



ADVANCING EARTH
AND SPACE SCIENCE

16 August 2018

Tom Sinks
Office of the Science Advisor
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Comment on the proposed rule entitled, “Strengthening Transparency in Regulatory Science”
(Docket ID No. EPA-HQ-OA-2018-0259)

Dear Mr. Sinks,

On behalf of the American Geophysical Union (AGU), a non-profit scientific society representing 60,000 Earth and space scientists, I’m writing to express concerns about the proposed policy changes at the Environmental Protection Agency (EPA) regarding transparency and use of scientific information in decision-making. The proposed rule would significantly alter how EPA uses and views scientific research without a clear explanation for why such changes are necessary. The proposal could also have widespread, potentially negative consequences for public health and the environment. We urge the agency to evaluate the unintended consequences of this policy and withdraw the proposal.

Several aspects of the proposed rule are of particular concern. First, the proposal would place restrictions on the use of science by requiring that all scientific information underlying a “significant rule” be able to be validated by the general public, thereby potentially excluding scientific information stemming from datasets that are highly detailed or contain personal information, such as those from studies of patients – data that is likely to be highly significant to decisions about the health of the American people. What’s more, the draft policy gives the EPA Administrator broad authority to decide which scientific information will be considered in decision-making rather than requiring the agency to use the best available science. Even where the agency uses other data, such as economic and technological information to provide context, EPA should evaluate and incorporate scientific studies based on merit to protect public health and avoid politicizing the science.

Second, the proposed rule lacks a significant amount of detail. For example, the EPA fails to adequately describe the justification behind this policy change, how it builds upon current policies regarding transparency, such as the Information Quality Act and EPA’s Information Quality



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Guidelines, or what the potential impacts of restricting science will be on current and future decision-making. We urge the agency to elaborate on these substantive details and provide the science community and the public the opportunity to provide feedback.

Additionally, the proposed rule was drafted and published without sufficient input from the scientific community. The agency is required by law to consult the EPA's Science Advisory Board (SAB) to provide scientific advice and guidance on the implications of any major proposed regulation. The SAB was established to inform the Administrator regarding science at EPA and includes members that have broad scientific expertise. Yet, a recent SAB memorandum indicates that the agency failed to consult the SAB on this proposed policy, regardless of the myriad scientific issues raised.¹ As the rule would substantially change the use of science in decision-making, insight from the scientific community, including the agency's in-house scientific experts, is essential to ensuring a sound policy.

Furthermore, the policy wrongly claims to parallel Transparency and Openness Promotion (TOP) guidelines adopted by peer-reviewed scientific journals like those managed by AGU. Unlike EPA's proposal, the TOP standards encourage open data while recognizing that each scientific discipline has its own constraints, as expressed by editors-in-chief of peer-reviewed publications cited in the proposed rule.² At times, underlying scientific information cannot be made public, particularly when it includes personal identifiable information that ethically and/or legally cannot be shared. However, even in these cases, the merits of a scientific study can still be evaluated by reviewers during the peer-review process and by scientists who are trained to assess scientific conclusions.

The EPA's proposed policy, conversely, undermines the peer review process by proposing that scientific information used in "significant regulatory actions" must be published in way that allows for public validation. The peer review process, which remains the global gold standard of academic achievement, affords the type of informed discourse necessary for the objectivity, rigor, and legitimacy of scientific information. Moreover, the proposed rule does not acknowledge the wealth of scientific expertise and review at the agency's disposal through bodies such as the EPA

¹ Chartered Science Advisory Board, Environmental Protection Agency, *Memorandum on Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)*, 12 May 2018 (available at [https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp_memo_2080-AA14_final_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf)).

² Berg, Jeremy, et al. *Joint statement on EPA proposed rule and public availability of data*, 30 April 2018 (available at <http://science.sciencemag.org/content/sci/early/2018/04/30/science.aau0116.full.pdf>).



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Science Advisory Board (SAB), EPA Clean Air Scientific Advisory Committee (CASAC), and the EPA Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel. These expert panels were established to examine the quality and relevance of scientific information, review research plans and proposals, and provide scientific advice to the Administrator. We urge EPA to use these resources and clarify how this expertise will be incorporated into rule-making under this proposal.

Input from these experts, and those in the scientific community more broadly, would also help the agency manage and ensure the scientific integrity of the extensive datasets envisioned in the rule and clarify terms that go undefined in the existing language. For example, the proposed policy calls for the “validation” and “replication” of scientific information—terms that are not defined and should be clarified. EPA should not miss the opportunity to leverage the expertise available to them in clarifying these concepts and identifying the mechanisms necessary for implementation.

The proposed rule “Strengthening Transparency in Regulatory Science” is a substantial policy change. However, the notice fails to indicate why the policy change is needed and provides little information about the process or data management infrastructure the agency would utilize to implement this policy. As written, the policy is vague and has the potential to adversely impact public health and the integrity of scientific data. Any policy changes at EPA regarding the use of science should not impede the use of peer-reviewed science from informing decision-making and should ensure that the agency is able to improve the health and well-being of our nation.

AGU welcomes the opportunity to work with you to address these and other critical issues and ensure that science can continue to appropriately inform decision-making.

Respectfully,

A handwritten signature in black ink that reads 'Christine W McEntee'.

Christine McEntee
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