



May 14, 2020

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency

Re: Docket ID: EPA-HQ-OA-2018-0259, *Strengthening Transparency in Regulatory Science*

Dear Administrator Wheeler,

The Association of Metropolitan Water Agencies (AMWA) is an organization representing the largest publicly owned drinking water utilities in the United States. Any changes in how the agency promulgates significant regulatory decisions or influential scientific information, particularly regarding national primary drinking water regulations, health advisories, and guidance, significantly impact our members. EPA has published a supplemental notice of proposed rulemaking: *Strengthening Transparency in Regulatory Science* published in the Federal Register on March 18, 2020. AMWA first engaged EPA regarding the proposed rule in our first set of comments, submitted to the docket August 15, 2018ⁱ. AMWA again applauds EPA’s goal to strengthen transparency and supports this objective whenever possible. The association reiterates the importance of increasing transparency in concert with actions that are protective of public health and the environment. The association has reviewed the supplemental notice and is happy to provide additional feedback.

AMWA appreciates EPA’s work to clarify the proposed rulemaking, as the agency’s initial proposal was too vague and missing key components, which would have made it difficult to understand and to put into practice. AMWA would like to thank the agency for adding and clarifying many definitions for key terms within the supplemental notice. These modifications to the proposal are critical in assuring any final rule is implementable and defensible.

To further clarify certain components of this rule, AMWA encourages EPA to follow the advice outlined in the Science Advisory Board’s April 24, 2020 commentsⁱⁱ to EPA suggesting the agency develop a guidance document before implementing the final rule. AMWA agrees with the board’s suggestion to include further context for the definitions included within both the proposal and supplemental notice and that it “may be beneficial for EPA to develop a guidance document with case studies based on past risk assessments to clarify some scenarios and how the requirement to make data and models publicly available in a manner sufficient for independent validation would be managed (p. 13).” AMWA supports the SAB’s recommendation that EPA

BOARD OF DIRECTORS

PRESIDENT

Steve Schneider
Saint Paul Regional Water
Services

Mike Armstrong
WaterOne

Richard Harasick
Los Angeles Department of
Water and Power

Ron Lovan
Northern Kentucky Water
District

VICE PRESIDENT

Angela Licata
New York City Department of
Environmental Protection

Shane Chapman
Metropolitan Water District of
Southern California

Robert Hunter
Municipal Water District of
Orange County

Sue McCormick
Great Lakes Water Authority

TREASURER

John Entsminger
Las Vegas Valley Water
District

Robert L. Davis
Cleveland Department of Public
Utilities

Ghassan Korban
New Orleans Water and Sewer
Board

Jeffrey Szabo
Suffolk County Water Authority

SECRETARY

Kathryn Sorensen
Phoenix Water Services

Scott Dewhurst
Tacoma Water

Carrie Lewis
Portland Water District

John P. Sullivan, Jr.
Boston Water and Sewer
Commission

**CHIEF EXECUTIVE
OFFICER**

Diane VanDe Hei

Steve Edgemon
Fairfax Water

James S. Lochhead
Denver Water

Douglas Yoder
Miami-Dade Water and Sewer
Department

Yvonne Forrest
Houston Public Utilities
Division

“consider seeking input from experts in library science, data curation management, and data retention to identify best practices and tools to ensure efficiency and utility of data that are made available (p. 14).”

AMWA supports EPA’s proposed alternative approach for addressing data when promulgating significant regulatory decisions or finalizing influential scientific information: “[with] other things being equal, the Agency will give greater consideration to studies where the underlying data and models are available in a manner sufficient for independent validation either because they are publicly available or because they are available through tiered access when the data includes CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects (85 FR 15399).”

This alternative approach will give the agency appropriate flexibility when implementing this new policy. As stated in AMWA’s 2018 comments, EPA should refrain from banning all studies from being utilized within the regulatory process solely due to data availability. For data that is not produced by EPA, such as data used for studies, which have been published in scientific journals, the process of peer reviewing may often be sufficient. As EPA notes in the supplemental notice, raw data may not be available for a variety of reasons including privacy, age of the data, etc. This proposed alternative will ensure that EPA is in a position to use all available data to inform the agency’s decision-making process. AMWA also supports EPA’s suggestion that the agency would provide a short description of why greater consideration was given to a particular study or data set. This will help to ensure the greater transparency that this proposal aims to promote.

AMWA appreciates EPA’s clarification and modification of the scope for exemptions granted by the Administrator to include instances where data may not be available due to technological barriers, such as the age of the data, models, or computer codes used. AMWA would like to specifically bring attention to EPA’s suggestion to remove the provision allowing the Administrator to grant exemptions from the rule on a case-by-case basis if he or she determines that compliance is impracticable because it is not feasible to conduct independent peer review on all pivotal regulatory science. AMWA suggests EPA maintain this provision to maximize the flexibility for the implementation of this rule. AMWA agrees with the SAB’s suggestion that the agency “develop specific criteria for such exceptions as part of the Final Rule” and that “outlining such criteria would benefit EPA and help ensure that the principles of transparency outlined in the Proposed Rule are accomplished (p. 16).” Reiterating our comments above, EPA should strive to ensure all applicable and reliable data is used to make informed regulatory decisions.

Finally, AMWA would like to reiterate the association’s 2018 comments that, regardless of the components of the final rule, EPA should seek to phase-in whatever requirements are justified to allow for sufficient time to respond and prepare for the implications of this rule. This rule should also not apply to the previous record. Trying to apply this proposal to models, rules, and research that has already begun or has concluded would only serve to set current work back and

complicate work already done. It makes sense to “grandfather” what has already been completed and to implement this rule in stages in order to not compromise or delay EPA’s work.

AMWA thanks EPA for the opportunity to provide further input on such an important rulemaking. If you would like to further discuss our concerns, please call Stephanie Hayes Schlea, Director of Regulatory and Scientific Affairs, at 202-331-2820.

Sincerely,



Diane VanDe Hei
Chief Executive Officer
Association of Metropolitan Water Agencies

cc: David Ross, Assistant Administrator for Water
Jennifer McLain, Director, Office of Ground Water and Drinking Water

ⁱ Association of Metropolitan Water Agencies. 2018. AMWA Comment Letter, Docket ID #: EPA-HQ-OA-2018-0259-6875

ⁱⁱ [Environmental Protection Agency’s Science Advisory Board. Consideration of the Scientific and Technical Basis of EPA’s Proposed Rule Titled Strengthening Transparency in Regulatory Science.](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf) (2020, April 24). Retrieved from [https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/\\$File/EPA-SAB-20-005.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf)