Administrator Andrew Wheeler  
U.S. Environmental Protection Agency  
1200 Pennsylvania Avenue, NW  
Washington, D.C. 20460  

RE: Docket ID No. EPA-HQ-OA-2018-0259  

Dear Administrator Wheeler:

Thank you for the opportunity to comment on the supplemental notice to the proposed rule for Strengthening Transparency in Regulatory Science, 85 Fed. Reg. 15396 (proposed March 18, 2020) [hereinafter “the supplemental proposal”].

We, the undersigned, are Member Scholars and staff with the Center for Progressive Reform (CPR), a non-profit research and educational organization that works to build thriving communities on a resilient planet. CPR’s mission is to educate, collaborate and advocate with the goal of driving public policy reform through rigorous and accessible legal analysis. CPR operates with a network of more than 60 Member Scholars who are leaders in various legal academic fields, and a professional staff of policy analysts, communication experts, and others. We work together to advance the idea that government safeguards and other regulations are key to social justice and planetary health. Our website may be found at [www.progressivereform.org](http://www.progressivereform.org). Responses to the comments below may be sent to Darya Minovi at dminovi@progressivereform.org.

CPR works with various grassroots organizations and frontline communities, primarily in the Chesapeake Bay Watershed, which depend on the U.S. Environmental Protection Agency (EPA) to protect them from harmful pollution. The provisions contained in the 2018 proposal¹ and the supplemental proposal that together comprise the EPA’s “Strengthening Transparency in Regulatory Science” rulemaking (RIN: 2080-AA14) [hereinafter “rulemaking”], if finalized, would harm these and other grassroots organizations by restricting the science that the agency could use,

undermining its ability to carry out its statutory mission of protecting public health and safeguard the environment. As detailed below, this supplemental notice does not address the concerns raised by more than half a million scientists and public interest advocates in response to the 2018 proposed rule but instead serves to further attack science and to harm public health and the environment. Unsurprisingly, the EPA is still unable to point to any authority that Congress has granted it to implement the dangerous policies contained in the rulemaking. In light of these concerns, the EPA should abandon this rulemaking and instead focus its limited resources on implementing evidence-based actions that affirmatively increase agency transparency and protect public health.

The EPA Has Failed to Identify Legal Authority to Support a Policy to Disregard or Discount Relevant and Objectively Sound Scientific Information When Engaging in Regulatory Decision-Making or Undertaking Other Policy-Relevant Scientific Determinations

In the 2018 proposal, the EPA glibly asserted that authority for the rulemaking could be found in “the statutes its administers, including provisions providing general authority to promulgate regulations necessary to carry out the Agency’s functions under these statutes and provisions specifically addressing the Agency’s conducting of and reliance on scientific activity to inform those functions.”2 (The 2018 proposal goes on to cite specific provisions in various authorizing statutes that provide general rulemaking authority or that create scientific research programs to support implementation of the particular statute.) Unsurprisingly, this position met almost immediately with broad condemnation and was singled out as one of the most flawed aspects of the 2018 proposal.3

The supplemental proposal now seeks to remedy this threshold weakness in the original proposal by offering a new alternative legal justification for the rulemaking. Specifically, the supplemental proposal employs a novel reading of an obscure law known as the Federal Housekeeping Statute to identify a legal basis for the rule.4 (The supplemental proposal also sought public comment on whether to rely on the Federal Housekeeping Statute as an independent basis for the rule or to use that statute’s authority in conjunction with the specific provisions of its authorizing statutes that were cited in the 2018 proposal.)

This new attempt to find legal authority for the rule has two critical flaws. First, the Federal Housekeeping Statute doesn’t apply to the EPA – only “Executive departments,” a category that does not include the EPA. Second, even if the statute did apply to the EPA, the modest authorities it confers on covered federal agencies would not supply the legal basis for the kind of far-reaching requirements and limitations contemplated in the rulemaking. Because neither the 2018 proposal nor the supplemental proposal has identified a sound legal basis for this rulemaking, the rulemaking presents a clear case of an action that is “in “in excess of statutory . . . authority,” rendering it highly vulnerable to rejection on judicial review.

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2 Id. at 18769.
Since the Federal Housekeeping Statute Does Not Apply to the EPA, the Agency Cannot Exercise the Authorities It Provides

The operative provision of the Federal Housekeeping Statute reads: “The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property.” A related law provides the definitive list of the “Executive departments” covered by the Federal Housekeeping Statute. Since its creation, the EPA has remained conspicuously absent from this list.

The supplemental proposal acknowledges this obvious shortcoming but asserts that the 1970 legislation that created the EPA, Reorganization Plan No. 3, still served to bring the agency within the scope of Federal Housekeeping Statute. Reorganization Plan No. 3 formally established the agency while laying out all the programs and authorities that were being transferred to it from already existing agencies, including the Department of the Interior and an agency then known as the Department of Health, Education, and Welfare.

Significantly, however, Reorganization Plan No. 3 never directly mentions the Federal Housekeeping Statute. To overcome this barrier, the supplemental proposal adopts the legal theory that the EPA’s Office of General Counsel (OGC) employed in a 2008 memorandum opinion concerning an unrelated regulation. That opinion contends that Section 2(a)(9) of the Plan implicitly confers this authority through a vague “catchall” provision. Specifically, this provision calls for the transfer of “So much of the functions of the transferor officers and agencies referred to in or affected by the foregoing provisions of this section as is incidental to or necessary for the performance by or under the Administrator of the functions transferred by those provisions or relates primarily to those functions.”

In essence, then, the supplemental proposal argues that, when Congress formally approved Reorganization Plan No. 3, it has also implicitly intended to regard the EPA as an Executive department – or at least imbue it with some of the trappings of an Executive department – but in the nearly 50 year since has not gotten around to officially declaring it by updating the relevant statutory list. This argument is unpersuasive.

Since the enactment of the Federal Housekeeping Statute, Congress has amply demonstrated that it knows how to update the statutory “Executive departments” list, and it has done so on several occasions both before and after it approved Reorganization Plan No. 3. Indeed, Congress updated the list a little over a month after Reorganization Plan No. 3 to remove the Post Office Department from the list. That seemingly would have provided an ideal opportunity for Congress to take the step of explicitly adding the newly created EPA.

Congress has had several opportunities in the nearly 50 years since the EPA was created to update the statutory “Executive departments” list, and it has conspicuously failed to do so. Most notably, Congress could have done so in 1979 when it updated the list to reflect the reorganization of the old Department of Health, Education, and Welfare – from which many of the EPA’s original functions and authorities had sprung – into the new Departments of Education and Health and Human Services, respectively. The fact that Congress has yet not

9 Postal Reorganization Act, Pub. L. 91–375 §6(c)(1).
updated the statutory “Executive departments” list to include the EPA despite ample opportunities to do so cannot be wished away by a memo from the agency’s OGC.

Of greater relevance, Congress has shown that it knows how to update the statutory “Executive departments” list to include new departments that are created through the transfer and consolidation of various existing programs and authorities spread across several federal agencies, as was the case with the EPA. Congress took precisely this step when it created the Department of Homeland Security. Like Reorganization Plan No. 3, the Homeland Security Act of 2002, adopted in response to the September 11th terrorist attacks, lays out those functions and authorities that were being transferred to the new Department of Homeland Security from where they had previously existed at agencies like the Departments of Agriculture, Energy, and Treasury.\(^{10}\) Significantly, in transferring these functions, the Homeland Security Act also specifically provides in Section 101 that the Department of Homeland Security was being “established . . . as an executive department of the United States within the meaning of [the title of the U.S. code that contains the Federal Housekeeping Statute].”\(^{11}\)

Another problem with the supplemental proposal’s argument is that the EPA has evolved as an agency in significant ways since its creation. This then raises intractable difficulties regarding the appropriate present day application of the catchall provision contained in Reorganization Plan No. 3. Through various authorization and reauthorization acts, the present day EPA is no longer the same agency that was established via Reorganization Plan No. 3, and it now carries out functions and authorities that were not contemplated at the time the Plan was drafted. Under the OGC’s theory adopted by the supplemental proposal, it stands to reason that these new functions and authorities would not benefit from the implicit transfer of the Federal Housekeeping Statute authorities. That result would put current EPA officials (and potentially reviewing judges) in the awkward position of policing the lines between those agency functions and authorities covered by the Federal Housekeeping Statute and those that are not. Such a bizarre result weighs further against accepting the theory that the catchall provision in Reorganization Plan No. 3 served as an implicit transfer of the authorities conferred by the Federal Housekeeping Statute.

To be sure, the EPA has for decades issued regulations under claimed authority from the Federal Housekeeping Statute and the appropriateness of the legal basis for these regulations appears to have gone unchallenged. But a legal wrong cannot be made right through simple repetition. If it did, then agencies would face strong incentives to break the law as much as they could before getting caught. It is also worth noting that these previous applications involved genuinely noncontroversial internal procedures for the agency – the kind of procedures that the Federal Housekeeping Statute was designed to authorize, as noted below. As such, it would be unreasonable to construe the lack of a challenge to the legal basis for these actions as a broad recognition or acceptance of the appropriateness of their legal basis. Instead, it is more likely that their noncontroversial nature was such that they failed to attract the kind of intensive legal scrutiny that would have exposed their inadequate legal basis to begin with.

The Federal Housekeeping Statute Does Not Authorize Policies Like Those Provided in the Rulemaking That are Intended to Have a Significant External Effect on Members of the Public That Inevitably Will Occur in the Course of the EPA’s Program Implementation

Even if the supplemental proposal was correct in its assertion that the EPA is covered by the Federal Housekeeping Statute, it does not necessarily follow that the authorities it confers would supply the legal basis for this rulemaking. On the contrary, it is clear that the modest authorities that the Federal Housekeeping Statute affords to covered agencies are insufficient to support this rule, since its primary effect is external in nature because it seeks to alter how the general public interacts with the EPA for the purpose of affecting its regulatory decision-making or informing its policy-relevant scientific determinations.

To support its contention that the Federal Housekeeping Statute provides it with authority to issue the rule, the supplemental proposal curiously cites the Supreme Court case Chrysler Corp. v. Brown.12 The citation of this case is curious because the Court’s reasoning there cuts unmistakably against this argument. At issue in Chrysler Corp. was a Department of Labor regulation that sought to compel the public disclosure of reports provided to the government by government contractors concerning their workforce composition, even though such disclosures would seemingly run afoul of the Trade Secrets Act. The Court struck down this regulation, finding that the modest reach of the Federal Housekeeping Statute was too limited to empower the Department of Labor to displace the mandates imposed on it by Trade Secrets Act.

Crucially, in reaching its decision, the Court emphasized the essential “‘housekeeping’ nature” of the Federal Housekeeping Statute and characterized the law as “simply a grant of authority to the agency to regulate its own affairs.”13 The Court had little trouble contrasting this understanding of the statute’s modest reach with the Department of Labor’s regulation. Indeed, the material impacts of this regulation unavoidably extended well beyond what might be considered routine internal agency operating procedures given that its function was to alter the application of the Trade Secrets Act, a law that Congress enacted to govern privacy issues that arise from the federal government’s interactions with private sector businesses. Accordingly, the Court concluded that Congress had not intended the Federal Housekeeping Statute to authorize something like the Department of Labor’s workforce composition disclosure regulation.

The logic employed by the Court in Chrysler Corp. is readily applicable to this rulemaking. As was the case there, this rulemaking cannot be reasonably understood as governing the EPA’s internal operating procedures. That is because the provisions in this rulemaking are directly and inextricably tied to the implementation of the EPA’s various authorizing statutes, as well as to its adherence to the Administrative Procedure Act (APA). The rulemaking’s impact on the APA is significant in this regard because the function of that law is to govern how the federal government interacts with members of the public in the development of new regulations. As such, this rulemaking is practically indistinguishable from the one at issue in Chrysler Corp., which, as noted above, sought to alter the Department of Labor’s adherence to the Trade Secrets Act, a law that similarly seeks to manage certain kinds of interactions between the government and the general public. In relevant part, the APA directs agencies to “give interested persons an opportunity to participate in the rule making through submission of written

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13 Id. at 309 (emphasis added).
data, views, or arguments.” It further directs them to develop a final rule based on the “consideration of the relevant matter presented.”

The rulemaking would undeniably impact the EPA’s compliance with these public participation requirements under the APA. In particular, its function is to fundamentally alter how members of the public are able to contribute to the development of the EPA’s regulations and policy-relevant scientific determinations. Among other things, it would limit the kinds of “written, data, views, or arguments” that “interested persons” can submit to the EPA during the public comment process, while also drastically overhauling what the EPA can regard as “relevant matter presented” for its “consideration” in developing a final rule. As such, because this rulemaking goes well beyond routine internal housekeeping procedures, it plainly exceeds the authority that could be granted to the EPA by the Federal Housekeeping Statute.

That the rulemaking would have such a significant impact on how the public interacts with the EPA on matters important to the public can also be seen in the considerable controversy it has provoked since its inception. The 2018 proposal received nearly 600,000 public comments, nearly all of which were in opposition. At a recent House Science Committee hearing on the rulemaking, none of the committee members present and none of the non-agency invited witnesses offered support for the 2018 proposal. It is also noteworthy in this regard that Congress has rejected several bills in recent years that have sought to impose limitations on the EPA’s consideration of science in developing new rules that are similar to those contained in this rulemaking. It would be hard to believe that the kind of modest and mundane authorities supplied by the Federal Housekeeping Statute could provide the legal basis for a rulemaking that has engendered such widespread opposition and controversy.

The Rulemaking Lacks a Scientific Basis, and Its Provisions Will Waste Agency Resources and Harm Public Health

While the EPA maintains that the provisions contained in the 2018 proposal and the supplemental proposal that comprise this rulemaking are intended to address concerns raised by scientists and health and environmental advocates, the reality is that this rulemaking lacks any scientific basis and serves to undermine the agency’s ability to protect public health.

At the most basic level, it is unclear why the EPA is pursuing this rulemaking. In the 2018 proposal, the agency claimed the rule would enable it to “apply the best available science to its regulatory decision-making.” Yet the agency has not described existing challenges with data quality or scientific integrity that this rule would address. Furthermore, the provisions do not align with any widely accepted standards regarding scientific rigor and review, as articulated in joint statements by editors of reputable journals including Science, Nature, PLOS, Proceedings of the National Academy of Sciences, Cell, and The Lancet. In the spirit of transparency, the

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EPA should describe a credible scientific origin for this proposal and provide evidence for how it aligns with best practices.

As written, the supplemental proposal, together with the 2018 proposal, will undermine, rather than promote, scientific transparency. First, it is unrealistic and harmful to require underlying data to be publicly available, since many environmental health studies rely on medical data and other proprietary information. There is also no evidence to suggest that this is a remedy to an existing problem. A 2013 study that reviewed 79 requests through the Information Quality Act asking the agency to reconsider or correct data used in regulatory decisions between 2002 and 2012 found only two requesting the raw data. The authors posit that having EPA acquire a collection of raw data would be burdensome to both the agency and study investigators, and “create major delays in rulemaking.” They suggest that rather than making all raw data available, the agency should instead establish a database that “registers studies and obtains systematic sets of parameters and results”, such as the National Institutes of Health’s clinical trials database.

The EPA claims that data be available to complete “reanalysis”, yet does not articulate why it is necessary to recalculate results of peer-reviewed research. Not only does this provision imply that existing, widely accepted standards are insufficient, but that the agency’s previous policies were flawed, as the EPA already has robust measures in place for peer review and evaluating information quality. This includes an “evaluation and review” process whereby the agency uses a questionnaire to independently validate external research, without the need to reanalyze the underlying data. In practice, this means that EPA researchers could be tasked with reanalyzing all of the underlying data for studies used in regulatory decision-making, including risk assessments for hazardous air and water pollutants. This exercise would be incredibly costly and time-consuming, wastefully directing staff time away from considering new research and taking action to protect communities currently burdened by harmful pollution. Furthermore, expanding the scope of the rule to cover research related to “influential scientific information” will not achieve a “broader approach to transparency” but further directs resources toward unnecessarily scrutinizing nearly every study the agency considers.

By applying the regulations retroactively, as the supplemental proposal suggests, the agency would essentially be given a free pass to throw out studies currently underpinning regulatory decisions. One example is the American Cancer Society’s seminal study on particulate matter and mortality, which serves as the basis for several of the agency’s air pollution regulations. Excluding influential studies would, in effect, kick the legs out from under health-protective standards, making it easier for the agency to pursue rollbacks or delay updating rules, even when the best available research says otherwise.

EPA’s response to concerns regarding data availability is to weigh more heavily studies where
the data is publicly available. This “compromise” runs counter to principles of transparency, as
the agency would rely more heavily on a study with publicly available data over one that meets
the highest scientific standards and yields compelling results. This approach may also exclude
older studies where the raw data may no longer exist or is difficult to access due to outdated
methods of storage. It also undermines the use of studies where the raw data cannot be
published, such as Harvard University’s groundbreaking Six Cities study, where the researchers
signed confidentiality agreements to track the private medical and occupational histories of
more than 22,000 people. The availability of data should not be the primary determinant of
scientific rigor and quality and only serves to exclude research which may influence the
outcomes of regulatory decision-making.

Finally, further calling into question the motives for this proposal, the agency has not articulated
whether and how it will keep track of studies that are excluded from regulatory decision-making.
In the interest of scientific transparency, the agency should in the least develop a protocol for
documenting and disclosing the reasons specific studies are excluded.

If the EPA truly sought to promote scientific transparency, the agency would evaluate studies
based on data collection methods, data quality, and the type of analysis, and prioritize
assessments of new and emerging research. Instead, the agency has directed their limited
resources to weakening and eliminating health-protective regulations, and as detailed in a
recent report by the U.S. Government Accountability Office, the agency fails to adequately
assess and control toxic chemicals. As outlined by various experts, including CPR’s Member
Scholars, there are more scientifically sound ways to achieve transparency, such as requiring
conflict of interest disclosures or applying the standards prospectively and providing researchers
with ample notice of the new requirements.

The rulemaking will weaken the scientific basis for protective standards, allowing the agency to
draw different conclusions from the same data, or ignore compelling data altogether in order to
roll back regulations put in place to protect public health. The lack of evidence underlying this
proposal demonstrates that this rulemaking is purely political and another in a long string of
efforts by the Trump administration to undermine the effectiveness and credibility of the EPA.

Implementation of the Rulemaking Would be Unjustifiably Costly

Despite the fact that the rulemaking has been classified as “significant” under Executive Order
12866, the EPA has conspicuously failed to include a regulatory impact analysis for either the
2018 proposal or the supplemental proposal in the electronic docket. (The fact that the EPA
classifies the rulemaking as significant further belies the agency’s claim that it amounts to the
kind of routine internal operating procedure that would be authorized by the Federal
Housekeeping Statute.) With the absence of this analysis, the EPA has failed to provide the

22 Popovich N, Albeck-Ripka L, Pierre-Louis K. The Trump Administration Is Reversing Nearly 100 Environmental
public with any meaningful accounting for what the implementation of this rulemaking would likely cost in terms of budgetary and staff resources as well as in new delays in issuing new rules.

In terms of the EPA’s resources, the best evidence we have suggests that the implementation of the rulemaking would be quite costly. For example, as noted above, Congress has in recent years considered several bills that would alter the EPA’s use of science in ways that are practically similar to what is contemplated in this rule. According to the Congressional Budget Office’s assessment of the bill, the EPA would likely expend at least $250 million per year implementing its provisions during at least the first several years after the bill’s passage. Given the similarity between those bills and this rulemaking, it is safe to offer as a ballpark estimate that implementation costs for the rulemaking would be at least $250 million annually as well.

The rulemaking would likely also be costly in terms of the forgone benefits that would occur as a result of the additional regulatory delays that it would create. For example, the “cost” of one year’s delay of some of the EPA’s biggest Clean Air Act rules could be measured in thousands of premature deaths and tens of thousands of asthma attacks and missed school and work days. As legal scholars across the political spectrum recognize, the rulemaking process has become extraordinarily slow, due in large part to the combination of agencies’ dwindling resources and the proliferation of additional procedural and analytical requirements that agencies must satisfy before issuing new rules. As a result, it already can take anywhere from five to ten years for the most complex rules to complete the rulemaking process. In 2012, the Government Accountability Office found that the Occupational Safety Health Administration (OSHA) spent an average of seven years on each of its major rulemakings.

Implementation of this rulemaking would only exacerbate this problem, leading to even more costly delays that harm public health, safety, financial security, and the environment. To better fulfill its mission of protecting public health and the environment, the EPA should be exploring opportunities to streamline its processes for issuing new safeguards – not making the problem of alarming delays even worse.

What makes these large implementation costs especially concerning is the fact that the rulemaking would do little, if anything, to improve the quality of EPA’s decision-making and enhance the scientific integrity of its program implementation, as documented in detail above. We note – without necessarily endorsing – that the Supreme Court has suggested that a hallmark of rational regulatory decision-making is that the costs created by a regulation not grossly outweigh the benefits it produces. As the forgoing confirms, this rulemaking would clearly fail under this standard.

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27 Michigan v. EPA, 576 U.S. ___, 135 S. Ct. 2699, 2707 (2015) (“One would not say that it is even rational, never mind ‘appropriate,’ to impose billions of dollars in economic costs in return for a few dollars in health or environmental benefits.”).
Conclusion

In its current form, EPA’s rulemaking rejects widely accepted scientific standards and will allow the agency to cherry-pick studies that align with the administration’s agenda - surely, the antithesis of scientific transparency and integrity. If implemented, it will be prohibitively costly to the agency, both in terms of taxpayer dollars and the unnecessary and avoidable harms to public health and the environment. Furthermore, the EPA has incorrectly identified the Federal Housekeeping Statute – which does not apply to the EPA and does not justify the far-reaching requirements of this rulemaking – as the legal authority for this rulemaking. As explained above, the EPA should abandon this unjustified, misleading, and dangerous rulemaking and instead implement regulations that assuredly improve scientific transparency and increase the agency’s ability to evaluate new and existing research.

We thank you for the opportunity to provide these comments and are happy to discuss them with you in further detail.

Sincerely,

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