



**American Water Works
Association**

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Government Affairs Office
1300 Eye Street NW
Suite 701W
Washington, DC 20005-3314
T 202.628.8303
F 202.628.2846

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Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Ave NW
Washington, DC 20460

Re: Comments on *Strengthening Transparency in Regulatory Science* (EPA-HQ-OA-2018-0259)

Dear Mr. Sinks:

The American Water Works Association (AWWA) appreciates the opportunity to comment on the advanced notice of proposed rulemaking titled “Strengthening Transparency in Regulatory Science,” published in the Federal Register on April 30, 2018. AWWA supports transparency in all Environmental Protection Agency actions (both regulatory and non-regulatory), including the data and information used to inform EPA decision-making. In taking steps to improve the transparency of current EPA rulemaking processes, it is important that the Agency address the following: EPA’s statutory obligations, transparency of influential (pivotal) decision-making processes, and the public and business communities’ right to privacy.

EPA must meet statutory requirements

The Safe Drinking Water Act requires that regulatory decisions be based upon “(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).” (Sec. 1412 (b)(3)(A)). Other environmental statutes have similar provisions. Should EPA finalize the “Strengthening Transparency in Regulatory Science” rule, the Agency must meet this statutory obligation with respect to setting regulatory requirements under SDWA, and EPA must assure that the rule does not interfere with the use of the best available science. EPA is required to utilize the best available science whenever the Agency makes a regulatory decision. EPA clearly contemplated using the “best available science” even when the underlying data was not publicly available (i.e., proposed §30.9). This provision may be used extensively as the research community transitions to meet new expectations for data access and transparency from scientific journals, funding organizations, and government agencies. How determinations under this section would be made warrants an extensive discussion with stakeholders so that the Agency has a full understanding of how to best utilize this embedded discretionary authority.

AWWA has long requested transparency in EPA decisions

AWWA has commented previously on numerous regulatory actions and policy decisions, requesting greater transparency in EPA's decision-making process. How EPA decides which studies and models to utilize, what assumptions or safety factors to incorporate, and which data is of adequate quality to support decision-making is critical to science-based decision-making. Section 30.1 of the proposed rule clearly speaks to this need, "*... ensure that the regulatory science underlying its actions is publicly available in a manner sufficient for independent validation.*"

To illustrate the importance of transparency within EPA's process, we have reviewed prior comments for examples. Attachment A includes a partial list of instances where greater transparency in EPA's decision-making process would have informed interested stakeholders and facilitated more effective information exchange.

AWWA recommends that EPA refocus the proposal on transparency in decision-making broadly, as openness and reproducibility of key influential decision points in a regulatory analysis can be much more significant than the availability of individual data points. Again, the experience of the engaged stakeholder community in a discussion of how to best focus efforts to improve transparency in Agency decision-making would be most effectively gathered through a collaborative stakeholder process.

EPA's own research

One way EPA could increase transparency in its decisions would be to focus on setting standards for the public disclosure of its own research and models. Currently, Agency staff seek to verify the quality of their work through publication in peer-reviewed journals and through small-group, peer-review processes. What is often lacking is the reproduction of model decision logic and external user testing of Agency models. By setting an appropriate 'high bar' for transparency in its own data and processes, EPA can be an example to others whose research is conducted elsewhere.

Evolving open data access policies

Open data access principles are increasingly an expected element of modern research. Investigators, whether funded by federal agencies or by private philanthropic organizations, such as the Bill and Melinda Gates Foundation, have clear expectations for open access to final data from the research they fund.^{1,ii} There is likewise a growing expectation for open data access in the peer-review, scientific publication process. However, open access policy is still maturing. In 2013, the federal emphasis was on simple public access to published research results. Today, open access repositories for actual data from research studies are becoming more common. Importantly, practices are evolving at different speeds in different research disciplines. Different fields of study face different data constraints, that is, the form (e.g., numeric, image, etc.), volume (e.g. megabytes, terabytes, etc.), utility, and protected status (e.g., personal or business confidential information) of the data researchers generate. Not unimportant is the level of funding available to support research; some fields are lucky to have funding to support essential work, while other topics receive a continuous and substantial funding stream that can support ancillary research infrastructure, such as data systems to support open access to data.

As open access principles will take years to fully integrate into practice, EPA will need to (1) apply reasonable expectations for data availability from historical studies given accepted practice at the time, (2) determine how it will assess research from projects that are underway now as EPA itself is changing its policies, and (3) set achievable expectations appropriate to different fields of research given unique constraints during the transition process. Given past Office of Management and Budget guidelines and the historic focus on peer-review not only at EPA but in scientific research broadly, EPA will need to rely heavily on peer-review rather than public access to underlying datasets for many key science-policy decisions for the immediately foreseeable future. As mentioned above, this emphasizes the need for EPA to engage stakeholders in a productive dialogue on how to implement this policy, including how to transition from current practice to the new policy.

Stakeholder engagement

AWWA sought an extension to the comment period for this notice in order to provide useful insights on the proposed rule. Providing recommendations on this proposal was difficult. The proposal, is worded in very broad terms and is not accompanied by any supporting guidelines to inform detailed evaluation. For example, proposed §30.9 provides for EPA Administrator authority to exempt research studies from the public data requirements on a case-by-case basis. The docket does not include documentation describing the protocol EPA would follow or factors that are critical for making such a decision under this section.

AWWA strongly supports using the best science to support regulatory decisions. Decisions intended to assure public health and safety require a high standard of care. It is also prudent to be sure that limited Agency and stakeholder resources are applied effectively. Toward that end, the proposed rule was not accompanied by an analysis of the costs and associated benefits of the proposed policy change. Preparing a clear description of how the new policy would be implemented would provide a basis for evaluation of implementation costs and hurdles both for EPA and those effected by the rule requirements. With this assessment in hand, it would be possible on at least a qualitative basis to describe the associated cost-benefit.

AWWA strongly recommends that EPA engage stakeholders to discuss how to best implement, and as necessary, refine this proposed rule prior to publishing a final rule. The quality of the science used to support EPA decisions is one of the most important organizational principles underpinning the soundness of Agency rules and the Agency's credibility. At present, AWWA, and likely many other stakeholders, do not understand how the proposed rule would in fact be implemented. This lack of clarity is best resolved before EPA finalizes the rule.

We appreciate the opportunity to provide comment on this matter. Please feel free to contact myself or Adam Carpenter at AWWA (202-628-8303, acarpenter@awwa.org) if you have any questions regarding these comments.

Respectfully,



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

cc: David Ross, OW
Peter Grevatt, OW/OGWDW
Andrew Sawyers, OW/OWM
Jennifer Orme-Zavaleta, ORD
Eric Burneson, OW/OGWDW

Attachments: 1

About AWWA: AWWA is an international, nonprofit, scientific and educational society dedicated to providing total water solutions assuring the effective management of water. Founding 1881, the Association is the largest organization of water supply professionals in the world. Our membership includes nearly 4,200 utilities that supply roughly 80 percent of the nation's drinking water and treat almost half of the nation's wastewater. Our over 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.

¹ 2011, Bill & Melinda Gates Foundation's Data Access Principles.
<https://docs.gatesfoundation.org/documents/faq.pdf>.

¹ 2013, Increasing Access to the Results of Federally Funded Scientific Research,
https://obamawhitehouse.archives.gov/sites/default/files/microsites/ostp/ostp_public_access_memo_2013.pdf.

Attachment A. Prior AWWA Comments Noting the Importance of Transparency

Date	Docket or Comment Link	Subject	Description
12/08/2017	EPA-HQ-OW-2015-0714-0010	Verbal comment to National Drinking Water Advisory Council	States that health advisories should be developed to meet transparency and other requirements of "economically significant guidance documents"
11/20/2017	EPA-HQ-OW-2016-0438	Perchlorate Maximum Contaminant Level Goal	Noted that the instructions for running the model referenced in this process were insufficient to reproduce and lacked rationale on the parameter values used
10/31/2017	EPA-HQ-OA-2017-0533	EPA 2018-2022 Strategic plan	Welcomes EPA's commitment to transparency in Objective 2.2
10/06/2017	EPA-HQ-OW-2016-0439	Perchlorate peer-review	Requests that peer-reviewers for perchlorate peer review panel be provided with all comments on charge questions for adequate transparency
03/14/2017	EPA-HQ-OW-2016-0715	Water Quality Criteria for Microcystins and Cylindrospermopsin	References 2015 AWWA letter to EPA Office of Policy on the need for transparency in health advisories by using "significant guidance" methodology
02/09/2016	EPA-HQ-OW-2015-0218	Unregulated Contaminant Monitoring Rule 4	Indicated that important portions of rule scope lacked transparency by being in footnotes
08/18/2014	EPA-HQ-OPPT-2011-1019	ANPR on Hydraulic Fracturing Chemicals and Mixtures in TSCA	Requests a transparent database of hydraulic fracturing chemicals and mixtures in response to ANPR
07/10/2012	Letter to SAB (no docket)	SAB Panel on Perchlorate	States that EPA limited time for public input at past perchlorate meetings prevented appropriate transparency with the public and among SAB members
03/09/2012	Letter to Administrator (no docket)	Release of Non-OCA data	States that EPA's current practice (as of writing) strikes an appropriate balance between transparency and security in non-OCA data, and discourages publication online
01/27/2012	EPA-HQ-ORD-2011-0895	Ground Water Investigation, Pavilion WY	Requests transparency in EPA study results and transparency in hydraulic fracturing chemicals
09/06/2011	Letter to Office of Science Advisory (no docket)	Scientific Integrity Policy	States that the EPA should explain how it will promote public access to EPA information and that EPA should not

Date	Docket or Comment Link	Subject	Description
			use draft status as a reason to withhold data and information
05/02/2011	EPA-HQ-OW-2009-0090-0080	UCMR3 Notice	Summarized lack of transparency in the "Technical Basis for the Lowest Concentration Minimum Reporting Level (LCMRL) Calculator," used to set UCMR3 MRLs; References prior AWWA comment on the lack of transparency in why groups of compounds were included in the UCMR3 over others that were on the CCL3
11/09/2010	EPA-HQ-OW-2010-068	2011 Drinking Water Infrastructure Needs Survey Agency Collection	States that more transparency in use of information was needed to justify certain information EPA requested in the survey to utilities
07/07/2009	Letter to Administrator (no docket)	Guidelines for Preparing Economic Analyses	Summarizes issues with past EPA Economic Analyses, including lack of both key citations and listing results from intermediate steps
06/09/2009	Letter to SAB Committee (no docket)	Revised Total Coliform Rule	States that transparency in the cost-benefit analysis of the RTCR should include describing underlying and simplifying assumptions
06/01/2009	Letter to SAB Committee (no docket)	Science Integration for Decision Making	Summarizes issues with past EPA Economic Analyses, including lack of both key citations and listing results from intermediate steps
04/17/2009	Letter to Assistant Administrator ORD (no docket)	IRIS Evaluation of Inorganic Arsenic	Requests that the EPA provide opportunity for public comment, engage the Science Advisory Board, and allow for internal review of the arsenic risk assessment to increase transparency
03/16/2009	Letter to OIRA OMB (no docket)	Federal Regulatory Review	States support for EPA's use of transparency and reproducibility in the regulatory process, including transparency in methods, stakeholder communication, and cost-benefit analyses

Date	Docket or Comment Link	Subject	Description
05/21/2008	EPA-HQ-OW-2007-1189	CCL 3 Draft	Notes that the CCL docket's length relative to the comment period, lack of post-scoring by outside experts, and lack of justification for changing of some scores does not contribute to transparency; suggests all materials used for CCL3 be publicly available in docket and suggests a document in the docket with listed experts will increase transparency
07/02/2007	EPA-HQ-OW-2007-0068-016	Regulatory Determinations Regarding Contaminants on CCL 2	States that EPA needs to raise the level of transparency in decision logic for regulatory determinations
06/11/2007	EPA-HQ-OW-2006-0958	Expedited Approval of Test Procedures	Recommends the EPA provide for peer-review and comment opportunities in its expedited method approval process
06/11/2007	Letter to OIRA OMB (no docket)	OMB Cost Benefit Regulations	Identified transparency issues with LT2 Rule economic analysis, including obscurity of presentation and model assumptions, and with EPA's use and analysis of ICR Data in the Stage 2 DBP Rule
03/12/2007	OMB-2007-0003-0001	OMB Report on Costs and Benefits of Federal Regulations	States that EPA should clearly state the intermediate results of a CBA estimation
06/21/2005	Letter to OIRA OMB (no docket)	Draft 2005 Report to Congress on the Costs and Benefits of Federal Regulations	Summarizes issues with past EPA Economic Analyses, including lack of both key citations and listing results from intermediate steps
06/23/2004	EPA-HQ-ORD-2004-0004-0016	Examination of EPA Risk Assessment Principles and Practices	States that EPA should reveal quantitative impacts of its assumptions on risk outcomes to be transparent
06/01/2004	EPA-HQ-OW-2003-0028-0020	CCL 2 Notice	States that use of expert judgment to automate contaminants should be documented
01/09/2004	EPA-HQ-OW-2002-0039-0562	LT2 Enhanced Surface Water Treatment Rule	Identified transparency issues with LT2 Rule economic analysis, including obscurity of presentation and model assumption and lack of approaches and results for r estimates used in the analysis

Date	Docket or Comment Link	Subject	Description
07/16/2003	EPA-HQ-OW-2003-0013-0011	Information Collection Request (ICR)	States EPA's methods for determining distribution of utilities required to prepare a emergency response plan and for determining how CWS burden costs were offset by grant money lacked transparency
02/03/2003	Letter to OIRA OMB (no docket)	Draft 2003 Report to Congress on the Costs and Benefits of Federal Regulations	Summarizes issues with past EPA Economic Analyses, including lack of both key citations and listing results from intermediate steps
08/02/2002	EPA-HQ-OW-2002-0021	Priority Contaminants for CCL	States that the EPA decision process and relevant criteria for narrowing the CCL was not transparent
07/03/2002	EPA-HQ-OPP-2002-0026-0001	Revised Human Health Risk Assessment for Atrazine	Indicated that lack of access to monitoring program data for review by the EPA prevented full public review
06/17/2002	EPA-HQ-OW-2002-0012	2002 Results of EPA's Review of Existing Drinking Water Standards	States that tables essential to understanding the agency's decision logic should be made available in the Federal Register notice and that summary of the Bayesian analysis was inadequate
05/28/2002	Letter to OIRA OMB (no docket)	Draft 2002 Report to Congress on the Costs and Benefits of Federal Regulations	States that data quality reviews are a more transparent avenue to address EPA's analyses than public comments
03/28/2002	Letter to NCEA (no docket)	Perchlorate Environmental Contamination: Toxicological Review Draft	States more transparency in risk characterization required more thorough explanation of diet in toxicological studies
10/31/2001	EPA-HQ-OW-2001-0001	NRDWR: Arsenic	Recommends EPA present information in reproducible, transparent methods in Notice of Data Availability on upcoming arsenic regulation
08/15/2001	Letter to OIRA OMB (no docket)	2001 Draft Report to Congress on the Costs and Benefits of Federal Regulations	States OMB should ensure the EPA follow CBA guidelines, including transparency, full disclosure, and replicability in CBAs
12/31/2000	EPA-HQ-OW-2001-0001-0096	NPDRWR: Radon-222	Identified transparency issues, including lack of consistency in concepts applied in the CBA of the radon rule

Date	Docket or Comment Link	Subject	Description
08/09/2000	EPA-HQ-OW-2002-0043-0020	NPDWR: Ground Water Rule	States that EPA was not transparent in failing to provide a GWR workshop summary to stakeholders and that the Regulatory Impact Analysis (RIA) was not clear in describing methodologies
06/09/2000	EPA-HQ-OW-2002-0008-0001	NPDWR: LT1 Enhanced Surface Water Treatment and Filter Backwash Recycle Rule	States that the Regulatory Impact Analysis (RIA) had critical inconsistencies in approach and methodologies
01/31/2000	EPA-HQ-OPP-2000-00625	OPP Policy Issues Papers Related to the Food Quality Protection Act	States that the EPA should be transparent by defining strategies and methodologies used for estimating aggregate exposure and risk assessment
04/12/1999	EPA-HQ-OW-2002-0046-0001	Radon in Drinking Water Health Risk Reduction and Cost Analysis (HRRCA)	Requests that the certain support documents be released before the proposed rule so that HRRCA could be reviewed
09/15/1998	Letter to the Tolerance Reassessment Committee (no docket)	Tolerance Reassessment Advisory Committee	States support for EPA's transparency in EPA's process on tolerance assessment and determining individual pesticide tolerances