Wed Aug 15 15:03:49 EDT 2018
CMS.OEX@epamail.epa.gov
FW: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259
To: "cms.oex@domino.epamail.epa.gov" <cms.oex@domino.epamail.epa.gov>

From: Hope, Brian
Sent: Wednesday, August 15, 2018 7:03:47 PM (UTC+00:00) Monrovia, Reykjavik
To: CMS.OEX
Subject: FW: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259

DRF

From: Stephanie Hayes Schlea [mailto:schlea@amwa.net]
Sent: Wednesday, August 15, 2018 2:27 PM
To: Wheeler, Andrew <wheeler.andrew@epa.gov>
Cc: Ross, David P <ross.davidp@epa.gov>; Grevatt, Peter <Grevatt.Peter@epa.gov>
Subject: AMWA Comment Letter for Docket EPA-HQ-OA-2018-0259

On behalf of the Association of Metropolitan Water Agencies, please find attached the comment letter regarding EPA's proposed rule, *Strengthening Transparency in Regulatory Science* (EPA-HQ-OA-2018-0259).

Stephanie Hayes Schlea
Manager, Regulatory and Scientific Affairs
Association of Metropolitan Water Agencies
Office: 202.331.2820
1620 I Street NW Suite 500
Washington, DC 20006
http://www.amwa.net/

ASSOCIATION OF
METROPOLITAN
WATER AGENCIES

LEADERS IN WATER

1620 I Street, NW, Suite 500
Washington, DC 20006

P 202.331.2820 F 202.785.1845
amwa.net

August 15, 2018

The Honorable Andrew Wheeler
Acting Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N. W.
Washington, DC 20460

Re: Docket No. EPA-HQ-OA-2018-0259, *Strengthening Transparency in Regulatory Science*

Dear Acting Administrator Wheeler,

The Association of Metropolitan Agencies (AMWA) is an organization representing the largest publicly owned drinking water utilities in the United States. Any changes in how the agency formulates rulemakings, particularly in regards to national primary drinking water regulations, significantly impact our members. EPA has published a request for comment on the proposed rule: *Strengthening Transparency in Regulatory Science* published in the *Federal Register* on April 30. AMWA applauds EPA's goal to strengthen transparency and supports this objective whenever possible, but would like to emphasize that increasing transparency in concert with the development of regulations, health advisories and guidance that protect public health and the environment is particularly important.

While EPA's objective to increase transparency is commendable, and AMWA appreciates the opportunity to provide feedback and strengthen the final rule, the current proposal is far too vague and missing key components that must be included in the final rule to ensure its understandability and appropriate implementation. For example, currently the proposal lacks definitions for many key terms, omits critical protocols and methodologies necessary to put this rule into action, and does not fully explore the implications of implementing a rule of this nature.

However, due to the importance of this proposed rule, AMWA is pleased to submit these comments for EPA's consideration. Our specific comments are provided as an attachment. If you have any questions, please contact Stephanie Hayes Schlea (schlea@amwa.net), AMWA's Manager of Regulatory and Scientific Affairs.

Sincerely,

Diane VanDe Hei
Chief Executive Officer

Attachment

cc: David Ross, Assistant Administrator for Water
Peter Grevatt, Director, Office of Ground Water and Drinking Water

BOARD OF DIRECTORS

PRESIDENT
Mac Underwood
Birmingham Water Works Board

VICE PRESIDENT
Steve Schneider
Saint Paul Regional Water Services

TREASURER
Angela Licata
New York City DEP

SECRETARY
John Entsminger
Las Vegas Valley Water District

Jerry Brown
Contra Costa Water District

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

Rudolph Chow
Baltimore City Department of Public Works

Robert L. Davis
Cleveland Department of Public Utilities

Kevin Gertig
Fort Collins Utilities

Julia J. Hunt
Trinity River Authority of Texas

Robert Hunter
Municipal Water District of Orange County

Carrie Lewis
Portland Water District

James S. Lochhead
Denver Water Department

Ron Lovan
Northern Kentucky Water District

Sue McCormick
Great Lakes Water Authority

J. Brett Jokela
Anchorage Water & Wastewater Utility

Charles M. Murray
Fairfax Water

William Stowe
Des Moines Water Works

Kathryn Sorensen
Phoenix Water Services

Jeffrey Szabo
Suffolk County Water Authority

Douglas Yoder
Miami-Dade Water and Sewer Department

CHIEF EXECUTIVE OFFICER
Diane VanDe Hei

General

1. AMWA agrees that any data, methodology, or models produced by EPA itself should be transparent and available to the public in a reproducible manner.
2. EPA should refrain from banning all studies from being used in the regulatory process solely due to data availability. For data that is not produced by EPA, such as in scientific journals, and particularly when dealing with sensitive data, the process of peer reviewing should often be sufficient. If multiple studies have gone through the peer review process and have come to the same conclusions, the agency should not disregard these findings simply because the raw data is not available. Raw data may not be available for a variety of reasons including privacy, age of the data, or due to a researcher's reluctance to share this information. However, an open process for justifying the use of data that is not public should be developed.
3. AMWA also encourages EPA to not base any regulatory determination on a single study, regardless of whether or not the data is publicly available. Relying on a single study, no matter how robust it may be, can bring bias to a model or regulatory decision. If EPA must base a decision off of a single study, it should be imperative that the data be publicly available as well as the reasoning and methodology behind why the study was chosen, how it is being used and why no other studies were deemed sufficient to be included.
4. EPA released a document titled *Plan to Increase Access to Results of EPA - Funded Scientific Research* in 2016 in response to a 2013 memo released by the White House Office of Science and Technology Policy (OSTP)[1]. The memorandum entitled "Increasing Access to the Results of Federally Funded Scientific Research" directs Federal departments and agencies that spend more than $100 million per year on research and development (R&D) to develop and submit a plan to OSTP to increase public access to peer-reviewed, scientific research publications and research data resulting from agency-funded R&D.[2] What is the status of this plan and what does this rule cover that this document does not regarding data funded and produced by EPA?

Definitions and Clarifications

1. According to Goodman, Fanelli, and Ioannidis (2016)[3], there is no scientific consensus for what "methodologically reproducible" is. If EPA wants to build a rule around transparency in regards to methodology, "methodologically reproducible" must be defined.

---

[1] Office of Science and Technology Policy, Executive Office of the President. (2013, February 22). Memorandum for the Heads of Executive Departments and Agencies: Increasing Access to the Results of Federally Funded Research. Retrieved from https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf

[2] Environmental Protection Agency. (2016). Plan to Increase Access to Results of EPA - Funded Scientific Research Version 1.1.

[3] Goodman, S.N., Fanelli, D., & Ioannidis, J.P.A. (2016). What does research reproducibility mean? *Science Translational Medicine*. *8*(341). pp. 1-6.

2. If the agency wants a rule focused on the raw data then EPA must better define what "data" would be included within this rule. Is it just data produced by EPA? If not, is it the methods and protocols or the actual raw data?
3. There are multiple terms that will need to be defined in the final rule. In particular, "transparency"; "data", singular versus set; and "reasonable effort/endeavor", in relation to how much work the agency must put in before justifying the use of data that can not be made available to the public.
4. EPA should also clarify what it considers to be "publicly available". A significant number of journals require a subscription or payment in order to read their articles. Does EPA consider these studies publicly available?

Methodologies and Protocols

5. EPA's proposal states, "EPA believes that concerns about access to confidential or private information can, in many cases, be addressed though the application of solutions commonly in use across some parts of the federal government." While this is reassuring, it is important that the agency outline a clear protocol that is transparent and clear and should solicit public comment on this protocol before implementing it agency-wide.
6. In an EPA news release the agency states, "[The] proposed rule is in line with the scientific community's moves toward increased data sharing…[and] is consistent with data access requirements for major scientific journals like *Science, Nature*, and *Proceedings of the National Academy of Sciences*[4]." However, those same journals have written a joint statement responding to the proposal and support "maintaining the rigor of research published in our journals and increasing transparency regarding the evidence on which conclusions are based", but caution stating, "It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes[5]." AMWA encourages EPA to consult with entities, including the journals that EPA references, that have implemented similar efforts in order to better inform the methods and protocols that should be in place for a rule of this nature.
7. Related to this, the proposed rule and Lutter and Zorn[6] (2016), which is cited in the proposal, both discuss current publishers and journals, which require authors to submit their data to public repositories. EPA should work to encourage the continuation of this, as well as

---

[4] Environmental Protection Agency Press Office, Office of the Administrator. (2010, April 24). *EPA Administrator Pruitt Proposes Rule To Strengthen Science Used In EPA Regulations*. [Press Release]. Retrieved from https://www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations

[5] Berg, J., Campbell, P., Kiermer, V., Raikhel, N., & Sweet, D. (2018, April 30). *Science*. Retrieved from http://science.sciencemag.org/content/early/2018/04/30/science.aau0116

[6] Lutter, R., & Zorn, D. (2016). On the Benefits and Costs of Public Access to Data Used to Support Federal Policy Making. Mercatus Working Paper. Accessed from https://www.mercatus.org/system/files/Mercatus-Lutter-Public-Access-Data-v3.pdf July 12, 2018.

considering giving preference, when possible, to studies where the data is publicly available in this manner.

8. Allowing for exemptions in a rule of this nature is useful and allows for flexibility within the implementation. However, regardless of when or how the Administrator is able to exempt significant regulatory decisions on a case-by-case basis, there should be explicit and clear expectations for what may or may not qualify for an exemption. Does the exemption cover the agency's project as a whole or just a single study and/or data set? Decisions to allow an exemption should be transparent and made available to the public.

Application

1. EPA's proposal states that it is looking for comment on how to make more data and models used throughout the agency's regulatory process available to the public "over time". AMWA agrees with the idea that, regardless of the strategy used, EPA should seek to phase-in whatever requirements are justified. The agency should note that the scientific community has just recently begun data access requirements. For example, EPA's proposal cites the journal PLOS ONE as informing the development of the rule's policies. However, this journal has only been requiring this open data since 2013[7]. Therefore, while the scientific community has been moving towards the idea of "open science", the policies are still new and phasing in requirements would give the scientific community sufficient time to respond and prepare for the implications of this rule. EPA would need to ensure that there are explicit and clear milestones to be achieved throughout the process.
2. This rule should 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.
3. In order for full transparency, the finished rule should apply to all stages of regulatory development. This would include full transparency in the methods, particularly in the development of models. The public does not need the individual data in order to determine if there are inherent issues within the study itself. The analysis of the data is already done multiple times throughout the publication process, via peer review. While it is useful to have the data EPA uses, it is perhaps more important to understand the methodology and reasoning behind why EPA chooses the data it does. In order to increase transparency it would be important to have the agency give a thorough explanation as to why certain studies and data sets were chosen and not others, rather than relying on public access to the individual data.

[7] PLOS ONE. Data Availability. Accessed from http://journals.plos.org/plosone/s/data-availability#loc-acceptable-data-sharing-methods