Addressing the Undermining of Science-Based Decision-Making by the EPA

Environmental Data and Governance Initiative's Comment on the Environmental Protection Agency's (EPA) Supplemental Notice of Proposed Rule-Making:
Strengthening Transparency in Regulatory Science
(Docket No. EPA-HQ-OA-2018-0259-9322)

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Comment compiled on behalf of the Environmental Data & Governance Initiative
By: Gretchen Gehrke and Marcy Beck

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Introduction

The Environmental Data and Governance Initiative (EDGI) welcomes the opportunity to comment on the Supplemental Notice of Proposed Rulemaking (SNPRM) published by the Environmental Protection Agency (EPA) regarding its proposed Strengthening Transparency in Regulatory Science rule, docket number EPA-HQ-OA-2019-0259-9322. The original proposal for the Strengthening Transparency in Regulatory Science rule (STRS)[1] represented a sweeping proposition to upend the use of science in the EPA's regulatory developments and decisions. EDGI's 2018 public comment on the proposed rule details its problematic ambiguity and misappropriation of transparency to stymie science-based regulations intended to protect human and environmental health.[2] While this SNPRM resolves some of the ambiguities of the original proposal, it vastly expands the scope of the proposed rule, actively dissuades public input, makes agency decision-making vulnerable to political persuasion, exploits the concept of transparency, and provides an avenue for unwarranted dismissal of high quality science. The SNPRM further clarifies that this proposed rule would undermine science-based decision-making at the EPA. The proposed rule should be rejected.

The SNPRM catapults the extensive 2018 STRS proposal into a comprehensive assault on science in agency decision-making by extending the scope of the proposed rule to apply to all "influential scientific information," rather than applying it to the already-broad category of science underlying regulatory decisions.[3] Thus, if this proposal were to move forward, the EPA would only consider--even for agency decisions such as those about new areas of research for the agency to engage in or fund--scientific information where the entirety of the underlying data were made public. The SNPRM clarifies that this includes personally identifiable information (PII) inherent to health studies,[4] and all data and models (not only dose-response models).[5] Interestingly, while this rule would affect all health-protective research and regulations the agency conducts, and could lead to the dismissal or devaluation

[1] Environmental Protection Agency (EPA), "Strengthening Transparency in Regulatory Science," *Federal Register 83*, no. 83: 18678-18774.
[2] Environmental Data and Governance Initiative (EDGI), "EPA's Proposed Rule Uses the Idea of Transparency to Reduce Real Transparency and Delay Protecting Environmental and Public Health," August 16, 2018: https://envirodatagov.org/wp-content/uploads/2018/09/Strengthening-Transparency-in-Regulatory-Science.pdf.
[3] Environmental Protection Agency (EPA), "Strengthening Transparency in Regulatory Science," Supplemental Notice of Proposed Rulemaking, *Federal Register 85*, no. 53: 15396-15406, 15398 (hereinafter cited as EPA, "Strengthening Transparency in Regulatory Science" SNPRM).
[4] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15401.
[5] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15398.

of most health studies, the SNPRM asserts that this rule "does not concern an environmental health risk or safety risk."[6]

The EPA introduces a new system of "tiered access" in this SNPRM for data that cannot be made fully public due to privacy concerns.[7] However, the proposal does not describe how tiered access would effectively mitigate privacy concerns, especially as it provides no description or metrics regarding those who could gain access to different tiers of data. This omission introduces an extraordinary potential vulnerability to political bias, which is further exacerbated by the absolute discretion given to the EPA Administrator for exemptions from public data requirements[8] without any mention of exemption criteria or oversight. As an alternative, the EPA proposes to consider all studies, but to apply a lower weighting factor to studies whose data are not made available.[9] The EPA provides no information about potential weighting criteria or calculations.

EDGI is a collective of academic and nonprofit professionals who document, analyze, and publish reports detailing changes to federal environmental governance in the U.S.[10] We seek to steward and expand public knowledge through our reports and ultimately to improve federal environmental public information and the public's ability to participate in environmental decision-making. We are committed to environmental and human health, justice, and information accessibility; we support scientific integrity and public knowledge creation.

In this public comment, we put forth several reasons for rejecting in sum the SNPRM for the Strengthening Transparency in Regulatory Science proposed rule. We detail ways in which the EPA undermines public input, especially through the assertion in this SNPRM that this proposed rule should fall under the EPA's "housekeeping authority."[11] We document the EPA's conspicuous introduction of several procedural avenues for manipulation and political bias, laid bare especially through the omission of any form of intra-agency or public oversight. We analyze how the EPA co-opts and exploits the basic concept of transparency to invite flawed reanalyses, while operating without transparency regarding the impacts, costs (or even aspirational benefits), or implementation procedures for this new rule. Finally,

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[6] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15404.
[7] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15399.
[8] Id.
[9] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15402.
[10] EDGI, "Mission, Vision, Values," https://envirodatagov.org/about/mission-vision-values/. Accessed May 7, 2020.
[11] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15397.

we document some of the most obvious likely impacts of this proposed rule, such as the dismissal and devaluation of public health studies by this agency tasked with protecting human and environmental health. EDGI firmly opposes the Strengthening Transparency in Regulatory Science rule and urges Administrator Wheeler to abandon this proposed rule in totality.

Undermining Public Input

This SNPRM demonstrates a disingenuous request for public input from the EPA. The EPA is obligated through the Administrative Procedure Act (APA) to notify the public and invite public comment on proposed regulations.[12] While fulfilling the procedural requirements of the APA through this SNPRM, the EPA downplays the public interest of this sweeping proposed regulation, repeatedly asserts that this proposed rule is an affair internal to the agency, and sets up a path for the agency to dismiss public input regarding the STRS rule.

In the first paragraph of the Executive Summary, the EPA appears to dissuade public comment by understating the interest of members of the general public in a proposed rule designed to significantly alter regulations protecting public health. First, the EPA frames the proposed rule as internal to the agency, stating "This SNPRM does not regulate any entity outside the Federal Government. Rather, the proposed requirements would modify the EPA's internal procedures regarding the transparency of science underlying regulatory decisions."[13] The EPA then concedes that "any entity interested in EPA's regulations may be interested in this proposal," providing an example of "entities that conduct research or another scientific activity that is likely to be relevant to EPA's regulatory activity."[14]

The EPA claims to have authority to make extensive changes to how the agency uses science in its decision-making through the Federal Housekeeping Statute, and dwells on this point in the SNPRM for several paragraphs.[15] Remarkably, the EPA suggests that this rule, which ignores established processes for evaluating scientific merit and would impact every regulation under the EPA's authority, is not a "substantive rule."[16] The EPA asserts that the proposed rule "exclusively pertains to the internal practices of the EPA"[17] and fails to mention that the EPA relies extensively on studies conducted by other entities, and indeed, is mandated to

[12] Administrative Procedure Act, 5 U.S.C. § 552.
[13] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15397.
[14] Id.
[15] Id.
[16] Id.
[17] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15398.

consider outside research under both the Clean Air Act and Clean Water Act. The EPA does not address how the application of the proposed rule could impact its ability to faithfully execute its statutory responsibilities under these acts; it simply makes reference to its intention to be consistent with its other statutes.[18] As the EPA repeatedly asserts that this proposed rule deals with internal EPA processes, the EPA invites public comment about whether to pursue this proposed rule under only its housekeeping authority, or under its housekeeping authority along with its other statutory authorities, and conspicuously does *not* invite comment about whether or not invocation of the housekeeping authority is appropriate at all.[19] Let it be clear: a rule of this breadth, with impacts extending into all significant agency decisions and actions, should by no means be considered a basic agency procedure and housekeeping.

In addition to asserting that the EPA can introduce these changes under its housekeeping authority, the EPA also lays the groundwork in this SNPRM to subvert public comment in the future. The EPA states that it is "considering how to proceed, apart from this supplemental proposal, to establish regulations interpreting provisions of, and/or exercising substantive rulemaking authority delegated to it by programmatic statutes."[20] Creating regulations specifically about how the EPA interprets or carries out its statutes could result in a process whereby many, perhaps all, new environmental regulations pursuant to the EPA's statutes, including the Clean Air Act and Clean Water Act, would be considered internal procedures and thus give the EPA leeway to circumvent the Administrative Procedure Act's required notice-and-comment rulemaking. The EPA has been acting with an aggressive deregulatory agenda for the last three years.[21] This action not only shuts the public out of federal environmental decisions, but could lay the groundwork for discarding all of the EPA's regulatory accountability. We firmly oppose the establishment of regulations that could allow the EPA to circumvent notice-and-comment rulemaking.

Facilitating Political Bias

The proposed rule and the SNPRM introduce a wide avenue for political bias and favoritism to be made part of the EPA's decision-making. By "allowing the Administrator to grant exemptions on a case-by-case basis,"[22] the rule, in effect,

[18] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15398.
[19] Id.
[20] Id.
[21] EPA, "EPA Deregulatory Actions," www.epa.gov/laws-regulations/epa-deregulatory-actions. Accessed March 7, 2020.
[22] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15403.

gives the EPA Administrator absolute discretion to determine which studies are exempted. There is no mention of any mechanism of oversight for these exemptions: no panel, no petition, no required record-keeping. The criteria for exemptions are not mentioned; the only mention of a potential exemption criterion is for a study's age due to increased likelihood of technical barriers to creating public access.[23] The unchecked power to select cases that would not be subject to public data and independent validation would be ripe for abuse. For example, academic and nonprofit institution public health studies might be either dismissed or devalued if their data couldn't be made fully public because of their sensitive personally identifiable information,[24] but without explanation or reprimand, the EPA Administrator could elevate industry-sponsored studies for consideration without penalty for keeping their confidential business information out of public view.

In addition to case-by-case exemptions from public data requirements, the EPA has introduced two approaches to addressing the proposed public data requirements that could be manipulated, and for which the EPA has proposed no criteria nor oversight mechanisms. In this SNPRM the EPA suggests the use of a "tiered access" system, whereby data that cannot be made public (because they cannot be de-identified enough to erase privacy concerns) would be made available in a restricted manner, rather than made fully public.[25] As described below in the "Disregarding Credible Science" section, there are significant barriers to producing multiple datasets for different tiers of access, but perhaps the most obvious vulnerability in the proposal of a tiered access is that the EPA does not provide any criteria or suggested process regarding who would or could receive access to which tiers of data. As written, the EPA could grant access to industry personnel eager to poke holes in public health studies and decline access to academic researchers interested in evaluating industry studies. Additionally, the EPA offers an alternative to outright dismissal of studies that cannot make their data public (which was met with significant resistance in the 2018 public comment period[26]) by considering those studies but weighting them lower than studies whose data are available publicly or through tiered access.[27] However, the agency provides no example weighting criteria or maximum weighting ratios that might inform the public about

[23] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15403.
[24] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15399.
[25] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15402.
[26] "Strengthening Transparency in Regulatory Science" Docket ID EPA-HQ-OA-2018-0259. Accessed at: https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=EPA-HQ-OA-2018-0259 on April 28, 2020.
[27] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15398, 15402.

what could be expected from this weighting proposal. As a result ,this generalized suggestion could be used to mollify those that oppose dismissal of public health studies that couldn't make their data public, but in essence, still dismiss them by assigning them a very small weighting factor.

Another crucial piece of omitted information in this SNPRM and the proposed rule relates to what will happen in the event of conflicting reanalyses of data. The SNPRM underscores that the purpose of this rule is to allow "independent validation" of study data.[28] We discuss the problems inherent to the EPA's stated approach below in the "Weaponizing Transparency" section, but here note the complete lack of information provided about what could happen if an attempted independent validation conflicted with original study results. The EPA provides no metrics for evaluating the appropriateness of methods used in a reanalysis, and conspicuously, provides no information about how a conflicting reanalysis result would impact the EPA's consideration of a study. This obvious omission introduces another way in which this proposed rule could be manipulated and result in the dismissal of credible scientific studies.

The recurring theme is that the EPA is recommending multiple options for agency or Administrator discretion without providing the public any details regarding decision-making criteria, much less opportunities for oversight. For a rule purported to increase agency decision-making transparency, the EPA has shrouded its proposed decision-making criteria and processes in mystery and thereby opened the door to manipulation and politicization. We strongly oppose these agency discretions without opportunity for additional input, response, or course-correction.

Weaponizing Transparency

Inviting Inappropriate Manipulation

One of the stated purposes of this SNPRM is to clarify vague, inaccurate, or inconsistent language in the 2018 proposed rule.[29] The "clarifications" offered in the SNPRM demonstrate the intention to undermine science through the façade of increasing transparency. While the EPA frames the rule as reflecting "recent innovations and policies surrounding information access,"[30] and there is indeed a widespread movement for open data and open science (which EDGI supports), this

[28] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15400.
[29] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15399, 15400.
[30] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15398.

proposed rule and its modifications in the attendant SNPRM are disingenuous to that spirit.

Publicly available datasets, especially those created under federal research grants, enable more researchers to utilize data that has already been collected and broadly increases research efficiency. Primary data collection is often extremely expensive and time-consuming, while secondary data analysis can often be accomplished more rapidly and on a much leaner budget. It is exceedingly rare for researchers to simply reanalyze other scholars' data, however, in part because there is no demonstrated need to do so. While the subject of scholarly retractions (of fabricated or otherwise flawed data and analyses) has received much attention in the last decade, the rate of retractions is still extremely low: 4 retractions for every 10,000 papers published even as the scientific community has focused considerable resources on self-correcting this rare problem.[31]

In this SNPRM, the EPA describes its intent for the proposed public data requirements to "allow stakeholders to reanalyze the data and models and explore the sensitivity of the conclusions to alternative assumptions."[32] This begs the questions of who the assumed "stakeholders" are and what the purposes are behind developing alternative assumptions, seemingly instead of exploring the theoretical and practical basis of the assumptions originally applied.

The EPA goes on to say the rule would "allow assessment of the robustness of the original analysis and conclusions by, for instance, showing the variability that can occur when a previously omitted variable is added to the statistical model, different functional form assumptions are made (*e.g.,* a linear marginal effect of treatment), or different assumptions are made when estimating standard errors and drawing statistical inferences (*e.g.,* allowing for spatial correlation in error terms)."[33] This is highly problematic, however, and is an overt way to attack credible science with unfounded critiques. All statisticians know that including too many variables is at least as flawed, and often moreso, than including too few variables, and one can artificially increase or decrease model fit without any theoretical grounding. Likewise, decisions about functional forms are typically grounded in theory, and even if they are not, clear relationships can be obfuscated by limiting or overwriting

[31] Jeffrey Brainard and Jia You, "What a massive database of retracted papers reveals about science publishing's 'death penalty,'" Science Magazine, October 25, 2018. Accessed at: https://www.sciencemag.org/news/2018/10/what-massive-database-retracted-papers-reveals-about-science-publishing-s-death-penalty on April 28, 2020.
[32] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15399.
[33] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15400.

functional forms. Applying a different functional form (e.g. linear rather than log-transformed) would always change the results and could obscure meaningful relationships. The EPA is not providing an opportunity to improve science through this proposed rule. For research that has gone through peer review (as the EPA, thankfully, clarifies it expects for research that is included in significant agency decisions[34]), altering model inputs, structure, and assumptions are easy mechanisms for unsophisticated and inappropriate muddling of credible and substantiated models. The examples of modified reanalysis the EPA listed would all be expected to generate conflicting results with the original study findings. Reviewing the conflicting results alone could be a drain on EPA resources, and even if the agency decided to dismiss the conflicting reanalysis, it could still substantially disrupt the utilization of credible science in EPA decision-making.

The kind of data required to be made public enhances the opportunity to apply inappropriate assumptions or otherwise faulty analyses. The EPA is requesting that clean data--raw data with obvious errors removed--be made public.[35] However, metadata is explicitly omitted from this requirement. The purpose of metadata is to orient a user to the data, often including its design, purpose, collection protocols, measurement precision, data architecture, etc. By requiring data be made public without metadata of any kind, the EPA opens the door to data misuse or misinterpretation, as well as incorrectly calling data and analyses into question.

Introducing Opaqueness

The EPA introduces new uncertainties in this SNPRM. While it is very helpful to have the definitions of "reanalyze," "independent validation," and "capable of being substantially reproduced" detailed in the SNPRM,[36] some questions arise. The EPA defines "reanalysis" as using the same data and applying the same *or different* methods of analysis, and indeed, as discussed above, details ways in which stakeholders might want to question previously published results using different analytical parameters. The definition the EPA introduces for "independent validation" narrows that to using the same data and the same methods to see if similar results are produced. While one can deduce that independent validation is a subtype of reanalysis, that isn't detailed in the SNPRM, and could lead to confusion. Substantially more problematic, however, is the lack of information provided about how the agency would respond to reanalyses and attempted independent validations, especially if they delivered conflicting results. Would reanalyses,

[34] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15403.
[35] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15401.
[36] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15400.

performed with different and perhaps inferior methods, be considered as evidence against the EPA utilizing a study in its decision-making? The EPA omits this pivotal information in the proposed rule and this SNPRM.

The EPA introduces additional confusion regarding tiered access and de-identified data. The EPA is proposing to allow "consideration of studies where there is tiered access to data and models that have CBI, proprietary data, or PII that cannot be sufficiently de-identified to protect the data subjects."[37] However, the EPA has not provided sufficient information about how tiered access to data could mitigate privacy concerns. Studies that concern the health of human subjects need to be approved by an Institutional Review Board (IRB), which considers the ethical foundations and implications of proposed research. In order to gain IRB approval, studies typically need to demonstrate a protection of personal privacy and obtain informed consent from participants. Participants' consent can not be violated by expanding access to sensitive data, even access to people who obtain "special authorization" from the EPA,[38] as that would never have been part of the original consent agreement for existing studies. Regardless of tiered access, data would need to be transformed to protect privacy. For example, health studies regarding ambient air that record a participant's address might transform the location data to be the nearest large roadway intersection or a ZIP Code centroid. The EPA mentions the potential creation of multiple versions of datasets that include privacy-related data transformations,[39] but fails to acknowledge that any data that needed to be transformed for any tier would need to be transformed for all tiers.

The EPA doesn't directly address its plan for consideration of studies with sensitive underlying data that had been transformed to protect privacy and made available through public or tiered access, but that could not be made available in a form that would meet the definitions of "reanalyze" or "independent validation." Under the EPA's alternative proposal to apply a lower weight to studies whose data cannot be exactly reanalyzed, it appears as though all health-related and location-specific studies would be weighted lower than studies without health or location information, which has the potential to substantially alter the types of studies informing agency decisions. The EPA also fails to acknowledge the substantial costs of data de-identification. Thorough data de-identification is not trivial, and if it was not included in an original project scope and budget, it is highly unlikely any academic researcher would have the capacity to undertake the de-identification

[37] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15402.
[38] Id.
[39] Id.

process. For existing studies, it is likely to be financially impracticable to de-identify data to make any sort of public access possible, thus excluding them or devaluing them in agency consideration, except through the sole discretion of the Administrator.

Another significant omission of information that limits public understanding of the proposed rule relates to the kind of "public availability" the EPA would deem sufficient. While the EPA states it is seeking input on the definition of "public availability," the basic definition offered for consideration of "information legally available from government sources, the media and the internet"[40] is insufficient. Most government records are legally available through the Freedom of Information Act (FOIA),[41] but anyone who has filed a FOIA request knows that the actual availability of information is often limited and can be extraordinarily laborious and often expensive to obtain. Studies originating outside of the government would not be subject to FOIA, so there would need to be another system for creating public access. However, there is currently no central place for academics to publish their data, let alone to publish data with tiered access. When discussing tiered access, the EPA offers the CDC's Research Data Center as an example repository and system.[42] The EPA fails to discuss, however, the costs associated with building, maintaining, and providing access to that repository, nor the cost of reviewing and evaluating applications for access.

The EPA must identify and create a structure for publicly available data before requiring studies to make their data public or make decisions about what data can safely be made public through that architecture. If the EPA sincerely seeks to make more studies' data public,[43] then the agency should, at the minimum: (1) create a public repository and user interface for such data, (2) provide funding explicitly for data de-identification in new federally funded research grants, and (3) admit de-identified data to the repository and into full consideration for influential scientific information.

Disregarding Credible Science

The requirements clarified in this SNPRM could unravel decades of environmental regulations. By retroactively applying this rule,[44] The EPA nearly guarantees that

[40] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15401.
[41] Freedom of Information Act, 5 U.S.C. § 552.
[42] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15402.
[43] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15403.
[44] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15403.

most existing public health studies would be stricken from consideration. Any study that includes primary collection of human health data would need to have obtained informed consent from subjects to participate in the study. Consent agreements are created to be very specific, scope- and time-limited agreements. For any study that did not originally make its data public--which describes the vast majority of studies conducted--participants haven't consented to their data being made public, even if a de-identification process has taken place. It could be an enormous undertaking to try to track down participants years after a study concludes to attempt to gain consent in order to comply with this rule. Furthermore, since many consent agreements are time-limited, researchers may not have the consent of participants to even attempt to contact them after the conclusion of the study. The EPA is leading researchers into a legal, ethical, and financial quagmire by retroactively dismissing or devaluing existing studies that do not comply with these unrealistic requirements.

It is also an ill-conceived move by the EPA to put current researchers in the position of either complying with privacy laws or allowing their research to have real-world impacts by informing regulations. In this SNPRM, the EPA explicitly bucks the use of the term "research data" in the 2018 proposed rule because "research data" excluded data that was protected under various privacy laws, such as confidential business information (CBI) and personally identifiable information (PII), and the EPA is requiring that that protected information be made public or be disregarded.[45] The effect of this is readily apparent: it will dramatically shift the balance of the kinds of studies that will be utilized in agency decision-making, reducing the proportion of public health studies and increasing the proportion of assay-based and computational modeling studies. This is likely to make the link between regulations and health protections less clear, not more. By expanding the public data requirements to all "influential scientific information" the agency considers,[46] this SNPRM conveys that the proposed rule will even more broadly undercut the EPA's ability to fulfill its mission--to protect human health and the environment[47] --than originally feared.

Conclusion

The SNPRM expands the scope of the proposed Strengthening Transparency in Regulatory Science rule to apply not only to significant regulatory decisions, but

[45] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15401.
[46] EPA, "Strengthening Transparency in Regulatory Science" SNPRM, 15397.
[47] EPA, "Our Mission and What We Do," www.epa.gov/our-mission-and-what-we-do. Accessed on May 7, 2020.

also to all influential scientific information that the agency considers. This could affect the future directions on the EPA's own research as well as all guidance, recommendations, and regulations. Remarkably, the EPA neglects to address any of the potential impacts of this rule, even though it would undoubtedly curtail the use of public health studies in agency decision-making. From ethical, legal, financial, and logistical considerations detailed earlier in our public comment, it is clear that compliance with this proposed rule is untenable for existing public health studies, and the rule could cause the EPA to disregard studies crucial for the protection of human health.

While expanding the scope of the proposed rule, the EPA also lays the groundwork to undermine public input in this proposed rule and a vast array of future rules. By suggesting that this proposed rule be considered a non-substantive, organizational matter that falls under the EPA's housekeeping authority, and seeking comment regarding how the EPA could establish regulations to interpret provisions of programmatic statutes, the EPA is laying the groundwork to excise public participation in its rulemaking. The SNPRM also creates new opportunities for the proposed rule to be manipulated and used for political aims. The EPA proposes two alternatives to outright dismissal of studies that can't make their underlying data public for legal or ethical reasons: tiered access to the data (which doesn't ameliorate privacy considerations) and a weighting scheme to devalue those studies. The EPA provides no accompanying details about how these measures would be implemented, leaving either or both open to manipulation for political ends.

The SNPRM's clarifications of the proposed rule's scope and definitions convey an attack on science rather than an effort to meaningfully add transparency to the rulemaking process. There is no explicit problem that this proposed rule effectively addresses, and it creates a scenario in which full consideration of public health studies is an impossibility. The EPA also provides no transparency about the potential implementation of a rule purported to increase transparency. There is no mention of public or intra-agency oversight, no criteria shared for the multiple agency discretions introduced. There are no analyses regarding costs, the types of research affected, or the existing rules that may be called into question when their underlying scientific basis is dismissed.

While EDGI supports transparency pursuant to data and information accessibility and expanding public knowledge, the proposed STRS rule would likely restrict public knowledge by dismissing and devaluing scientific input to the EPA's

decisions. It is important to note that there are several ways the EPA could actually make its regulatory decision-making more clear to the public and support public access to data, including: (1) funding researchers to de-identify data, (2) creating a user-friendly data repository with de-identified data, (3) conducting scientific assessments for all proposed regulations, and (4) providing syntheses and summaries of science assessments at multiple levels of detail to be comprehensible by various interested parties. Neither the 2018 proposed rule nor this SNPRM offer potentially meaningful advances in the EPA's decision-making or the public's engagement with the decision-making process. We strongly urge the EPA and Administrator Wheeler to abandon this proposed rule.