

August 16, 2018

Filed Electronically Via www.regulations.gov

U.S. Environmental Protection Agency
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460.

Attention: Docket ID No. EPA-HQ-OA-2018-0259

Re: Comments on EPA's Proposed Rule Strengthening Transparency in Regulatory Science

Dear Sir or Madam:

Please accept and docket the attached Comments of the Utility Water Act Group (UWAG) in response to EPA's Request for Comment on *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768 (April 30, 2018)

Should you have any questions, please call me at (804) 783-7145.

Sincerely,

-s-

Penny A. Shamblin

Attachment



**Comments of the Utility Water Act Group
on EPA's Proposed Rule:
Strengthening Transparency in Regulatory Science
83 Fed. Reg. 18768 (Apr. 30, 2018)
Docket ID No. EPA-HQ-OA-2018-0259**

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Introduction

The Utility Water Act Group (UWAG) appreciates the opportunity to comment on EPA's Proposed Rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18768 (Apr. 30, 2018) (Proposed Rule). UWAG is a voluntary, non-profit, unincorporated group of 146 individual energy companies, which own and operate over 50 percent of the nation's total generating capacity, and three national trade associations of energy companies: the Edison Electric Institute, the American Public Power Association, and the National Rural Electric Cooperative Association. UWAG's purpose is, among other things, to participate on behalf of its members in federal agency rulemakings under the Clean Water Act (CWA) and related statutes. UWAG has a particular interest in this rulemaking because of the great importance that scientific data and models play in implementing the CWA.

UWAG appreciates EPA's dual commitment to transparency and data protection. A transparent process facilitates public participation in rulemakings and increases the likelihood of valid and defensible final rules. The unavailability of underlying data or models prevents independent validation of key findings and limits meaningful public participating, therefore potentially robbing EPA of vital information that could (and should) inform its regulatory decisions. As such, increasing access to underlying data and models—while respecting existing legal and policy protections—both assists EPA to accomplish its long-established goals and subsequently benefits the general public.

To that end, EPA should expand the scope of the Proposed Rule so as to further its commitment to transparency while at the same time maintaining reasonable restrictions necessary to ensure privacy, confidentiality and national security. Specifically, UWAG recommends that EPA expand the scope of the Proposed Rule to address all data and models

used for agency decision-making, not just dose response data and models. Additionally, the data and models provided should include all supporting quality assurance/quality control data and be accompanied with adequate explanatory materials so that the public can readily understand all models and all inputs and formulas to the models. Our specific comments are as follows.

1. EPA’s Long-Standing Goals and Values Would Be Further Met By Enhancing Transparency in Additional Rulemakings or Other Proceedings.

UWAG believes EPA should expand the scope of the Proposed Rule to additional proceedings and documents that would benefit from increased transparency. The core transparency requirements of the Proposed Rule, as written, apply only to “dose response data and models” underlying “pivotal regulatory science” that EPA uses “to justify significant regulatory decisions.” 83 Fed. Reg. at 18773. But a number of important EPA actions fall outside of these definitions entirely and many significant regulatory decisions rely on data, information, or models outside the definition of “dose response data and models.” UWAG has frequently commented that access to the underlying data and models is necessary for meaningful public comments, which in turn are key to producing valid, enforceable rules. UWAG highlights the following examples to illustrate opportunities for increased transparency that would not be addressed by the current Proposed Rule.

A. *Water Quality Criteria*

As UWAG interprets the Proposed Rule, EPA’s water quality criteria would not be covered as they are not considered “regulations.” Per CWA § 304(a), EPA is required to develop, publish, and periodically revise water quality criteria “accurately reflecting the latest scientific knowledge” regarding effects to aquatic life and human health. The federal water quality criteria are important because they initiate a chain of actions that ultimately result in water quality-based effluent limits (WQBELs). EPA requires states and tribes to consider the

federal water quality criteria during triennial review of their own water quality standards and they often form the basis of those standards.¹ These state and tribe standards, in turn, are incorporated into the wastewater discharge permits that UWAG members obtain. As such, the federal water quality criteria are an essential part of the regulatory scheme and must be subject to meaningful public comment, both to satisfy public participation values and to promote validity of both the criteria and the WQBELs they ultimately inform.²

We applaud EPA for seeking both public comments on draft water quality criteria and review of the criteria from interagency and outside consultants.³ UWAG has commented on multiple occasions, however, that it cannot adequately comment on EPA's draft water quality criteria because some of the key data or models justifying them were not provided. UWAG has consistently requested that EPA include underlying data and models for its water quality criteria and adequately explain them such that the public can comment on EPA's overall approach when revising the water quality criteria. The following are some recent examples of draft water quality criteria where some of the necessary underlying data and models were not provided for review.

- Draft Aquatic Life Ambient Water Quality Criteria for Aluminum, 82 Fed. Reg. 35198 (July 28, 2017) – EPA based the criteria on an as-then unpublished model. As UWAG noted in its comments, this deprived the public of the opportunity to review and understand the key information justifying the Draft Criteria during the comment period, which in turn harmed EPA's ability to obtain informed, useful public comments.⁴

¹ 40 C.F.R. § 131.20(a) (“In addition, if a State does not adopt new or revised criteria for parameters for which EPA has published new or updated CWA section 304(a) criteria recommendations, then the State shall provide an explanation when it submits the results of its triennial review to the Regional Administrator consistent with CWA section 303(c)(1) and the requirements of paragraph (c) of this section.”)

² Validity is a key aspect of the water quality criteria, both under the CWA and EPA's regulations. They both specify that criteria shall be based on the “latest scientific information” about the effect of a constituent concentration on aquatic life and/or human health. 33 U.S.C. § 1314(a); 40 C.F.R. § 131.3(c).

³ We note that while EPA typically publishes the comments of external peer reviewers, we think a similar practice should be done for comments submitted by sister agencies.

⁴ UWAG Comments, Docket ID No. EPA-HQ-OW-2017-0260-0061 (Oct. 26, 2017).

- Draft Aquatic Life Ambient Estuarine/Marine Water Quality Criteria for Copper, 81 Fed. Reg. 49,982 (July 29, 2016) – EPA used altered models without explaining those changes and how they account for vital variables, such as sensitivity to the pollutant in question. EPA adopted, prematurely, a saltwater biotic ligand model based on a single study that was not appropriate for national application. To adapt the single study model for broader use, EPA “made ‘changes to the model,’” but did not explain “when, how, or where its” altered model was “verified, calibrated, or otherwise developed across” the necessary range of environments for use in a nationwide setting.⁵
- Draft Updated National Recommended Water Quality Criteria for the Protection of Human Health (Notice of Availability), 79 Fed. Reg. 27,303-04 (May 13, 2014) – EPA failed to give sufficient analysis and/or explanation of the model used for estimating the bioaccumulation factors (BAFs). As presented, the draft criteria document did not allow the public to determine how EPA “(i) addressed certain factors shown to impact the accuracy of the model, (ii) incorporated discrete concentrations of a chemical in water, and (iii) implemented the model using EPI (Estimation Programs Interface) Suite™.”⁶

Since the purpose of water quality criteria is to protect human health and aquatic life, they necessarily are based on dose response data and models. As the above examples illustrate, those data and models have not always been made available by EPA for review and comment. Including them in the Proposed Rule could rectify these issues in the future.

B. *Data/Model Selection Issues*

When appropriate, EPA should also apply transparency principles to data and models that EPA has considered but rejected, particularly when EPA relies on data or models that do not meet stated acceptance criteria for their use. The water quality criteria are illustrative on this point. In the past, EPA has accepted or rejected certain toxicity data when determining the water

⁵ UWAG Comments, Docket ID No. EPA-HQ-OW-2016-0332-0029 (Sept. 27, 2016) at 2-7.

⁶ UWAG Comments, Docket ID No. EPA-HQ-OW-2014-0135-0128 (Aug. 13, 2014), at 7-8.

quality criteria when those data do not meet EPA's testing protocols.⁷ One reasonable way for EPA to ensure the validity of its rules is to explain why certain data were rejected but others were accepted, especially if they do not meet pre-established requirements, and provide the public the opportunity to comment on that explanation. Adopting a policy of explaining acceptance and rejection of data or models would be well-supported by EPA's long-held policies of transparency, validity, and public participation.

Further, EPA should make rejected data and models available for public review and evaluation. By declining to use said data and models, EPA has, in essence, relied on its omission in developing its proposed action. EPA's policy values should include a policy of increased transparency as to the entire decision-making process, not merely EPA's preferred universe of facts. By allowing comments on data and models that EPA evaluated but excluded, EPA will further its goals and provide a check on its own assumptions and analyses.

C. Scientific Evaluations with High Regulatory Potential

Limiting transparency obligations only to significant regulatory actions ignores that EPA's actions outside of the rulemaking context can often have significant impacts on those later regulatory decisions. One context in which this arises is the Integrated Risk Information System (IRIS).⁸ IRIS is a voluntary program EPA created in 1985 to assess the human health effects of chemicals. In the IRIS assessment process, EPA may develop reference concentrations or reference doses that will be critical for later rulemakings regarding those chemicals. EPA's commitment to transparency and validity should motivate the same actions for the IRIS comment period as for any other. Access to the underlying data and models produces better and more

⁷ EPA, *EPA Aquatic Life Ambient Water Quality Criteria for Selenium – Freshwater*, EPA-822-R-16-006 (2016).

⁸ General information is available at <https://www.epa.gov/iris/basic-information-about-integrated-risk-information-system>.

useful comments, which EPA can then use to ensure valid results. Supplying the underlying data/models during the IRIS process and providing sufficient opportunity to the public to comment and participate in the process is far preferable to waiting until those reference doses are employed in a later significant rulemaking, which could occur years or decades later.

Additionally, there are some states that have adopted chemical-specific reference doses (used, subsequently, to derive water quality criteria for the protection of human health) despite the fact that the EPA IRIS database does not recommend a specific reference dose value (e.g., thallium compounds)⁹. In the absence of a scientifically-defensible human health carcinogenic or non-carcinogenic threshold, speculative thresholds should not be used to derive human health criteria.

2. UWAG Supports a Valid, Reasonable Exemption Process.

UWAG recognizes and supports the need for exemptions to address lawful and reasonable restrictions on underlying data and models. UWAG also supports EPA's clear intent to ensure that the exemption process does not effectively cancel out the general policy of transparency. UWAG advises EPA to undertake all reasonable efforts to provide access to underlying data and models while protecting legal and policy interests in privacy, confidentiality, and national and homeland security.

EPA's clear intent in the Proposed Rule is to seek solutions for protected data that are consistent with relevant laws and policy motivations for limiting access. Proposed § 30.5 states:

The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data is controlled by third parties, EPA shall work with

⁹ EPA *Toxicological review of thallium and compounds – in support of summary information on the Integrated Risk Information System (IRIS)*, EPA/635/R-08/001F (2009).

those parties to endeavor to make the data available in a manner that complies with this section.

83 Fed. Reg. at 18774. UWAG supports this language and encourages EPA to consider additional methods for ensuring that the exemption process does not overrule this language or viewpoint. Legal protections on data are vital; intellectual property and privacy laws protect important interests and must be supported. To the extent reasonably possible, however, EPA should explore all methods to allow for data access without impinging on privacy and confidentiality concerns. Data masking procedures should be explored, and possibly further developed for these purposes. And for models upon which EPA relies, public access for review and comment should be a top priority.

3. UWAG Supports Broad Efforts to Ensure Validity.

UWAG appreciates EPA's interest in scientifically supportable, valid actions and regulations. EPA has proposed to apply enhanced validity procedures for "all pivotal regulatory science used to justify regulatory decisions." 83 Fed. Reg. at 18774 (proposed 40 C.F.R. § 30.7). UWAG supports this general principle. UWAG, in addition, supports EPA's recent policy decision to have external scientific advisory boards be represented by a diverse group of stakeholders, including those representatives from regulated industry. UWAG recommends, however, that EPA adopt a broader view of what is necessary to ensure validity. In the Proposed Rule, EPA proposes to require independent peer review in all instances. UWAG advises EPA to recognize, as it has in the past, that a variety of quality assurance and quality control measures can result in properly validated data that is appropriate for use in justifying regulatory decisions, not just that which has been independently peer reviewed.¹⁰

¹⁰ See, e.g., US EPA, *Guidance on Environmental Data Verification and Data Validation (QA/G-8)*, EPA/240/R-02/004, November 2002, <http://www.epa.gov/quality/qs-docs/g8-final.pdf>.

4. UWAG Supports a Definition of “Available” that Requires Contextual and Accompanying Information to Understand and Validate Data and Models.

UWAG supports EPA’s emphasis in its proposed regulatory text that, to be truly publicly available, the underlying data or models must include “the information necessary for the public to understand, assess, and replicate findings.” 83 Fed. Reg. at 18773-74 (proposed 42 C.F.R. § 30.5). UWAG agrees that such necessary information may include:

- (a) Data (where necessary, data would be made available subject to access and use restrictions).
- (b) Associated protocols necessary to understand, assess, and extend conclusions;
- (c) Computer codes and models involved in the creation and analysis of such information;
- (d) Recorded factual materials; and
- (e) Detailed descriptions of how to access and use such information.

Id.

In addition, UWAG encourages EPA to consider other elements that are necessary for information to be deemed publicly available. For instance, the data and models should be presented in a such a fashion and be accompanied with adequate explanatory materials so that the public can readily understand their relevance and how they were used in reaching a decision. EPA should consider document format as part of providing meaningful public access and evaluate the legibility of the document, taking into consideration acronyms, headings, and other relevant labels.