves stepping back and looking at the totality of regulatory requirements with a focus on effective risk reduction.

For purposes of this review, AWWA identified the following regulations and major guidances for the Agency's consideration:

1. Risk Management Program Rule, 82 FR 4594, 40 CFR Part 68, January 13, 2017
2. State Revolving Loan Fund Rule, 65 FR 48286, 40 CFR Subpart L, Aug. 7, 2000
3. Integrated Municipal Stormwater and Wastewater Planning Approach Framework, Office of Water Memo, June 5, 2012
4. Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR), 71 FR 654, 40 CFR Parts 9, 141, and 142, January 5, 2006
5. Drinking Water Health Advisories for Cyanobacterial Toxins, 80 FR 34637, June 17, 2015 and perfluorinated compounds (Perfluorooctanoic Acid and Perfluorooctane Sulfonate), 81 FR 33250, May 25, 2016
6. Phase I, II, IIB, and V Chemical Contaminant Rules, 52 FR 25690, January, 1987; 56 FR 3526, January 1991; 56 FR 30266, July 1, 1991; and 57 FR 31776, July, 1992.
7. Unregulated Contaminant Monitoring Rule, 81 FR 92666, 40 CFR 141.40

It is important to bear in mind that water utilities and their customers will face a significant financial challenge in the years ahead as utilities address the nation's aging water infrastructure. Water and wastewater system repairs and replacements are critical for public health protection, fire protection and our quality of life, and in many places, they will usher in substantial increase in household water bills. Keeping water service affordable for low-income households is an issue of growing concern.

In selecting these rules, AWWA focused on rulemakings and guidance documents where opportunities exist for cost savings. Attached are detailed comments that explore the opportunities for improvements to these regulations.

Please feel free to contact AWWA if you have any questions regarding the attached. If you have any questions regarding this correspondence, please contact me or Kevin Morley at 202.326.6124 or kmorley@awwa.org.

Best regards,

G. Tracy Mehan, III
Executive Director of Government Affairs

cc: Samantha K. Dravis, Regulatory Reform Officer and Associate Administrator, OP
Mike Shapiro, Acting Assistant Administrator, OW
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Peter Grevatt, Director, OW/OGWDW
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Attachment: (1)

What is the American Water Works Association?

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

Comments of the American Water Works Association

on

Evaluation of Existing Regulations

82 FR 17793, DOCKET ID No. EPA-HQ-OA-2017-0190

American Water Works Association
1300 Eye Street, NW
Suite 701W
Washington, DC 20005

May 15, 2017

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Executive Summary

AWWA is committed to protecting public health through safe and reliable drinking water and therefore advocates for cost-effective regulations based on sound science. The current review is an opportunity to improve the effectiveness of our regulatory system and should not be used to eliminate important public health protections.

AWWA's review focused on opportunities for cost-savings, streamlining and efficiencies that reduce burden without adversely impacting public health, indeed AWWA is hopeful that improved efficiency in the implementation of existing regulations allows for more funds to be spent locally on actions that have positive public health benefits and help ensure that the cost of water service remains affordable for Americans of all incomes.

AWWA identified the following opportunities to revise or modify existing regulations and major guidance's for the Agency's evaluation:

Risk Management Program Rule

The 2017 RMP Rule acknowledges the limited opportunity for protecting the public through making the water sector respond to the rule requirements, but does so anyway. AWWA recommends that EPA revise the RMP Rule to reduce the impacts of the rule on water utilities and the communities they serve.

Based on the unique characteristics of the water sector, the disproportionate economic impacts and low risk profile of its regulated processes, AWWA recommends that EPA consider developing a tailored approach for the RMP regulatory requirements that accounts for these differentiating characteristics. This approach would classify facilities under North American Industry Classification System codes 22131 and 22132 under a "lowest risk" subset of EPA's existing "simple process" category that would further distinguish the water sector from other categories with higher risk profiles within the "simple process" category.

State Drinking Water Revolving Loan Fund Rule

In 2000 EPA promulgated a rule guiding the implementation of the Safe Drinking Water Revolving Loan funds by states. This rulemaking and associated guidance could be revisited as a mechanism to improve the efficient delivery of revolving loan funds.

There are opportunities for improved program transparency, and streamlining loan application processes, minimizing hindrances caused by federal cross-cutters. AWWA recommends that EPA review the current rule and modify the rule or associated guidance.

Integrated Municipal Stormwater and Wastewater Planning Approach Framework

EPA responded to input from stakeholders to develop its current integrated planning guidance. Now, four years later, implementation of the current policy is inconsistent and does not adequately account for the costs, capital and operational, necessary for communities to assure delivery of safe drinking water. AWWA recommends that the EPA revise the current policy to explicitly (1) prioritize projects which protect public health as the first-priority and (2) incorporate community drinking water infrastructure needs into the prioritization of projects under the integrated planning framework.

Long Term 2 Enhanced Surface Water Treatment Rule

In finalizing the LT2ESWTR, EPA decided to prohibit open finished water reservoirs. The initial proposed rule was premised on an "agreement in principle" developed by the Stage 2 Microbial-Disinfection Byproduct Federal Advisory Committee. That agreement and the proposal allowed, under state supervision and approval, open finished water reservoirs to continue to exist under well designed and implemented risk management plans. AWWA recommends that EPA revise the current rule to allow the use of open finished water storage facility risk management plans per the Stage 2 M/DBP Agreement in Principle.

Drinking Water Health Advisories for Cyanobacterial Toxins and Perfluorinated Compounds (Perfluorooctanoic Acid and Perfluorooctane Sulfonate)

EPA published health advisories for microcystins and cylindrospermopsin in 2015 and PFOA and PFOS in 2016. All of these advisory levels were set at nanogram per liter levels without public input on either the draft advisory level or accompanying guidance on what responsible states, systems, and households should do based on observed levels above advisory levels. AWWA recommends that EPA establish a process for transparent public review and quality assurance for health advisories and accompanying recommendations. While AWWA is not recommending repeal of these HAs; it would be appropriate for EPA to modify them through reclassification and review as significant guidance documents.

Phase I, II, IIB, and V Chemical Contaminant Rules

In the wake of the 1986 SDWA amendments, EPA raced to meet Congressional mandates for regulating a laundry list of contaminants. Some of those contaminants are not found in drinking water supplies and have been found only rarely if at all historically. AWWA recommends that EPA utilize the data collected through the Six-Year Review process to identify contaminants with long-term negligible occurrence, and eliminate these MCLs. Eliminating these MCLs would be consistent with EPA's SDWA anti-backsliding policy as there is no risk reduction provided by the current MCLs. If other SDWA provisions make eliminating these MCLs problematic, then EPA should work with stakeholders to revisit the current standard monitoring framework so that monitoring burdens are reduced and limited to those situations where there is a plausible basis for anticipating the presence of an otherwise infrequently measured contaminant occurring. Monitoring is not a trivial expense, particularly for small systems, and monitoring for contaminants that are not present misallocates resources that could be used to better protect public health.

Unregulated Contaminant Monitoring Rule

UCMR is an important element of SDWA, which AWWA strongly endorses. It is however a recurring cost that might be organized differently and thereby reduce implementation burden. AWWA recommends that EPA review and evaluate the current scope of monitoring in anticipation of the fifth round of UCMR monitoring. The review would consider whether a representative sampling strategy for large systems and a revised sampling strategy for small systems could successfully represent national contaminant occurrence in drinking water but doing so at a lower cost to EPA and water systems.

Comments of the American Water Works Association

on

Evaluation of Existing Regulations

82 FR 17793, DOCKET ID No. EPA-HQ-OA-2017-0190

Introduction

AWWA is committed to protecting public health through safe and reliable water services and advocates for cost-effective regulations based on sound science. The current review is an opportunity to improve the effectiveness of our regulatory system and should not be used to eliminate important public health protections. AWWA's review focused on opportunities for cost-savings, streamlining and efficiencies that reduce burden without adversely impacting public health, indeed AWWA is hopeful that improved efficiency in the implementation of existing regulations allows for more funds to be spent locally on actions that have positive public health benefits and help ensure that the cost of water service remains affordable for all Americans.

Detailed Review

The following comments are detailed summaries of the history and rationale that underlie AWWA's recommendations.

Risk Management Program Rule

82 FR 4594, 40 CFR Part 68, January 13, 2017

AWWA recognizes and supports the need to periodically review chemical safety protocols such as those in the Risk Management Program (RMP). However, AWWA has several concerns with the rule as revised, which center around the fact that drinking water and wastewater treatment facilities do not represent the same risk profile as many of the other industries regulated by the RMP program and have demonstrated a strong record of safety throughout the life of the program. AWWA is offering specific recommendations that would provide flexibility to the water sector that builds on criteria that EPA applied in the proposed and final rule.

AWWA's comments represent a concern that aspects of the RMP rule are arbitrary, unjustified and overly burdensome. These comments are organized to address five major categories of issues:

1. Safety: The drinking water and wastewater treatment sector has a demonstrated record of safety and is not representative of the chemical process safety risks that the proposed RMP regulatory revisions are intended to address.

2. Affordability: Drinking water and wastewater treatment systems are uniquely impacted by the proposed RMP regulatory revisions and warrant considerations for flexibilities afforded by EPA's discretion under CAA section 112(r), and the requirements of the Small Business Regulatory Enforcement Act (SBREFA) and Unfunded Mandates Reform Act (UMRA).
3. Risk Reduction: Several of the proposed RMP revisions are overly burdensome and do not appreciably decrease risks of catastrophic chemical releases.
4. Benefit/Cost: The social benefits of the proposed regulatory revisions as outlined in EPA's regulatory impact analysis (RIA)[1] are grossly overestimated and the social costs to water sector are severely underestimated.
5. Flexibility: Recommend regulatory flexibilities for the drinking water and wastewater treatment sector.

Safety: Demonstrated Safety Record of the Water Sector Under RMP

Drinking water and wastewater treatment systems represent a substantially lower risk profile than other sectors regulated by the RMP program. The water sector has a demonstrated record of safety under the existing RMP regulatory requirements as demonstrated by EPA's own data on the 10-year accident history of the industry under the program. Per EPA's data, there are approximately 2,000 drinking water and wastewater treatment facilities regulated under RMP representing 16% of all total RMP regulated facilities. Over this 10-year period of analysis these facilities represented about 4.9% of all RMP reportable incidents with an approximate annual average of .037 incidents per facility over that same compliance period. The low accident rate indices is acknowledged by EPA's classification of the water sector facilities as a 'simple' regulated process. Given this safety record under the existing RMP requirements it is not clear, nor demonstrated, how the Agency's recent revisions to the RMP requirements reduce the risk of reportable incidents in the sector beyond the current, extremely-low baseline.

In prior comments,[2] AWWA noted an absence of information on how the Agency believes recommended changes would reduce risk to the public. The comments also made the point that revised regulatory requirements would not change the risk associated with a facility that fails to comply with the existing regulatory standards. The Agency's record for the final revision does not establish that the actions taken mitigate documented inadequacies of the existing rule when implemented appropriately.

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[1] http://www.regulations.gov/contentStreamer?documentId=EPA-HQ-OEM-2015-0725-0037&disposition=attachment&contentType=pdf

[2] AWWA, 2016, Comments on the Proposed Rule: Accidental Release Prevention Requirements: Risk Management Programs under the Clean Air Act, https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0554

The Agency did not appropriately examine the costs and benefits of each proposed RMP regulatory change to ensure that each provision will in fact reduce the risk of potential releases of chemicals in communities, recognizing that RMP regulated processes present different risk profiles. EPA acknowledges the dynamic of tiered risk by establishing categories of "simple" and "complex" facilities in the proposal. Water sector facilities are almost always labeled as "simple" since they have fewer processes and number of chemicals than the average RMP facility. In addition to just recognizing this inherent difference, EPA should tailor the requirements using these differences.

Small Business Entity Impacts

There are over 50,000 community water systems in the U.S. and of the approximately 2,000 water sector facilities subject to the Risk Management Program regulations, 49% are classified as small business entities under the U.S. Small Business Administration. In addition to a preponderance of small entities in the water sector, many of these facilities are owned and operated by municipal government entities operating on constrained budgets that are not easily adaptable to costly federal mandates. In the Unfunded Mandates Reform Act (UMRA) analysis presented in the proposed rule[3], EPA acknowledges that the RMP revisions may have significant budgetary impacts on State, local, or tribal government. UMRA, Pub. L. 104-4, was passed to limit the number of unfunded federal mandates imposed by the federal government on state, local, and tribal governments. In addition, UMRA was intended to strengthen the partnership and communications between the federal government and its state, local, and tribal counterparts. AWWA appreciate the efforts of EPA to consult with states and local communities through the National Association of SARA Title III Program Officials annual meetings prior to the issuance of the proposed rule. However, the Agency engagement effort did not consider critical local stakeholders such as municipal fire departments that are captured by the exercise provisions. Moreover, no assessment of the burden imposed by the rule on fire departments was examined in the Regulatory Impact Assessment. Additional efforts should be undertaken by the Agency to fulfill its obligation per section 7(b) of UMRA to,

> "require that Federal agencies prepare and consider estimates of the budgetary impact of regulations containing Federal mandates upon State, local, and tribal governments and the private sector before adopting such regulations, and ensuring that small governments are given special consideration in that process." [4]

In consideration of the unique impact the RMP revisions have on municipally owned and operated water systems, EPA should devote additional efforts to consult with these entities regarding the impact of the revisions on their operating budgets. Specific attention should be paid to how compliance with the proposed revisions may impact the operational imperatives that these systems face when making decisions about resource tradeoffs. Considering its obligations under UMRA and the significant and unique impacts to municipally owned water

[3] 81 FR 13701

[4] 2 USC 1501 (7)(b)

systems, AWWA encourages EPA to consider additional flexibilities for these entities as it considers future action.

In the RIA for the proposed rule, EPA acknowledges that it

> "had no data to project the specific impact of each proposed rule element on the probability and magnitude of chemical accidents. Indeed, the frequency and severity of the accidents themselves would be difficult and challenging to predict."[5]

The inability to appropriately match the costs and benefits of the proposal's program elements makes it difficult to ascertain whether a particular provision would in fact reduce the risk of chemical safety incidents.

EPA's estimate that the RMP revisions were likely to result in impacts to regulated entities of $161 million annually. The rule meets the criteria of an "economically significant regulation" under Executive Order 12866[6] and therefore is subject to the requirements of OMB Circular A-4. In particular, Circular A-4 instructs agencies to "explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives." [7] While AWWA appreciates EPA's approach in developing low, medium and high cost estimates for each of the proposed revisions, the agency did not quantify the benefits associated with of individual program elements. Lacking a clear benefit estimate for the proposed revisions, it was not possible for stakeholders to understand how proposed revisions were expected to reduce the risk from a release or improve safety.

In addition to the lack of clarity regarding the costs and benefits of each program element, some of the revisions also introduced potential unintended consequences that can further detract from the stated purpose of the regulation to "improve chemical safety and security." To comply with Executive Orders for regulatory review and EPA's statutory obligations, the agency prepared a RIA. AWWA reviewed the RIA and found numerous instances where EPA did not use fundamental economic science, follow executive branch guidelines for regulatory impact analysis, and follow its own economic guidelines. These flaws have the effect of substantially overstating social benefits and understating social costs derived from this regulatory action. Moreover, the analysis did not provide information to policy officials and the public to allow effective comment on the proposed rule by not appropriately identifying the costs and benefits associated with each of the proposed rule's provisions. EPA's RIA contains numerous methodological flaws and is inconsistent with EPA's Economic Analysis Guidelines, Executive Orders, and government-wide requirements for regulatory analysis issued by the

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[5] RMP Regulatory Impact Analysis, pg. 7

[6] Executive Order 12866: Regulatory Planning and Review, September 30, 1993. https://www.archives.gov/files/federal-register/executive-orders/pdf/12866.pdf

[7] OMB Circular A-4, 2003, https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf

Office of Management and Budget (OMB). In most instances, the effect of these flaws is to overstate this rules likely social benefits.

The principal concerns include the following:

1. The RIA claimed a level of social benefit that implicitly assumes the rule revisions will prevent all future accidents;
2. The RIA includes private benefits as social benefits;
3. The RIA claims as a benefit of this rule all existing state, local, other Federal regulations and independent efforts to increase facility safety; and
4. The RIA assumed future hazards will be as great as they have been in the past, ignoring trends in reduced severity of accidents and technology improvements.

Each of these concerns were discussed in more detail in comments previously submitted to the Agency.[8] In addition, AWWA estimated that the maximum social benefits associated with water and wastewater facilities from this rulemaking would be extremely small, approximately $10,000 per year. EPA's own data show that water utilities have an excellent track record of serving their communities safely. Additional regulation would provide almost no incremental benefit above current regulation and practices.

Water utilities are also a tiny proportion -- 0.12 percent -- of the maximum potential social benefits across all sectors using EPA's approach. Even if EPA finds additional regulation is needed, it should tailor the requirements to those sectors where some social benefit may occur.

Although the maximum incremental social benefits for the water sector are extremely low, even these low numbers overstate the likely social benefits. These numbers still assume that the rule eliminates all accidents, ignores existing local and Federal regulation, and the other flaws in the social benefit analysis described in AWWA comments on the RIA.

Regarding costs, AWWA examined the major provisions of the rule to estimate the expected impact on the water sector. The analysis found that the RIA contained systematic errors which led to an underestimation of the real resource costs that will likely be necessary for compliance.

Finally, since the social costs of the proposed rule as applied to the water sector is approximately $125 million (or 200,000 times) greater the social benefits for each year, EPA's proposal represents a significant transfer of resources away from drinking water and wastewater systems to other sectors of the economy. The rule is coming at a time when our nation's water infrastructure needs resources to maintain constant, safe, and affordable water to the public, water sector facilities. While required under OMB regulatory review guidelines, EPA did not estimate the opportunity costs of the rulemaking. The opportunity costs include

[8] AWWA, 2016, Comments on Proposed Risk Management Plan Rule, https://www.regulations.gov/document?D=EPA-HQ-OEM-2015-0725-0554.

greater service disruptions due to failing distribution pipes, higher water rates and economic impacts on low and fixed income households, and deferred investments to improve the efficiency and capacity of water system.

Recommended Action

Clean Air Act §112(r)(7)(B)(i)) calls for EPA regulations to recognize differences in "size, operations, processes, class and categories of sources,"[9] when designing regulatory requirements for the RMP program. AWWA applauds EPA's efforts to acknowledge that an underlying principle of the regulations is that "one size does **not** fit all" (emphasis added), when structuring the revisions in a way that the costs of implementation vary based primarily on the complexity of the processes involved. In doing so, EPA has designed several provisions in the rule in a manner that differentiates the stringency of program requirements based on the profile of regulated processes. For example, EPA differentiates regulated processes under RMP between "simple" and "complex" processes to acknowledge that certain regulated processes,

> "… have more covered processes per facility and more complex issues to consider when evaluating hazards, designing exercises, conducting audits, investigating incidents, and explaining information to first responders and the public compared to facilities that simply store or use chemicals in simple processes (e.g. refrigeration systems and water and waste water treatment systems.)[10]"

To further distinguish between the complexity of regulated processes, EPA established three RMP Program Levels to ensure that individual processes are subject to requirements appropriately matched the complexity of their operations and risk profile. In addition, the requirement to conduct Safer Technology and Alternatives Analysis hinges on the classification of a subset of Program 3 facilities distinguished by 3 specific NAICS codes. Those specific sectors were selected because they represent relatively complex processes that have had a high frequency of accidental releases accounting for 49% of all RMP reportable incidents.[11]

As described previously, the water sector represents the lowest safety risk profile under the RMP program. In addition, nearly half of all RMP facilities in the water sector are classified as small business entities under SBREFA. Many RMP facilities in the water sector are also municipally owned and operated and are fully dependent on local rate payer financing to provide important public health services. When faced with costly regulatory requirements with no clear benefits, the very real potential for unintended consequences can result in the water sector when making decisions about the allocation of scarce resources devoted to public safety, affordability and reliability of public water resources. AWWA believes that these considerations should be taken into account as EPA reconsiders how it should support risk management planning.

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[9] 81 FR 13646

[10] Regulatory Impact Analysis pp 28

[11] Ibid, pp 28

Based on the unique characteristics of the water sector, the disproportionate economic impacts and low risk profile of its regulated processes, AWWA recommends that EPA consider developing a tailored approach for the RMP regulatory requirements that accounts for these differentiated characteristics. This approach would classify facilities under NAICS codes 22131 and 22132 under a "lowest risk" subset of EPA's existing "simple process" category that would further distinguish the water sector among other categories with higher risk profiles within the "simple process" category. This approach would be consistent and like the risk-tiering approach that EPA undertook for the STAA requirement for the most complex regulated processes. By exercising discretion to provide for these risk-based flexibilities for the water sector, EPA would achieve the following objectives thorough this approach:

1. Provide relief to the water sector under SBREFA by adopting recommendations of the SBAR panel for streamlined requirements for small entities.
2. Consider the disproportionate impacts of the rule on municipally owned drinking water and wastewater utilities under UMRA.
3. Avoid unintended consequences associated with shifting resources among severely constrained water utility budgets that protect critical infrastructure and provide important public health benefits.
4. Integrate a regulatory lookback approach that would provide for a periodic review (eg. Five years) of accident rates and offsite consequences, and consideration of the need for additional requirements as appropriate if warranted.

State Revolving Loan Fund Rule

65 FR 48286, 40 CFR Subpart L, Aug. 7, 2000

The authorizing language for the State Revolving Loan Funds (SRF) in the Safe Drinking Water Act tasked EPA with publishing guidance and promulgating regulations "as may be necessary" to carry out the program.[12] In addition to the rule requirements, EPA has developed 38 guidance documents regarding SRF implementation, which could benefit from review and consolidation. This review would provide the Agency with an opportunity to gather practical knowledge and challenges identified in the years since these guidance materials were issued. AWWA's comments focus specifically on two drinking water SRF guidance documents:

- SRF Fund Management Handbook, EPA-B-01-003, April 2001; and
- Drinking Water State Revolving Loan Fund Program Operator's Manual, EPA-816-B-06-007, October 2006.

[12] 42 U.S.C. 300j–12(g)(3)

Efficient Use of SRF Capitalization Grants

EPA requires each state to annually report disbursements as a percentage available funds.[13,14] This snapshot in time does not provide clarity on whether funds are idle or if they move out into loans after the reporting day. EPA analysis[15] suggests that in some states there are more projects than available SRF funds and yet other states the SRF is "undersubscribed" implying missed opportunities for use of available funds. Developing a better operating picture on undersubscribed funds and by how much is complicated because of the complex and varying accounting methods used in each state. To improve the efficiency and transparency of SRF implementation, consideration should be given to the following actions:

1. Guidance from EPA on using the SRF, such as the *SRF Fund Management Handbook*,[16] should include a requirement that undisbursed SRF balances be reported on a quarterly basis to provide a better assessment of fund distributions from state agencies.
2. In states with consistently large undisbursed fund balances, EPA should survey water systems to determine why they are not requesting funding from the SRF.
3. Less than 30 states are leveraging capitalization grants on the bond market to expand the funds they have available to loan. EPA should undertake a study to determine why states are not leveraging their funds, particularly states with larger loan applicant needs than available funds.

The Application Process

The application process for an SRF loan must be streamlined, particularly for smaller systems. A complicated application process often results in a utility paying fees to a consultant just to put together an application, driving the costs of projects even further up. While application processes are established by each state SRF authority, EPA's SRF guidance, such as the *Program Operations Manual*,[17] could provide application templates that provide a consistent approach and address the following:

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[13] EPA, 2001, Data Elements for the DWSRF Information System (DW NIMS). https://www.epa.gov/sites/production/files/2015-12/documents/dwdatadefs.pdf

[14] EPA, 2016, Drinking Water SRF Program Information National Summary. https://www.epa.gov/sites/production/files/2015-12/documents/dwus10.pdf

[15] EPA Inspector General, 2014, *Unliquidated Obligations Resulted in Missed Opportunities to Improve Drinking Water Infrastructure*, Report No. 14-P-0318. https://www.epa.gov/office-inspector-general/report-unliquidated-obligations-resulted-missed-opportunities-improve

[16] EPA, 2001, *SRF Fund Management Handbook*, EPA 832-B-01-003 https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=200041A2.txt

[17] EPA, 2006, Drinking Water State Revolving Fund: Program Operations Manual - Provisional Edition, EPA-816-B-06-007. https://nepis.epa.gov/Exe/ZyPDF.cgi?Dockey=P1007ZKN.txt

1. SRF applications should be scalable to the size and scope of a project.
2. To help scale an application, forms should be tailored to the type of project, such as
    a. Consolidation/regionalization of water systems
    b. Addressing source water needs or problems
    c. Upgrades or additions to treatment works
    d. Distribution infrastructure

EPA should consider a study to assess how the SRF is administered in each state with consideration of best in class approaches that improve the efficiency of the application process. EPA should also explore insights from USDA's Rural Development water system loan program implementation. Finally, the SDWA required an evaluation of the program's effectiveness in 2001. It would be prudent for the Agency to update that assessment to determine current level of effectiveness.

Recommended Action

It would be appropriate to update this rule, associated guidance, and supporting resources in a comprehensive manner. AWWA recommends that the Agency review and revise the current rule as necessary to streamline and otherwise improve SRF implementation efficiency and transparency.

Integrated Municipal Stormwater and Wastewater Planning Approach Framework

Office of Water Memo, June 5, 2012

AWWA encourages the Agency to include drinking water considerations in the Integrated Planning guidance such that it is reflective of the cumulative burden imposed on the ratepayer within the same community by combined regulatory actions. [18] Given limited local resources the Agency should facilitate a comprehensive assessment of the total burden various actions may have on a community to ensure proposed regulatory action provide the greatest public health benefit. Water utilities and the communities they serve have limited resources. Therefore, investments should first address the most important risks to public health and deliver maximum benefits at a cost that is affordable.

In 2013 AWWA collaborated with the US Conference of Mayors and the Water Environment Federation to develop a report, Affordability Assessment Tool for Federal Water Mandates, which highlights the need for a more comprehensive approach and the opportunity costs

[18] EPA, 2012, Office of Water Memo on Integrated Municipal Stormwater and Wastewater Planning Approach Framework, https://www3.epa.gov/npdes/pubs/integrated_planning_framework.pdf

associated with the current policy. The following excerpt from this report summarizes the issue for the current evaluation:

> "EPA's consideration of affordability for wastewater and CSO compliance is aimed at assessing an individual community's ability to comply with regulatory mandates and schedules, EPA's consideration of affordability in the context of potable water supply is limited to assessing the national-level affordability of regulatory options for small communities. EPA does not consider the affordability of drinking water requirements in a manner that pertains to individual utilities (even small ones), or to the category of medium and large utilities.
>
> EPA's stated view on potable water—that it is affordable if it costs less than 2.5% of small community Median Household Income (MHI)—influences the perceived affordability of combined water and wastewater bills. Specifically, it is commonly inferred that EPA would consider a combined annual water and wastewater bill of less than 4.5% of MHI to be affordable (2.5% for water, plus 2% for wastewater services and CSO controls).
>
> A central issue in assessing affordability of federal water mandates is the reasonableness of community-wide MHI as a primary yardstick. MHI can be a highly misleading indicator of a community's ability to pay.
>
> EPA's proposed Integrated Planning and Permit Policy (IPPP) provides one potential avenue by which the costs and benefits of all federal water mandates could be addressed. The IPPP process could be used to set priorities, adjust requirements, and set reasonable timetables. Such adjustments would help ensure that local resources are used to secure the greatest public health and environmental benefits at an affordable cost. Moving the IPPP process forward as suggested offers important potential advantages:
>
> 1. Comparing the environmental, social, and financial benefits of all water-related obligations would allow municipalities to develop priorities that reflect the totality of tradeoffs and commitments facing the community.
> 2. Considering all water-related obligations together, and assessing financial capability in light of total water-related obligations, would focus local resources where the community will get the greatest total environmental, public health, and other benefits.
>
> EPA does not include drinking water mandates in the Integrated Municipal Stormwater and Wastewater Planning process, even though drinking water investments must be carried on the same customer bill as investments needed to comply with wastewater and CSO mandates. The USCM, AWWA, and WEF have recommended that EPA include consideration of drinking water investments in the

Integrated Planning and Permit Program. The program should also consider necessary but nonmandatory investments in the ongoing rehabilitation of water and wastewater infrastructure."

Recommended Action

AWWA recommends that the EPA revise the current policy to explicitly (1) identify public health as the first-priority in project prioritization and (2) incorporate community drinking water infrastructure needs into the prioritization of projects under the integrated planning framework.

Long Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR)

71 FR 654, 40 CFR Parts 9, 141, and 142, January 5, 2006

EPA concluded in the final LT2ESWTR that it is not feasible to implement a risk mitigation plan that could provide equivalent protection to covering or treating a reservoir. This decision was inconsistent with the Stage 2 M/DBP Agreement in Principle to which EPA is a signatory. [19] In commenting on the proposed LT2ESWTR, AWWA reiterated that under the Agreement in Principle, a risk management plan approved by the primacy agency is an adequate remedy for an uncovered reservoir. If treatment strategies are included in such a risk management plan for an uncovered reservoir, then the plan should address the range of microbes for which treatment is necessary. The primacy agency can specify treatment for *Cryptosporidium, Giardia lamblia*, and/or viruses, if needed, depending on site specific circumstances and the adequacy of other aspects of the risk management plan.

At the time of the rulemaking, EPA estimated that the total annualized present value cost for covering or treating the water from uncovered finished water storage facilities would be approximately $10 million at a 3 percent discount rate and $13 million at a 7 percent discount rate. Subsequent analysis of implementation costs finds that this mandate alone is estimated to exceed $1.4 billion in capital costs at one single facility, that being for the New York City Department of Environmental Protection. When LT2ESWTR was promulgated in 2006 there were tens of open finished water reservoirs, only a very small fraction of the installed finished water storage capacity in the United States. Today more than a decade later only the most challenging retrofit situations remain. Against the current backdrop, of very few open-finished water reservoirs (AWWA is aware of four utilities including New York City DEP with remaining open finished water facilities); more sophisticated tools for assessing the effectiveness of risk reduction measures; and greater state experience with replacement, covering, and treatment options for such facilities, it would be reasonable for EPA to revisit the current requirement to allow site-specific cost-benefit analyses utilizing risk management plans as one possible management option. Given what we now know, very few situations would be amenable to a

[19] EPA, 2000, Stage 2 M/DBP Agreement in Principle. https://www.epa.gov/sites/production/files/2015-11/documents/stage_2_m-dbp_agreement_in_principle.pdf

risk management plan-based approach, but in the case of a situation like New York City DEP, such a plan may be the most viable alternative.

Recommended Action

AWWA recommends that EPA revise the current rule to allow the use of open finished water storage facility risk management plans per the Stage 2 M/DBP Agreement in Principle. However, to implement this recommendations EPA would need to modify 40 CFR 141.714(c) (uncovered finished water storage facilities) and 40 CFR 142.16 (special primacy conditions). Modifications should:

1. Reflect the principles originally specified in the Stage 2 M/DBP Agreement in Principle.
2. Continue to prohibit the creation of new open finished water reservoirs.
3. Establish criteria by which an alternative risk management strategy's effectiveness achieving equal public health protection can be measured.
4. Ensure compatibility with delivered water treatment objectives, particularly maintenance of adequate corrosion control.
5. Ensure adequate state primacy agency approval and oversight of implemented risk management strategies.

In our understanding, such an approach would address the issue faced with the largest single example cited above, i.e., New York's situation, reflecting the uniqueness of its situation.

Health Advisories

SDWA provides EPA with the authority to issue drinking water health advisories as a risk management tool. The SDWA provides little specific direction on the application this tool, though it is reasonable to apply the themes of prudent public health protection that are pervasive throughout the Act. In 2015 and 2016, EPA published drinking water advisories for cyanotoxins (microcystins and cylindrospermopsin), and perfluorooctanoic acid and perfluorooctane sulfonate (PFOA/PFOS). These advisory levels were accompanied by specific recommendations for actions by public water systems and state primacy agencies. In many respects this combination of health-based levels of concern and recommendations for action appear to the public and water systems as *de facto* rulemakings. Under SDWA, health advisories are not regulations, and in practice the health advisory is essentially a maximum contaminant level goal, which is also not enforceable under SDWA. As a practical matter, the combination of the Agency's imprimatur and the language used by the Agency gave these latest health advisories the force and effect of a regulation.

For context, there are only two regulated contaminants with maximum contaminant levels that warrant do-not drink orders and in those instances, nitrate and nitrite, the order is limited to bottle-fed infants. In contrast, all the advisories listed above and described subsequently in more detail, impose a default requirement of community-wide do-not-drink orders. With the *de facto* regulatory effect of advisories and the community level impacts that resulted from recent EPA practice in mind, we believe the Agency should:

1. Keep the overall construct and considerations of SDWA in mind when crafting health advisories, and
2. Meet the standards of care imposed on "significant" Agency guidance documents when developing health advisories.

A review of the development history for either the cyanotoxin or PFOA/PFOS health advisories illustrates that meeting the appropriate standard of care will not necessitate delaying health advisories (see Table 1). However, we are recommending a change in the way health advisories and accompanying recommendations are managed, including the level of public transparency during the development process. Health advisories and associated recommendations are not developed quickly, each of the advisories listed in these comments represent multi-year processes. To provide greater public transparency and review of draft advisories and associated recommendations is not an onerous burden for guidance documents that will have substantial impact on local communities.

Table 1. Health Advisory Actions and Public Comment Opportunity

Cyanotoxin Health Advisories		PFOA/PFOS Health Advisories	
Agency Action	**Public Comment Opportunity**	**Agency Action**	**Public Comment Opportunity**
1998 – Contaminant Candidate List includes cyanotoxins	Limited stakeholder engagement focused almost exclusively on inclusion in CCL, and analytical methods post-CCL to support occurrence data development.	2001 -- Dupont consent decree (WV and OH)	Subsequent stakeholder engagement focused almost exclusively on inclusion in CCL and analytical methods for UCMR.
2001 – Expert meeting on	No information exchange with stakeholders for 5-year period while health	2009 -- Provisional drinking water health advisories	No direct opportunity for public review or comment. [20]

[20] In 2005, the EPA Science Advisory Board convened a panel to review the Draft Risk Assessment of the Potential Human Health Effects Associated with Exposure to Perfluorooctanoic Acid and its Salts, which includes the opportunity for public comment. The Agency's response to the SAB report stated that "EPA will seek a second SAB review upon completion of a final risk assessment", which did not occur prior to the issuance, 3 years later, of the provisional HA.

Cyanotoxin Health Advisories		PFOA/PFOS Health Advisories	
Agency Action	**Public Comment Opportunity**	**Agency Action**	**Public Comment Opportunity**
cyanobacteria & cyanotoxins	support document was developed.	for PFOA and PFOS	
2006 – Cyanotoxin Health Support Document Public Review	No information exchange with stakeholders for 9-year period in which health advisories were developed.	2009 -- Superfund soil screening levels for PFOA and PFOS	Developed internally by EPA's Office of Superfund Remediation and Technology Innovation (OSRTI) and the Office of Emergency Management (OEM). [21]
2015 – Public meeting on cyanotoxin recommended actions	No outreach in 9-year development period until 2 months prior to final recommended actions being released.	2012 -- C8 Science Panel Probable Link Report	Panel report did not trigger outreach to stakeholders.
		2014 – PFOA and PFOS Health Support Document Public Review	Comment period for the health support documents when those documents were externally peer-reviewed.
		2016 -- Final drinking water health advisories and recommendations for PFOA and PFOS	No information exchange with stakeholders in 7-year period of development recommended actions.

Drinking Water Health Advisories for Cyanobacterial Toxins

80 FR 34637, June 17, 2015; 42 U.S.C. 300 g– 1(b)(1)(F)

Individual recommendations included in the EPA documents associated with the Cyanotoxin HAs are flawed. The process used to prepare the HA lacked transparency in key respects, marginalized the opportunity for public review and comment on important risk management and operational decisions, and did not satisfy the quality standards necessary to support the

[21] USEPA, November 20, 2009, Memo from EPA Region 4 Superfund Division regarding Soil Screening Levels for Perfluorooctanaoic Acid (PFOA) and Perfluorooctyl Sulfonate (PFOS). https://archive.epa.gov/pesticides/region4/water/documents/web/pdf/final_pfc_soil_screening_values11_20_09.pdf

Agency's action. Finally, this HA was issued without the full consideration of the feasibility, cost, and related issues normally assessed during the development process of significant guidance. The following are issues AWWA has identified regarding the Agency's health advisory and recommendations where EPA did not meet the standard of care expected of significant guidance, and which warrant additional consideration. If EPA had provided the opportunity for public review expected of significant guidance documents, these issues would have been identified prior to the final HA.

1. *The HA favors a potentially flawed detection method for Microcystins known to have over-reporting and interference issues (ELISA) instead of an approved EPA standard method that has been rigorously tested and is known to meet accuracy standards (i.e. LC/MS/MS).* At the time of the publication of the HA there was no EPA or other recognized standard method for using ELISA to detect microcystins. Page 24 of the EPA recommendations advises water systems to:

   > *"… analyze finished water samples with a quantitative laboratory ELISA test for total microcystins … if a system wants to detect and quantify individual microcystin variants, a more selective method, such a liquid chromatography/tandem mass spectrometry (LC/MS/MS) can be used (recognizing this method does not identify the majority of microcystin congeners and may underestimate the total concentration of microcystins in the sample)…"*

   The best available research demonstrates that the opposite may in fact be true. A recent study by the Metropolitan Water District of Southern California demonstrated +/- 25% method variability in observed occurrence when microcystins are measured at levels relevant to the HA. ELISA-measured MC-LA concentrations were 2 to 3 fold higher than the spike concentrations using kit-provided MC-LR standards.[22] This means that the ELISA method may substantially over-report certain microcystin variants by as much as three times the actual concentration. The LC/MS/MS method does not have this limitation. EPA's recommendation could lead to unnecessary public concern and potentially inappropriate actions by utilities with negative impacts and costs to the public (such as issuing a "do not drink / do not boil" notice when one is not actually necessary).

2. *The HA is based on health effects information from Microcystin-LR only and may be based on a limited study, making potentially invalid assumptions about toxicity of other microcystin variants.* The health advisory for Microcystins is based upon a study of Microcystin-LR only, which is among the most toxic and most frequently detected. Many microcystin congeners have unknown toxicity (they may have

[22] Guo, Y, A.K. Lee, R.S. Yates, S. Liang, and P.A. Rochelle. March 2017. *Analysis of Microcystins in Drinking Water by ELISA and LC/MS/MS*. Journal – American Water Works Association, 109:3. DOI: http://dx.doi.org/10.5942/jawwa.2017.109.0027.

greater, lesser, or no toxicity), and therefore grouping microcystins together in the HA, as if they were all equal toxicity, is not appropriate and is not justified based on available science. Analysis of microcystin variants based upon their actual toxicity of at least the most commonly seen microcystin variants beyond microcystin-LR would likely lead to a different and more useful health advisory and set of recommendations.

Additionally, there are challenges with the underlying toxicological data and the ways that EPA has made management decisions around those data. Several states, countries, and the World Health Organization have analyzed the risks posed by microcystin and/or cylindrospermopsin. The EPA's analysis is markedly different from those other authoritative bodies, including analyses with access to the same studies as EPA. The differences result from a series of risk assessment choices that when taken together lead to different conclusions in the other risk assessments:

1. A single replicated critical study which has not been replicated and utilizes a particular rat breed,
2. Use of a secondary measure of toxicity without demonstrated linkage to direct measures of toxicological effect,
3. Not reducing the uncertainty factors when data is available related to mechanisms and modes of action for microcystin-LR, and
4. Deriving a level of concern for all microcystins as one similar group when the data is almost exclusively derived from microcystin-LR.

The HAs have concentration levels of concern that are substantially lower than those set by other regulatory and scientific organizations, such as World Health Organization and Health Canada, due to these differences in methodology. EPA should reevaluate the underlying science to assure that the data utilized are truly the most appropriate, are replicable and otherwise considered of sufficient quality for use in regulatory processes, and have correctly applied risk assessment methodologies. For example, in the Heinze et al (1999) study, the strain of rat used may have impaired liver function and be biased towards showing larger liver impairments than strains typically used in Agency risk assessments.[23] Replication of this study's findings by EPA or other qualified scientists may be necessary before making decisions that could drive tens to hundreds of millions of dollars in capital upgrades at utilities and potentially result in at least $100 million in economic disruption for inappropriate "do not drink / do not boil" notices. One facility in Ohio is spending nearly $300 million to upgrade its treatment plant, and although upgrades will address several issues, cyanotoxins is one of the major

[23] Heinze 1999 utilized the first generation progeny of breeding pairs of female WELS/Fohm and male BDIX rats.

drivers of much of this expense.[24] To conduct several of such studies would cost a tiny fraction of the costs likely to be driven by the study's data. Given the importance of the decisions to be made with these criteria and with the existing health advisories, EPA should examine this and other issues to assure relative consistency among risk assessments and the underlying high quality science and appropriate use of it.

3. *The HA suggests (pages 25-26) a "do not drink / do not boil" advisory for either children below school age or for everyone (depending on concentration) within 24 hours based upon one confirmed sample above the relevant threshold, a timeframe which is incongruent with the health advisories themselves*. The health advisories (described in detail in other documents) specifically indicate that they are toxicologically relevant for 10-days of sustained exposure, not for a period of time shorter than that. EPA does not provide scientific justification for why the action timeframe is different than the advisory timeframe, nor does it provide scientific justification as to why the default remedy for an exceedance is a "do not drink / do not boil" advisory. Several states have already announced that they will be using EPA's Recommendations, either directly or through a similar derivation, as a required level that will be enforced on the state level. Actions by states are a natural outcome of EPA's HA and will over time lead to economically significant consequences.

4. *EPA recommends (page 26) "for PWSs where source waters have public access for recreation, the system's notice may include statements about recreational use of waters with cyanobacterial blooms to prevent exposure of humans and animals to cyanotoxins."* Although a proposed recreational advisory level has since been proposed, at the time of the recommendations there was no guidance, and absent a final advisory level it is unclear what message EPA expected drinking water systems to send to recreational users and under what circumstances.[25] In many cases the PWS has neither control nor authority over source waters, and does not have the authority to close or alter recreation in those areas, and a blanket recommendation like this places an inappropriate burden on and standard for water systems in general.

5. *The HA includes (page 21) a table about the chlorine contact times to reduce Microcystin-LR concentration to 1 µg/L under various scenarios, meant as a tool to assist utilities in implementing the recommendations*. Based upon the HAs and the rest of the *recommendations*, this is the wrong compound and points to the wrong target concentration. This table is misleading and confusing in its present

[24] Henry, T. 23 May 2016. *Cost Climbs for Collins Park Water Treatment Plant.* http://www.toledoblade.com/local/2016/05/23/Cost-climbs-for-Collins-Park-Water-Treatment-Plant-Modernizing-facility-will-cost-188-million-more-than-thought.html

[25] *Human Health Recreational Ambient Water Quality Criteria and/or Swimming Advisories for Microcystins and Cylindrospermopsin* (81 FR 91929).

form, because the health advisories (and all of the Recommendations) refer to total Microcystins (not Microcystin-LR alone) and to reducing concentration to either 0.3 µg/L or 1.6 µg/L (depending on which threshold).

A thorough, participatory stakeholder process will reveal important scientific, technical, process, and policy concerns with the HA. To ensure that these important questions do not remain unanswered, AWWA recommends that the cyanotoxin HA be classified as an Economically Significant Guidance Document and that EPA take appropriate action to modify this guidance in accordance with the procedures required for such a document.

Lifetime Health Advisories and Health Effects Support Documents for Perfluorooctanoic Acid and Perfluorooctane Sulfonate (PFOA/PFOS)

81 FR 33250, May 25, 2016; 42 U.S.C. 300 g– 1(b)(1)(F)

AWWA concurs with the Agency's concern regarding the impact of perflorinated compounds on drinking water quality. PFOA and PFOS are manmade chemicals believed to have significant health impacts. The compounds are also persistent in the environment, particularly groundwater. With the issuance of 81 FR 33250, EPA lowered the levels of concern for PFOA and PFOS and recommended public water systems notify primacy agencies and install treatment. Despite noting that the HA is non-enforceable and not meant to be regulatory, it has nonetheless had major regulatory impacts as some states have made it policy to have sources above the level of concern shut off or treated. Because the recommendations were not subject to public comment, they did not benefit from thorough public review and consideration of important technological and scientific matters, including feasibility of implementation, and the costs and benefits of action.

The PFOA/PFOS HA is leading to significant costs at many utilities and generating substantial public concern. At a single utility in Pennsylvania serving ~20,000 people, the operating costs for new treatment processes as several wells that tested below the HA levels is expected to cost $1.2 million annually. This will result in an increase on an average residential water bill of 38%.[26] This utility is also receiving tens of millions of dollars in grants to assist with capital upgrades. Other utilities have had to take some wells out of service, meaning that although there were no direct treatment costs, there are opportunity costs associated with the stranded infrastructure and cost of acquiring alternate supplies.

The Pennsylvania Department of Environmental Protection has made it a policy to require utilities to take wells offline if they exceed the HA level, stating that "*this* [safe drinking water] *program … works to take wells offline when concentrations of PFCs are found to exceed the*

[26] Horsham Water & Sewer Authority. September 12, 2016. Letter from Horsham Water & Sewer Authority to the Secretary of the Navy. Available at: https://www.horshamwater-sewer.com/sites/default/files/09.12.16%20military%20funding%20request%20Navy%20signed.pdf

HA".[27] As a result, one utility is installing nearly $2.5 million in treatment and laboratory equipment in response this policy decision.

Utilities in other states, such as Colorado and Massachusetts, have also experienced similar concerns. The Third Unregulated Contaminant Monitoring Rule identified a total of 95 and 117 water systems with detections of PFOS and PFOA. There were 43 and 13 utilities with at least one detection above the level of concern for either PFOS or PFOA (the total number exceeding the combined HA would be greater because the HA is based on the total concentrations of both substances).[28] EPA has not completed an analysis of feasibility or the projected costs for implementing the HAs, which would be required for either a National Primary Drinking Water Standard regulation or for a significant guidance document.

Given the importance and cost of the decisions being made at the state and local level in response to the issuance of EPA's HA, the HA should be classified as a Significant Guidance Document and EPA should take appropriate action to modify this guidance in accordance with the procedures required for such a document. Utilization of the review criteria for a "significant guidance document" will help to ensure that the best available scientific, technical, and economic information is compiled and utilized to ensure that the decision-making processes associated with issuance of HAs is appropriate.

Recommended Action

Given the importance of managing cyanotoxins, PFOA, and PFOS in communities where these contaminants are present, AWWA is recommending that these HAs undergo further review as significant guidance documents. Equally importantly, EPA should establish a consistent process that ensures transparent public review and quality assurance for health advisories and accompanying recommendations.

Phase I, II, IIB, and V Chemical Contaminant Rules

52 FR 25690, January, 1987; 56 FR 3526, January 1991; 56 FR 30266, July 1, 1991; and 57 FR 31776, July, 1992; 56 FR 3526; Guidance EPA 570/F-91-045, February 1991; 40 CFR 141.23, 141.24, 141.26

Based on the prescribed schedule in the Standardized Monitoring Framework, drinking water systems routinely monitor for an array of contaminants. The historical data indicates that many water systems have never been detected many of these contaminants and that in all but a small subset of systems occurrence levels are negligible. EPA should evaluate regulatory options

[27] Pennsylvania Department of Environmental Protection. Unknown Date. PFOA and PFOS In Pennsylvania – DEP Program Involvement. Available at: http://www.dep.pa.gov/Citizens/My-Water/drinking_water/Perfluorinated%20Chemicals%20–PFOA%20and%20PFOS%20–%20in%20Pennsylvania/Pages/DEP-Program-Involvement.aspx

[28] U.S. Environmental Protection Agency. January 2017. The Third Unregulated Contaminant Monitoring Rule (UCMR3: Data Summary, January 2017. Available at: https://www.epa.gov/sites/production/files/2017-02/documents/ucmr3-data-summary-january-2017.pdf

where the historical compliance monitoring data indicates *de minimus* occurrence of currently regulated contaminants, and eliminate MCLs which do not represent an opportunity for risk reduction. Table 2 represents the detection concentration level at 50th and 90th percentile from the third Six-Year Review contaminant occurrence data sets.

Table 2. Summary Statistics for EPA's Third Six-Year Contaminant Occurrence Data Collection

No.	Contaminant	50th percentile (mg/L)*	90th percentile (mg/L)*
1	1,1,1-Trichloroethane	0	0
2	1,1,2-Trichloroethane	0	0
3	1,1-Dichloroethylene	0	0
4	1,2,4-Trichlorobenzene	0	0
5	1,2-Dichlorobenzene (o-Dichlorobenzene)	0	0
6	1,2-Dichloroethane	0	0
7	1,2-Dichloropropane	0	0
8	1,4-Dichlorobenzene (p-Dichlorobenzene)	0	0
9	2,3,7,8-TCDD (Dioxin)	0	0
10	2,4,5-TP (Silvex)	0	0
11	2,4-D	0	0
12	Alachlor	0	0
13	Gross Alpha (pCi/L)	3	9.2
14	Antimony	0	0
15	Arsenic	0	0.01
16	Asbestos (MFL)	0	0
17	Atrazine	0	0
18	Barium	0.018	0.16
19	Benzene	0	0
20	Benzo[a]pyrene	0	0
21	Beryllium	0	0
22	Beta Particles (Gross Beta)(pCi/L)	4	12.6
23	Cadmium	0	0
24	Carbofuran	0	0
25	Carbon Tetrachloride	0	0
26	Chlordane	0	0
27	Chromium	0	0.0025
28	cis-1,2,-Dichloroethylene	0	0
29	Combined Radium-226_228 (pCi/L)	0.7	*6.5***
30	Cyanide	0	0
31	Dalapon	0	0

No.	Contaminant	50th percentile (mg/L)*	90th percentile (mg/L)*
32	DBCP	0	0
33	Di(2-ethylhexyl)adipate (DEHA)	0	0
34	Di(2-ethylhexyl)phthalate (DEHP)	0	0
35	Dichloromethane	0	0
36	Dinoseb	0	0
37	Diquat	0	0
38	Endothall	0	0
39	Endrin	0	0
40	Ethylbenzene	0	0
41	Ethylene dibromide (EDB)	0	0
43	Glyphosate	0	0
44	Heptachlor	0	0
45	Heptachlor Epoxide	0	0
46	Hexachlorobenzene	0	0
47	Hexachlorocyclopentadiene	0	0
48	Lindane	0	0
49	Mercury (inorganic)	0	0
50	Methoxychlor	0	0
51	Monochlorobenzene (Chlorobenzene)	0	0
52	Nitrate (as N)	0.32	6.3
53	Nitrite (as N)	0	0.01
54	Oxamyl	0	0
55	Pentachlorophenol	0	0
56	Picloram	0	0
57	Polychlorinated biphenyls (PCBs)	0	0
58	Selenium	0	0.0011
59	Simazine	0	0
60	Styrene	0	0
61	Tetrachloroethylene	0	0
62	Thallium	0	0
63	Toluene	0	0
64	Toxaphene	0	0
65	trans-1,2-Dichloroethylene	0	0
66	Trichloroethylene	0	0
67	Uranium	0.003	0.025
68	Vinyl Chloride	0	0
69	Xylenes	0	0
70	Bromoform	0.0039	0.0078
71	Chloroform	0.0234	0.0468
72	Dichloroacetic acid	0.0089	0.0222

No.	Contaminant	50th percentile (mg/L)*	90th percentile (mg/L)*
73	Trichloroacetic acid	0.0067	0.0167
74	Lead	0	0
75	Copper	0	0
76	N-nitrosodiethylamine (NDEA)	0	0
77	N-nitrosodimethylamine (NDMA)	0	0
78	N-nitrosodi-n-butylamine (NDBA)	0	0
79	N-nitrosodi-n-propylamine (NDPA)	0	0
80	N-nitrosomethylethylamine (NMEA)	0	0
81	N-nitrosopyrrolidine (NPYR)	0	0
82	Acetochlor	0	0
83	Alachlor	0	0
84	Metolachlor	0	0.003
85	2,4,6-trinitrotoluene (TNT)	0	0
86	1,3-dinitrobenzene	0	0
87	RDX	0	0
88	Bromodichloromethane	0.010	0.0195
89	Dibromochloromethane	0.0039	0.0078
90	Bromate	0	0
91	Chlorite	0	0

* Units are in mg/L unless stated otherwise

** The 90th percentile combined radium concentration of 6.5 pCi/L is higher than its MCL value of 5 pCi/L

Given the limited and low levels of occurrence for these contaminants and the overall framework of this review, there appear to be opportunities to reduce burden, including the constraints imposed by 42 U.S.C. 300g–1(a)(4) [use of 1996 amendment criteria to eliminate earlier MCLs] and 42 U.S.C. 300g-1(b)(9) [anti-backsliding]).

Recommended Action

AWWA recommends that EPA utilize the data collected through the Six-Year Review process to identify contaminants with *de minimus* occurrence. This review could include evaluating the appropriateness for eliminating specific MCLs, limiting the applicability of the MCL to systems meeting certain criteria (e.g., a risk-based framework like the LT2ESWTR), or revision of the Standard Monitoring Framework. In undertaking this analysis, EPA also has the information gathered in response to 42 U.S.C. 300g-7(b) (permanent chemical monitoring relief).[29] The PCMR analysis conducted in 1997 was intended to address excessive sampling burden, but lacked the breadth of occurrence information available through the subsequent rounds of Six-

[29] EPA, August, 1997, Alternative Monitoring Guidelines, EPA 816-R-97-011

Year Review Information Collection Requests.[30, 31, 32] The resulting alternative monitoring framework prepared through the PCMR effort was not effective because the alternative developed was more challenging to implement than the standard monitoring framework it was intended to simplify.

Unregulated Contaminant Monitoring Rule

The 1996 SDWA amendments provided a mechanism to obtain reliable nationwide occurrence data for contaminants in drinking water.[33] The purpose of the data gathered through the UCMR is to support EPA decisions to regulate (or not) and inform the analysis to determine what standard is appropriate. SDWA requires that EPA develop a monitoring program for 30 or few contaminants every five years:

> *"…The Administrator shall promulgate regulations establishing the criteria for a monitoring program for unregulated contaminants. The regulations shall require monitoring of drinking water supplied by public water systems and shall vary the frequency and schedule for monitoring requirements for systems based on the number of persons served by the system, the source of supply, and the contaminants likely to be found, ensuring that only a representative sample of systems serving 10,000 persons or fewer are required to monitor. …"*

The UCMR construct at present utilizes three "lists."

> List 1 is assessment monitoring, collects data from all water systems serving 10,000 persons or more and a representative sample from smaller systems.
> List 2 is screening survey monitoring, for which data is collected by all systems serving 100,000 persons or more.
> List 3 is pre-screening testing; utilizes a select set of systems based on the contaminant of interest.

List 1 and 2 analytes are monitored at each point of entry (POE) to a water system's distribution system, so a system with multiple wells takes multiple POE samples. Also, POE samples are frequently matched with a distribution system sample, doubling the sample volume. Systems that purchase water wholesale, must also conduct monitoring for most analytes, not just the

[30] EPA, March, 2002, Occurrence Summary and Use Support Document for the Six-Year Review of National Primary Drinking Water Regulations, EPA-815-D-02-006

[31] EPA, March, 2010, Six-Year Review 2 Contaminant Occurrence Data (1998-2005), available May 4, 2017 at https://www.epa.gov/dwsixyearreview/six-year-review-2-contaminant-occurrence-data-1998-2005

[32] EPA, January, 2017, Contaminant Occurrence and Related Data for Six-Year Review of Drinking Water Standards, available May 4, 2017 at https://www.epa.gov/dwsixyearreview/contaminant-occurrence-and-related-data-six-year-review-drinking-water-standards

[33] 42 U.S.C. 300j–4(a); 40 CFR 141.40

systems that treat drinking water. Because UCMR serves a very influential role in the rulemaking process, sample analysis is done by a select set of laboratories.

The construct of UCMR is important because systems serving 10,000 persons or more are responsible for all costs associated with UCMR monitoring (e.g., sampling, analysis, data logging, etc.). Frequently, contaminants are placed on List 1, meaning that all systems are conducting the required monitoring. EPA requires monitoring for the count of allowed analytes, and seeks to minimize the number of different analytical methods required.

While water systems bear the expense of this national monitoring program, the resulting occurrence observations have been quite limited. While modern analytical techniques are capable of detecting things in the low parts per billion and parts per trillion, very few of the observed occurrence levels for most UCMR contaminants are greater than the health benchmark value (e.g., a level calculated much the same as an MCLG or HA).

EPA has adhered to good practice in developing the UCMR in each of the four rounds executed to-date. So, the issue at present is whether the current evaluation presents an opportunity to ask whether it is necessary to collect a census of all large systems and a representative sample of smaller systems to evaluate national occurrence of contaminants that are seldom present at levels of health concern.

Recommended Action

AWWA supports and recognizes the UCMR as an important element of SDWA that supports the development of sound drinking water regulations. Given the historical trend in the UCMR data, we believe the current monitoring scope should be re-evaluated in anticipation of the fifth round of UCMR monitoring. Such a review, could utilize a priority list of target analytes from the Contaminant Candidate List, the factors that affect the occurrence of those analytes in drinking water, and information on available analytical techniques to evaluate a representative sampling strategy for large systems and a revised sampling strategy for small systems that would be successful representing national contaminant occurrence in drinking water but doing so at a lower cost to EPA and water systems.

Appendix A.

AWWA Letter to the EPA Office of Policy on Cyanotoxin Health Advisories

July 2, 2015

American Water Works Association
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July 2, 2015

Ms. Caryl Muellerleile
Office of Policy (1803A)
Attn: Good Guidance Practices
U.S. Environmental Protection Agency
1200 Pennsylvania Ave, NW
Washington, DC 20460

Dear Ms. Muellerleile:

On June 17, 2015, the Federal Register contained the notice *Availability of Health Effects Support Documents and Drinking Water Health Advisories for Cyanobacterial Toxins, etc.* (80 FR 34637-34638).

The American Water Works Association (AWWA) believes that the document titled "Recommendations for Public Water Systems to Manage Cyanotoxins in Drinking Water" (hereafter "Recommendations") constitutes a "Significant Guidance Document" as defined by the Office of Management and Budget January 18, 2007 memo *Final Bulletin for Agency Good Guidance Practices.* To date, EPA has not classified the Recommendations as a Significant Guidance Document. Furthermore, we also believe that the Recommendations also satisfy the classification criteria for an "Economically Significant Guidance Document". We believe that EPA should reissue this guidance after completing the necessary procedures associated with an economically significant guidance document.

It is important to clarify that AWWA and the water sector at large support taking action to address cyanotoxins, and welcome opportunities to collaborate with EPA to address the challenge they pose to public health. We believe that there are many opportunities to address both the causes of cyanotoxins (such as high nutrient loads in water bodies) and to work with the water sector to develop monitoring, treatment, and other strategies needed to address these issues.

AWWA believes that both the process and content used by EPA to prepare the Recommendations are flawed. The process used by EPA to date has lacked transparency, marginalized the opportunity for public review and comment, and failed to satisfy the high

quality standards necessary to support the Agency's actions. Finally, EPA's Recommendations were issued without the full consideration of their feasibility and related issues normally assessed during the significant guidance development process.

Justification for Classification as an Economically Significant Guidance Document

The *Final Bulletin for Agency Good Guidance Practices* lays out "four prongs" of a significant guidance document. If at least one prong is "reasonably anticipated" to be met, the document must be classified as significant. AWWA believes that the Recommendations issued by EPA satisfy at least two of the four prongs:

Prong 1: Lead to an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities

The Recommendations meet several of the criteria in Prong 1. Given EPA's Recommendations regarding the health effects of Microcystins and Cylindrospermopsin, it is reasonable to anticipate that this action will influence the behavior of Public Water Systems (PWSs) and State primacy agencies that will lead to a significant economic effect on a community or set of communities exceeding $100 million per year. It is reasonable to anticipate this economic impact given the Recommendation's direction to issue "do not drink, do not boil" advisories, which result in a use restriction that will simulate a loss of water service. The Recommendations can reasonably be anticipated to affect in a material way local governments and communities served by water systems that comply with the Agency's recommendations

A community, under a "do not drink, do not boil" advisory, will lack or will be perceived to lack access to drinking water for the duration of the advisory. Although the Recommendations include different advisory levels for young children and those at higher risk (elderly, immunocompromised, dialysis patients, etc.) versus healthy adults, we reasonably anticipate that the challenges of risk communication and the broad scope of these groups will result in essentially the entire population following the advisory at the lowest threshold. This will result in the cancellation of planned activities within the community, restaurant and hotel closures, the activation of emergency protocols, challenges to hospitals and nursing homes, and the challenge and cost of securing and distributing alternative water supplies, which can reasonably be anticipated to be approximately the same impact as complete loss of service.

Using the best available data to estimate the value of lost water service we have developed several scenarios to demonstrate that the Recommendations meet the OMB criteria. FEMA's valuation for disruption of water service is $103 per person per day[1], which provides the lower bound projection of the economic impact on the effected community. For comparison purposes,

[1] Federal Emergency Management Agency (2010) Hazard Mitigation Assistance Unified Guidance.

an upper bound value has also been included in the scenario assessments using $220 per person per day[2,3].

Given the low levels of microcystin that trigger a "do not drink, do not boil" advisory based on Recommendations issued by EPA, it can be reasonably anticipated that multiple communities will be impacted annually, resulting in economic impacts that exceed $100 million per year.[4]

Scenario 1: Toledo Incident under New Recommendations

If the new Recommendations issued by EPA had been in place during the 2014 incident in Toledo, OH, available data suggests that a "do not drink, do not boil" advisory (>0.3 µg/l of microcystins) would have lasted at least 7 days within a 19 day window[5]. This single incident would have met the criteria for economic significance.

Scenario 1			
Days Under Advisory	7	**Estimated Economic Impact**	
Population Served	500,000	**Lower**	**Upper**
		$360,500,000	$770,000,000

Scenario 2: Multiple Medium Size Communities

This scenario applies a 5 day "do not drink, do not boil" advisory for a medium size community of 50,000. The result is that 2-4 incidents across the nation will exceed the $100M threshold criteria for economic significance.

Scenario 2			
Days Under Advisory	5	**Estimated Economic Impact**	
Population	50,000	**Lower**	**Upper**
		$25,750,000	$55,000,000
# of Incidents to exceed $100M annually		**4**	**2**

[2] Aubuchon, C.P. and K.M. Morley. 2013. The Economic Value of Water: Providing Confidence and Context to FEMA's Methodology. *Homeland Security & Emergency Management 10:1:1-12.* *http://dx.doi.org/10.1515/jhsem-2012-0081*

[3] FEMA (2010) uses a Standard Value of Water of $93 per person per day ($2008 dollars) in their assessment of Hazard Mitigation Grants. Aubuchon and Morley (2013) provided a sensitivity analysis of the FEMA methodology and found that the mean value of economic impacts was $208 per person per day ($2011). These values assume a complete loss of service during supply disruptions. Both have been adjusted for inflation to 2015 dollars using the BLM inflation calculator (http://www.bls.gov/data/inflation_calculator.htm) on June 23, 2015, and rounded to the nearest dollar.

[4] Estimates of water's value under the advisory conditions in the Recommendations have never been developed by the Agency. While this assessment provides a series of economic impacts based on total loss of service, adjustments to limit the estimate to consumptive loss will still generate a significant economic loss annually if only a small number of communities are impacted.

[5] Ohio EPA. *Harmful Algal Blooms*. See the "Algal toxin results" section at http://epa.ohio.gov/ddagw/HAB.aspx. Accessed 25 June 2015.

Scenario 3: Large Size Communities

This scenario applies a 5 day "do not drink, do not boil" advisory for a large size community of 100,000. The result is that 1-2 incidents across the nation will exceed the $100M threshold criteria for economic significance.

Scenario 3			
Days Under Advisory	5	**Estimated Economic Impact**	
Population	100,000	**Lower**	**Upper**
		$ 51,500,000	$ 110,000,000
# of Incidents to exceed $100M annually		**2**	**1**

Scenario 4: Multiple Communities

This scenario applies a 5 day "do not drink, do not boil" advisory to 10 very small (pop 5,000), 5 small (pop. 20,000) and 1 medium size (pop. 50,000) community of 50,000. The result is that these 16 incidents would exceed the $100M threshold criteria for economic significance.

Scenario 4			
Days Under Advisory	5	**Estimated Economic Impact**	
		Lower	**Upper**
Very Small (10)	5,000	$ 25,750,000	$ 55,000,000
Small (5)	20,000	$ 51,500,000	$ 110,000,000
Medium (1)	50,000	$ 25,750,000	$ 55,000,000
Total		**$ 103,000,000**	**$ 220,000,000**

Five (5) days was chosen as the default for each scenario as a conservative estimate for the time needed to implement changes to drinking water treatment, resample drinking water quality, and confirm a resample per the EPA Recommendations.

These scenarios do not capture the expected costs associated with monitoring and additional treatment (temporary or permanent) that could potentially be installed because of these Recommendations. Several communities are already considering additional treatment and related upgrades in anticipation of these Recommendations. Such monitoring and treatment costs are likely to be very substantial but cannot be approximated at this time without the benefit of the proper EPA significant guidance analysis.

Prong 4: Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in Executive Order 12866, as further amended.

AWWA believes that the Recommendations raise novel policy issues associated with the issuance of Health Advisories (HA) under the Safe Drinking Water Act (42 USC 300g-1(b)(1)(F)). Traditionally, health advisories have been used to describe a potential health issue

with drinking water and to set a level for which there are no known impacts to human health. The HA is then useful for *fostering discussion* within the water sector and to help direct research and future regulatory agendas.

However, in this instance, the Recommendations that accompany the HAs include very specific triggers for when a "do not drink, do not boil" advisory should be issued by a public water system. There is no scientific, regulatory, or other appropriate precedent to recommend this action based on an HA, and EPA has failed to provide a justification in the Recommendations.

Critical Policy Issues

Many of AWWA's concerns were communicated directly to the Office of Water several times between May 11 and June 15, prior to the issuance of the Recommendations on June 17. However, as very little information was available until shortly before EPA's May 11 public meeting, AWWA and the water sector as a whole did not have sufficient opportunity to review and provide comment. Information provided before the Recommendations were released consisted of limited derivative information provided in a press release and several presentations. This information did not address the details found in the final Recommendations. Therefore, we believe the Recommendations document fails to meet the standard of "developed with appropriate review and public participation" as required by OMB and EPA's significant guidance document assessment procedures. The following are several of the critical policy issues that AWWA has identified.

1. *The Recommendations directly and explicitly favor a non-standardized detection method for Microcystins known to have over-reporting and interference issues (ELISA) instead of an approved EPA standard method that has been rigorously tested and is known to meet accuracy standards (LC/MS/MS).* Specifically, Page 24 of the Recommendations states that water systems "analyze finished water samples with a quantitative laboratory ELISA test for total microcystins". It goes on to state that "if a system wants to detect and quantify individual microcystin variants, a more selective method, such a liquid chromatography/tandem mass spectrometry (LC/MS/MS) can be used (recognizing this method does not identify the majority of microcystin congeners and may underestimate the total concentration of microcystins in the sample)". Because the health advisories are based upon a study of Microcystin-LR only, and many microcystin congeners have unknown toxicity (they may have greater, lesser, or no toxicity), we believe that lumping Microcystins together in this fashion, as if they were all of equal toxicity, is not appropriate and is not based upon any scientific source or justification. We believe this assertion fails to meet the standard of "high quality" as required by the OMB good guidance memo and published on EPA's significant guidance document page.

2. *The Recommendations suggest (pages 25-26) a "do not drink / do not boil" advisory for either children below school age or for everyone (depending on concentration) within 24 hours based upon one confirmed sample above the relevant threshold, a timeframe which is*

incongruent with the health advisories themselves. The health advisories (described in detail in other documents in this suite) specifically indicate that they are toxicologically relevant for 10 days of exposure, not for any period of time shorter than that. EPA does not provide any scientific justification for why the action timeframe is different than the advisory timeframe, nor does it provide any scientific justification as to why the default remedy for an exceedance is a "do not drink / do not boil" advisory, rather than any of the many other remedies available to the sector and currently in use in standard practice and in regulatory constructs. Several states have already announced that they will be using EPA's Recommendations, either directly or through a similar derivation, as a required "not to exceed" level that will be enforced on the state level. Therefore, we believe these assertions fail to meet both the standard of "high quality" and the standard of "not improperly treated as legally binding requirements" as required by the OMB good guidance memo and published on EPA's significant guidance document page.

3. *EPA recommends (page 26) "for PWSs where source waters have public access for recreation, the system's notice may include statements about recreational use of waters with cyanobacterial blooms to prevent exposure of humans and animals to cyanotoxins."* The following sentence then states that EPA has not yet developed any advisory levels for recreational waters, and therefore it is unclear what message EPA expects drinking water systems to send and under what circumstances. In many cases the PWS has neither control nor any authority over source waters, and does not have the authority to close or alter recreation in those areas, and we believe a blanket recommendation like this places an inappropriate burden on and sets an inappropriate standard for water systems in general. A public review would have identified this issue, and we believe this provides a clear example of the Agency's failure to develop the Recommendations with "appropriate review and public participation" and to meet the standard of "high quality" as required by the OMB good guidance memo and published on EPA's significant guidance document page.

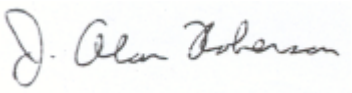
4. *The Recommendations include (page 21) a table about the chlorine contact times to reduce microcystin-LR concentration to 1 µg/L under various scenarios. Based upon the HAs and the rest of the Recommendations, this is the wrong compound and points to the wrong target concentration*. This table is misleading and confusing in its present form, because the health advisories (and all of the Recommendations) refer to total Microcystins (not Microcystin-LR) and to reducing concentration to either 0.3 µg/L or 1.6 µg/L (depending on which threshold). We believe this section fails to meet the standard of "high quality" as required by the OMB good guidance memo and published on EPA's significant guidance document page. And again, this problem would have been identified to the Agency if there had been "appropriate review and public participation."

As previously stated, AWWA believes that a thorough, participatory stakeholder process will reveal other scientific, technical, process, policy, and similar concerns with the Recommendations, as well as additional details on the concerns noted above. In order to assure that these important questions do not remain unanswered, we hereby request that the

Recommendations be classified as an Economically Significant Guidance Document and EPA reissue this guidance in accordance with the procedures required for such a document.

We look forward to hearing from you soon, and we welcome your questions and feedback. Please feel to call me or Adam Carpenter at 202-628-8303 if you have any questions about this request.

Yours Sincerely,



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