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| **TO:** | **U.S. Environmental Protection Agency (EPA)**<br>Docket Number: EPA-HQ-OA-2018-0259<br>Docket Name: Strengthening Transparency in Regulatory Science<br>Docket RIN 2080-AA14 |
| **FROM:** | **National Rural Water Association** (contact: Mike Keegan, Analyst) |
| **DATE:** | **August 16, 2018** |
| **SUBJECT:** | **Comments on Strengthening Transparency in Regulatory Science** |

Headquartered in Duncan (Oklahoma), NRWA is the non-profit association of the federated state rural water associations with a combined membership of over 30,000 small and rural communities. NRWA is the country's largest water utility association and the largest community-based environmental organization. State Rural Water Associations are non-profit associations governed by board members elected from the membership.

Our member utilities have the very important public responsibility of complying with all applicable U.S. Environmental Protection Agency (EPA) regulations and for supplying the public with safe drinking water and sanitation every second of every day.

Most U.S. water utilities (community water systems) regulated by the SDWA are small; over 91% of the country's approximately 51,000 drinking water supplies serve communities with fewer than 10,000 persons. Small and rural communities often have difficulty providing safe, affordable drinking water and sanitation due to limited economies of scale and lack of technical expertise. Similarly, when it comes to providing safe water and compliance with federal standards, small and rural communities have a difficult time due to their limited customer base. This is compounded by the fact that small and rural communities often have lower median household incomes and higher water rates compared to larger communities. As a result, the cost of compliance is often dramatically higher per household.

**NRWA supports the Agency's proposal to promulgate a regulation to strengthen the transparency of science utilized by EPA to support regulatory policies in regulations promulgated under the Safe Drinking Water Act (SDWA).**

SDWA regulations and National Primary Drinking Water Regulations (NPDWRs) result in a significant economic burden on small and rural communities and often force local communities to pay for federally mandated compliance that the communities do not believe is in their best interest for advancing public health policy. Under SDWA, this often results in a requirement to pay for treatment for nominal reductions of naturally occurring elements and compounds in drinking water supplies. Considering that rural and small communities are controlled and governed by people who are locally-elected, all data, scientific studies and discretionary

administrative decisions underlying federal actions that supercede local decisions should be made *"publicly available in a manner sufficient for independent validation"* and with clear explanation of discretionary decisions. NRWA fully supports a new regulation that requires use of peer-reviewed information, consistent data evaluation procedures, data transparency, and reproducible scientific assessments.

## Recommendations for Regulatory Development and Existing SDWA Issues

Any regulations should improve the status quo and result in the following public disclosure of:

- A clear principle for implementing the discretion provided to the Administrator for selecting new contaminants for regulations under SDWA Section 1412. The lack of a clear principle or interpretation has allowed EPA to make a determination **not** to regulate perchlorate on October 10, 2008 and a subsequent affirmative EPA decision on February 11, 2011, that perchlorate meets the Section 1412 criteria for regulation as a contaminant. Such ambiguity in decision-making does not provide for regulatory certainty or persuasive reasoning for the local governments.

- Levels of regulated substances that are unsafe in drinking water as referenced in the SDWA (*"unreasonable risk to health,"* Section 1415 and *"protective of public health,"* Section 1412). For example, the EPA established a standard of 10 parts per billion (ppb) for arsenic in drinking water. The public naturally infers that any level above the standard is a health risk. However, when pressed by Congress to confirm this health risk, EPA failed to do so. In 2002, EPA did not find that arsenic concentrations above their standard necessarily present an "unreasonable risk to health." In their reply to a Congressional inquiry, EPA stated that it is *"determining what does not pose an unreasonable risk to health with respect to arsenic, rather than address the much more complex issue of what does constitute an unreasonable risk to health."*[1] EPA should identify these public health levels for all NPDWRs.

- An explanation of why EPA selectively releases only certain peer-review studies to support NPDWRs. In 2014, NRWA questioned the Agency about why it was not considering recent published studies that contradict the Agency's current arsenic in drinking water risk assessment findings. The new studies specifically examined the low dose range data, the behavior of the risk function across the full exposure range, and developed a new methodology to be able to examine the transition range between high risk and no risk. The first study (Lamm et al., RTP 2013)[2] demonstrates that the finding of a dose-relationship among the low dose villages is a consequence of the use of the external reference group that among the low-dose study villages there is no positive dose-response. The second study (Lamm et al., Tox 2014)[3] demonstrates that the data

[1] Exemptions & the Arsenic Rule, August 2002, Appendix G-2 Arsenic Guidance
[2] Steven H Lamm; Jun Lu; Shayhan A Robbins; Chao Zhou; Rusan Chen; Manning Feinleib, Bladder/lung cancer mortality in Blackfoot-disease (BFD)-endemic area villages with low (<150 µg/L) well water arsenic levels--an exploration of the dose-response Poisson analysis (Regulatory toxicology and pharmacology: RTP 2013;65(1):147-56)
[3] Steven H. Lamm; Shayhan Robbins; Rusan Chen; Jun Lu; Brian Goodrich, Manning Feinleib, Discontinuity in the cancer slope factor as it passes from high to low exposure levels – arsenic in the BFD-endemic area (Toxicology 326 (2014) 25–35)

from the high-dose villages show a high cancer risk, but that risk disappears at 100 ug/L and below. The methodologies of the later papers are more refined and should be appreciated by the Agency. They demonstrate that extrapolation of the risk found at high doses to lower doses is inappropriate and significantly overpredicts the risk in the range of 10-100 ug/L.

- All data used to craft SDWA policy including risk assessments. For example, a recent study (Mendez et al., J Expo Sci Environ Epidemiol 2017)[4] analyzes the dose-response slope for certain public health endpoints for certain drinking water using data from the National Cancer Institute and the U.S. Geological Survey. The conclusion of this study could influence the current Integrated Risk Information System (IRIS) Program that is developing an updated assessment of inorganic arsenic. However, the Mendez complete data set includes some data that is available to government agencies but not to the general public. Release of this data would allow for further assessment and demonstrate the repeatability of conclusions and comparisons to similar studies.

The SDWA mandates that the Agency consider a detailed risk and cost assessment, as well as best available peer-reviewed science, when developing NPDWRs. Crafting a regulation that strengthens the transparency of science utilized by EPA will result in improved federal public policy and SDWA implementation. NRWA wants to ensure that the understanding of the public health risks of particular concentrations of substances (especially naturally occurring elements) in public drinking water are properly understood and applied in making public policy.

Thank you for the opportunity to comment.

[4]William M. Mendez Jr.; Sorina Eftim; Jonathan Cohen; Isaac Warren; John Cowden; Janice S. Lee; Reeder Sams, Relationships between arsenic concentrations in drinking water and lung and bladder cancer incidence in U.S. counties (Journal of Exposure Science and Environmental Epidemiology (2016) 00, 1-9)