

Congress of the United States

House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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May 6, 2020

Dear Democratic Members of the Committee on Science, Space, and Technology:

For years, opponents of strong public health protections and environmental regulations have attempted to wield the concept of “transparency” as a pretense to weaken environmental and public health safeguards. I have seen this effort take a number of different forms. All share the same goal: to undermine the Environmental Protection Agency’s (EPA) ability to use the best available science in crafting environmental and public health standards. The latest manifestation of this dangerous idea, which many of you are familiar with as Members of this Committee, is the EPA’s “Strengthening Transparency in Regulatory Science” rule, which was first proposed in April 2018 and updated with a Supplemental Notice of Proposed Rulemaking (SNPRM) in March 2020. The rule would prohibit EPA from considering a scientific study in Agency rulemaking unless the study’s underlying data and models are publicly available in a manner sufficient for independent validation. Stakeholders across the scientific, environmental, and public health communities vehemently oppose the rule because it would threaten the Agency’s ability to consider studies that are unable to publish their underlying data due to longstanding privacy laws and guidelines governing the use of individual health and medical data in scientific research. I chaired a full Committee hearing about the proposed rule on November 13, 2019, and many of you joined me in expressing serious concerns about the rule’s potential impact on the environment and public health. On April 24, the EPA’s Science Advisory Board issued its comments on the rule. The SAB said that the Agency has not justified “why existing procedures and norms utilized in the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes.” They went on to warn that it may lead to “inappropriate exclusion of scientifically important studies.”¹ Nevertheless, EPA has continued to move forward with the rule.

After EPA published the SNPRM on March 18, I requested that the Agency brief Committee staff on the content of the supplemental. Two briefings took place, on April 2 and April 14. Staff

¹ Letter from the Environmental Protection Agency Science Advisory Board to Administrator Andrew Wheeler, April 24, 2020, accessed here:
[https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/\\$File/EPA-SAB-20-005.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf)

concluded that the Agency provided important new information about the rule and summarized the briefings in a memorandum to me. Due to the current extraordinary situation, during which the opportunities for the Committee to publicly engage with the Agency on the rule may be limited, I am attaching the staff memo to this letter so that you may review its contents. If you have any questions regarding the contents of the memo, please contact the staff of the Committee for further information.

Thank you for your dedication to upholding the role of science in federal policymaking. Now more than ever, it is clear that science must lead the way rather than politics or ideology. I agree with the SAB that the rule as written “risks serious and perverse outcomes.” I am proud of the Committee’s work and remain confident that we will continue to stand for rational, science-based policies in these difficult times.

Sincerely,

A handwritten signature in blue ink that reads "Eddie Bernice Johnson". The signature is written in a cursive, flowing style.

Eddie Bernice Johnson
Chairwoman
Committee on Science, Space, and Technology

MEMORANDUM

TO: Chairwoman Johnson
FROM: Democratic Staff, Committee on Science, Space, and Technology
DATE: April 30, 2020
RE: Summary of Staff-Level Briefings from the Environmental Protection Agency on the “Strengthening Transparency in Regulatory Science” Supplemental Proposed Rule

Background

On March 20, you sent a letter to EPA Administrator Andrew Wheeler requesting that the Agency extend the public comment period of the Supplemental Notice of Proposed Rulemaking (SNPRM) for the “Strengthening Transparency in Regulatory Science” proposed rule. In the letter, you requested a staff-level briefing on the rule, to occur by March 27. On April 2, EPA provided Committee staff with an hour-long phone briefing, and the Agency accommodated Committee staff’s request for a 90-minute follow-up briefing on April 14.

The briefing was provided by representatives from the EPA Office of General Counsel, the Office of Research and Development, and the Office of Congressional and Intergovernmental Relations.

Application of the Rule to Regulations Up for Review

EPA has frequently dodged and obfuscated when asked whether the rule would apply to existing regulations that are up for review. In one such instance, Dr. Jennifer Orme-Zavaleta, at the November 2019 Committee hearing, was asked whether the rule would be applied to regulations EPA was opening up for reconsideration, whether on a statutory basis or at the Agency’s own discretion. She responded, “should this rule be finalized, then it will apply prospectively to new rules and regulations.” While it was obvious at face value that this would open up existing regulations to being reworked under the confines of the proposed rule, EPA did not acknowledge this until the April 2 phone briefing, confirming to staff that the rule’s application to “prospective rulemaking” includes statutorily mandated reviews of existing standards, such as the National Ambient Air Quality Standards (NAAQS).

Clarification on the Designation of Influential Scientific Information

EPA clarified that the designation of Influential Scientific Information (ISI) – which the Agency added to the scope of the rule in the SNPRM – would be made by the office producing the work product. This designation would occur at the initiation of the product, meaning that every study considered by the Agency in writing a rule, regulation, risk assessment, and more would be subject to these data transparency requirements.

In describing the breadth of the rule’s impact on ISI, an EPA representative stated that the rule would only apply to “pivotal” studies used in a piece of ISI, rather than those that provide

“context.” This is not made clear in the text of the rule and would constitute a significant narrowing of the rule’s scope. If EPA intends the rule to only apply to a select few studies underlying ISI work products, it must be made explicit in the final version of the rule.

Tiered Access Approach

EPA provided far more detail on the so-called “tiered access” approach than what was presented in the SNPRM. For the first time, EPA told Committee staff that the burden of implementing this proposal would be on researchers. EPA’s envisioned implementation – absent from the text of the SNPRM – would be as follows:

- EPA staff would reach out to the researchers involved in a study that the Agency wants to consider during the development of significant regulatory actions or Influential Scientific Information.
- The researchers would be responsible for managing the logistics of making the data and models publicly available in a manner that complies with the rule, in consultation with EPA staff.
- The researchers would be responsible for judging the sensitivity of the study’s data and models and what information can or cannot be made publicly available through tiered access.
- The researchers would decide what tier of access should be designated for different types of information.

EPA was not able to say how conflicts between the researcher’s judgment and the Agency’s judgment would be handled. They were also inconsistent concerning how the data and models would be managed. While they largely placed the responsibility on the researchers, they also discussed the secure data enclave pilot project the Agency is conducting with the Centers for Disease Control (CDC). The latter would involve CDC hosting the data and models on its own servers, with CDC personnel working at the secure data enclave reviewing research proposals submitted by members of the public seeking to conduct their own analyses of study data and determining the level of access to grant on a case-by-case basis. While the CDC pilot project is mentioned in the SNPRM, this is the first time the Agency has described an implementation scenario that would potentially place such a large responsibility on an outside agency. EPA also raised the possibility that the data could be stored on multiple outside “secure enclaves,” managed by CDC or another third party, who would also be responsible for reviewing research proposals.

Between the two implementation scenarios presented by EPA, it is notable that the bulk of the responsibility for instituting new methods for access to data and models falls on outside parties. This is problematic considering EPA’s assertion that the rule is “a proposed internal rule of agency procedure” and its plans to promulgate the rule under its Housekeeping Authority at 5 U.S.C. 301.

It is concerning that EPA has decided internally that key implementation responsibilities will fall on the research community without providing the same level of detail to the public as it provided to Committee staff. The research community cannot be expected to meaningfully comment on this proposal and its imposition on their research practices without such detail.

EPA Could Not Provide Additional Information for Several Topics

While Committee staff were able to learn the critically important new information detailed above, EPA was unable to answer many questions posed. Committee staff sought clarity on a number of policies presented in the SNPRM, including several logical gaps and inconsistencies arising from the text of the rule. EPA was largely unable to address these issues and frequently declined to answer questions, admitting that the Agency had simply not considered the issue this far into the rulemaking process. They explained that they hoped public commenters would provide the requisite insight on key implementation details. It is certainly true that public comments should always inform the rulemaking process, and we appreciate that EPA intends to carefully review the comments submitted for the SNPRM. However, on fundamental matters of structure and logic, the public comment period is no substitute for a well-reasoned, deliberative policymaking process. EPA's inability to answer basic questions about the rule's operation and implementation reflects the ill-conceived nature of the "Strengthening Transparency" rule. The Agency could not provide satisfactory answers on the following topics:

- *The role of "reanalysis" in future Agency rulemaking:* The SNPRM proposes a definition for the term "reanalyze." The definition addresses the characteristics of a reanalysis, but the SNPRM does not detail how any reanalysis would be integrated into EPA's rulemaking process for significant regulatory actions. During the briefing, EPA was unable to answer questions regarding how the Agency would handle a reanalysis conducted by a third party. Specifically, EPA acknowledged that it had not devised procedures for assessing a reanalysis during a rulemaking. EPA also did not know how the absence of peer review for a reanalysis would influence the incorporation of those findings into ISI or a rulemaking. Finally, EPA did not know how the Agency would balance the timeline of a rulemaking with the timeline of a reanalysis, given that a reanalysis of a major study can take years and may not be completed before a regulatory deadline. Despite its emphasis on publicly available data, EPA does not appear to have considered key aspects of how "reanalysis" would fit into and ultimately influence its regulatory actions, or how making underlying data publicly available for reanalysis would enhance the Agency's use of science.
- *The logistics of data storage:* The SNPRM does not directly address the issue of data storage, specifically how EPA intends to handle and store the enormous amount of data that would be made publicly available under the rule. Committee staff asked whether EPA had considered the data storage burden that the rule would create and where data would be stored. EPA could not answer either question. According to the Agency, EPA has not yet decided whether the data storage infrastructure would be hosted internally or externally. In terms of the responsibility for data storage, EPA questioned whether the rule would actually create a significant new burden but acknowledged that further consideration would be necessary. Two years after the publication of the proposed rule, the Agency still does not have a plan for how to carry out one of the most obvious implementation duties associated with the rule.
- *The "weighted system" alternative approach:* The SNPRM introduced a new alternative approach to the rule, whereby some studies would receive "greater consideration" than others

in Agency regulatory actions based upon the extent to which they are able to make their data and models publicly available for independent validation. During the briefing, however, EPA was unable to expand on how this potential weighted system would operate. The Agency has not identified implementation details for the weighting approach, including any concrete ideas about how the scale of a weighted system would be structured. The Agency also did not know what information would be contained in the “short description” explaining to the public why a given study received greater or lesser consideration, or even whether such descriptions would be quantitative or qualitative. Finally, the Agency said that further examination would be required to understand whether the weighted system might upend the traditional balance between certain types of studies in the regulatory process: for example, by compelling EPA scientists to give greater consideration to data from a small-scale animal study than a large-scale human epidemiological study. EPA’s consideration of the weighted system approach appears to be minimal thus far.

- *The need for a cost analysis:* Despite the new obligations that the rule would create for both the external research community and the Agency itself, neither the proposed rule nor the SNPRM contains any type of cost-benefit analysis. In the briefing, EPA stated that the Agency had not yet decided whether to conduct a cost analysis before finalizing the rule. EPA asserted that it was still evaluating whether a cost analysis was necessary, and that it would be difficult to make that decision before finalizing the text of the rule itself. EPA also did not know whether the focus of any potential cost analysis – if it occurs – would be the cost of the rule for the Agency, for the external research community, or both. EPA cannot answer the simple question of whether it plans to conduct a cost analysis for the rule, to say nothing of what the results of the analysis might be.
- *Legal authority and external obligations:* The SNPRM asserts that the Agency’s legal authority for the rule is derived from the Federal Housekeeping Statute (5 U.S.C. 301) because the rule is “a rule of internal agency procedure” that would “not regulate the conduct or determine the rights of any entity outside the federal government.” However, given the Agency’s explanation of the new obligations that would be placed upon external researchers to make their own data and models publicly available and determine the levels of restricted access that would apply to different categories of data, Committee staff asked how these obligations could be consistent with a rule of internal agency procedure. EPA did not have an answer, merely stating that the precise role for researchers within the framework established by the rule was not yet finalized and that comments from the public could consider this question. The Agency’s response did not address the logical inconsistency.

Ongoing Public Comment Period

Committee staff urged EPA to extend the comment period further due to the complexity of the SNPRM and the disruptions caused by the ongoing COVID-19 pandemic. EPA stated that the Agency views the current comment period as appropriate and believes that no further extension beyond May 18 is necessary. EPA claimed that the Agency is back to “business as usual” and that members of the public have sufficient time to deliver their comments. EPA also said that public hearings for the SNPRM will not be necessary because comments submitted to the written docket are the most effective and sufficient means for the public’s input.