



July 18, 2018

Acting Administrator Andrew Wheeler
Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

**Re: Comments on proposed rule “Strengthening Transparency in Regulatory Science,”
Docket ID No. EPA-HQ-OA-2018-0259-0025**

Dear Acting Administrator Wheeler,

The below comments have been prepared on behalf of SPARC, the Scholarly Publishing and Academic Resources Coalition, which represents academic and research libraries at more than 230 colleges and universities across the country.

The proposed regulation published in the Federal Register on April 30, 2018, Docket ID No. EPA-HQ-OA-2018-0259-0025, will significantly and negatively affect how scientific research can be used by the Environmental Protection Agency (EPA) in the regulatory decision-making process, and we urge the EPA to withdraw this proposed rule.

Our organization and its members strongly support open access to research outputs to democratize access to information, accelerate scientific discovery, and stimulate innovation. However, we are concerned about the rule’s proposed selective use of “open” as an enabling strategy in the EPA’s policy-making process. We strongly support requirements to make data underlying scientific studies openly available for the purposes of validation, replication and new research, however, we recognize that there are many instances when it is simply not possible—or preferable—to do so.

For example, important studies on public health often contains data that can be tied back to an individual’s identity, and this data should not be made openly available in order to protect the participants’ privacy. Many studies also contain data that is sensitive in terms of security, business confidentiality, and intellectual property reasons, and this data should also be exempt from blanket data sharing requirements. However, studies based on this data should not be automatically excluded from the EPA’s policy-making progress, which is what proposed rule is designed to do. **Excluding studies for which the data cannot be made available for legitimate reasons would undermine the rule’s stated goal of using the “best available” science to support evidenced-based policymaking.**

The proposed rule points to data sharing policies currently used by respected scientific journals, including *PLOS*, the *Proceedings of the National Academies*, *Nature* and *Science* as justification for this action, claiming that these publications are already employing this practice. This claim is

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incorrect. The data sharing policies that these journals use explicitly recognize the wide variety of workflows in use across scientific disciplines, and provide for data sharing at different levels of openness. They expressly state that not in every case can all data be shared, and in some cases, it is permissible for data to not be shared at all for legitimate and stated reasons.

As these journals – and the research community as a whole – well knows, this does not mean that the data underpinning these studies cannot be assessed. Even if the data is not made openly available, reviewers can be given confidential access to key data where appropriate. Just as importantly, researchers are trained to assess the logic and articulation of a study's research design, its methodology for data collection and analysis, as well as, the appropriate citation of previous results. This helps to ensure rigorous quality control throughout the research lifecycle.

The scientific community is working to make science more accessible and reproducible, and rather than providing transparent access to *more* information, this rule will force the EPA to make decisions based on *less* information, thereby, making it more difficult for the agency to make science-based decisions to protect public health as its mission requires. **Therefore, we urge the EPA to withdraw this proposed rule.**

We look forward to receiving your acknowledgment of these comments requests, and look forward to your response.

Respectfully yours,

A handwritten signature in cursive script that reads "Heather Joseph". The signature is written in black ink and is positioned below the text "Respectfully yours,".

Heather Joseph
Executive Director