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EPA Docket Center
Office of Research and Development Docket
Mail Code 28221T
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Submitted via Regulations.gov

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

Ms. Hawkins:

I appreciate this opportunity to provide comments1 to the Environmental Protection Agency (EPA) on the supplemental notice of proposed rulemaking (supplemental notice) connected to the 2018 “Strengthening Transparency in Regulatory Science Proposed Rulemaking” (proposed rule). This comment will address both the supplemental notice and the proposed rule.2

The Importance of the Rule

On March 9, 2009, President Barack Obama issued a memo on scientific integrity to the heads of executive departments and agencies.3 The memo explains:

If scientific and technological information is developed and used by the Federal Government, it should ordinarily be made available to the public. To the extent permitted by law, there should be transparency in the preparation, identification, and use of scientific and technological information in policymaking.4

Later in 2009, a Bipartisan Policy Center report recommended “federal agencies, universities and journals should encourage or require on-line publication of the methods and data underlying published scientific studies.”5 In 2013, the Administrative Conference of the United States adopted “Administrative Conference Recommendation 2013-13.”6 This document states:

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1 The views I have expressed in this comment are my own, and should not be construed as representing any official position of The Heritage Foundation.
2 When the comment refers to the rule or rulemaking, it is referring to the entire transparency rulemaking effort, unless it specifies otherwise.
4 Id.
To the extent practicable and in compliance with applicable legal restrictions, privileges, protections, and authorities, agencies should seek to provide disclosure of data underlying scientific research, including both privately and federally funded research being considered by the agencies.\textsuperscript{7}

These examples highlight the wide bipartisan support for promoting transparency in the use of science by federal agencies. The public should know how federal agencies have made regulatory decisions. Simply pointing to a scientific report is insufficient. The merits of any report can only be ascertained if the authors “show their work.” President Obama, in his scientific integrity memo explained, “the public must be able to trust the science and scientific process informing public policy decisions.”\textsuperscript{8} [Emphasis added]. He was absolutely right.

The public is not going to trust the scientific process if it does not have any way to evaluate the scientific process. This trust problem is only exacerbated by the peer review problems that exist in the scientific literature. This is a not a new phenomenon. In its 2002 Information Quality Act (IQA) Guidelines, the Office of Management and Budget (OMB) wrote, “there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research.”\textsuperscript{9}

Numerous experts have drawn attention to the problems of peer review. For example, Richard Smith, former editor of the British Medical Journal wrote in 2006 “peer review is a flawed process, full of easily identified defects with little evidence that it works.”\textsuperscript{10} In 2015, Richard Horton, editor of The Lancet, asserted that “much of the scientific literature, perhaps half, may simply be untrue.”\textsuperscript{11}

A 2016 Nature survey found “more than 70% of researchers have tried and failed to reproduce another scientist’s experiments, and more than half have failed to reproduce their own experiments.”

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\textsuperscript{7} Id.

\textsuperscript{8} OFFICE OF THE PRESS SECRETARY, THE WHITE HOUSE, Memorandum for the Heads of Executive Departments and Agencies 3-9-09 (March 9, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09 (last visited May 18, 2020). For purposes of this comment, quotes taken from documents that start with a capital letter may be adjusted to a lower case letter, such as with this quote.


\textsuperscript{11} Richard Horton, Offline: What is medicines 5 sigma?, 385 The Lancet 1380 (2015), https://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2815%290020124-1.pdf?code=lancet-site (last visited May 18, 2020); See also, John P. A. Ioannidis, Why Most Published Research Findings Are False, 2 PLOS Medicine e124 (2005), https://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.0020124 (last visited May 18, 2020) (John Ioannidis: “It can be proven that most claimed research findings are false”).
experiments.\footnote{Monya Baker, \textit{1,500 scientists lift the lid on reproducibility}, 533 Nature News (2016), \url{https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970} (last visited May 18, 2020).} An astonishing 90 percent of the respondents agreed that there was either a significant or slight reproducibility crisis. Only 3 percent said there was no crisis.\footnote{Id.}

So, the question is not \textit{whether} the EPA should be taking action to promote transparency and ensuring the public has access to underlying information used in the science. The question is \textit{how} can the EPA do so in a manner that is truly committed to achieving transparency while taking appropriate steps to address genuine obstacles.

**Legal Authority for the Rule**

In the supplemental notice, the EPA is seeking feedback on the following issue, “[t]he Agency continues to consider whether it is appropriate to rely on its authority in the above-reference environmental statutory provisions (potentially in conjunction with its housekeeping authority).”\footnote{ENVIRONMENTAL PROTECTION AGENCY, \textit{Strengthening Transparency in Regulatory Science}, Supplemental Notice of Proposed Rulemaking, 85 Fed. Reg. 15396 (March 18, 2020), \url{https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9322} (last visited May 18, 2020). For purposes of this comment, additional quotes/references to the supplemental or proposed rule will not be cited in the footnotes.}

To put it succinctly, the answer is yes. The EPA should rely on both the substantive environmental statutes and the housekeeping authority.

The EPA would not be implementing these statutes properly if it was using flawed science in the promulgation of its rules. To highlight one example, it is useful to reexamine the U.S. Supreme Court case \textit{Michigan v. EPA}.\footnote{\textit{Michigan v. EPA}, 135 S. Ct. 2699 (2015), \url{https://www.law.cornell.edu/supremecourt/text/14-46} (last visited May 18, 2020).} In discussing the “appropriate and necessary” language in \textsection\textsection 112(n)(1)(A) of the Clean Air Act (CAA),\footnote{\textsection 112(n)(1)(A) of the Clean Air Act; 42 U.S. Code \textsection 7412(n)(1)(A), \url{https://www.govinfo.gov/content/pkg/USCODE-2013-title42/html/USCODE-2013-title42-chap85-subchapI-partA-sec7412.htm} (last visited May 18, 2020).} the U.S. Supreme Court argued “[o]ne 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.”\footnote{\textit{Michigan v. EPA}, 135 S. Ct. 2699 (2015), \url{https://www.law.cornell.edu/supremecourt/text/14-46} (last visited May 18, 2020).}

Similarly, it would not be rational for the EPA to use science for these very costly policies without even knowing whether the science is credible. Nor would it be rational for the agency to fail to take every possible step to ensure scientific accuracy, including making underlying information available to the public (especially since the EPA is well aware of the problems that pervade the science). Making the information available to the public is not some nice gesture to appease the public. It is a critical step to help the agency itself get necessary feedback to better assess the science.
A further scan through these statutes would find additional language that would suggest a need for accurate information. Looking at just the criteria pollutant language in the CAA, “[a]ir quality criteria for an air pollutant shall accurately reflect the latest scientific knowledge.”18 [Emphasis added]. The national ambient air quality standards shall be “based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health.”19 It is impossible to know if something is “requisite” (or “necessary”) if that decision is based on inaccurate science. The science in a given situation very well may be accurate, but it is incumbent upon the EPA (and other agencies) to take necessary steps to ensure this accuracy.

Beyond the specific statutory sections, the need for accuracy should be simply inferred. After all, did Congress delegate regulatory power to the EPA so that it can develop regulations that are based on inaccurate information?

There is also a practical reason for utilizing these environmental statutes as statutory authority for the rule. It should help affected parties to enforce EPA’s compliance with the rule. Relying upon the housekeeping authority alone might make this regulation covering internal procedures more difficult to enforce. Regarding this enforcement concern, the EPA should learn some lessons from the IQA. It is extremely important that the rule itself have clear and objective requirements, without creating so much flexibility and discretion that there is nothing for a court to enforce.20 In addition, by having clear requirements, this will limit future administrations from getting around the rule.

To its credit, the EPA is undertaking this extremely important transparency initiative. It would do a disservice to the public and the agency itself if the rule has no “teeth” and is simply ignored whenever it is convenient for future administrations.

**Influential Scientific Information and Pivotal Science**

The supplemental notice’s addition of influential scientific information (ISI), and the underlying science (pivotal science) informing influential scientific information, is an important change. The EPA is correct in recognizing that the science the agency disseminates even outside the regulatory context can have a major impact. The imprimatur of the federal government carries significant weight and can help shape public opinion. When the EPA disseminates scientific information, this can influence the work of other federal agencies, impact private and public funding and research, and can help to create the conventional wisdom on a specific issue.

In its IQA Guidelines, OMB recognized how agency disseminated information can have a major impact as evidenced by its inclusion and definition of “influential” in the term “influential

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20 This is not to suggest that the IQA does not have requirements, because it does. However, the discretion in the IQA has created problems for judicial review. As for the EPA’s transparency rule, clear requirements would make it less likely for a court to even try and assert there is nothing to enforce.
scientific, financial, or statistical information.”\textsuperscript{21} “Influential” when used in this term “means that the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decision.”\textsuperscript{22} OMB’s “Final Information Quality Bulletin for Peer Review” sent to agencies in 2004 created a specific definition for “influential scientific information” that mirrors the language from the Guidelines.\textsuperscript{23} “‘Influential scientific information’ means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.”\textsuperscript{24} This is the definition used in the supplemental.

**Clarifications**

While clarification may be needed in various place in the rule, there are two clarifications in particular that should be made in any final rule to reflect what EPA is in fact trying to convey.

1) “If the proposed or alternative approach were finalized, EPA would consider the availability of underlying data and models only for studies that are potentially pivotal to EPA's significant regulatory decisions or influential scientific information that are developed in the future.”

This language comes from the preamble. Does “developed in the future” describe “data and models,” “studies,” or “significant regulatory decisions or influential scientific information?” The EPA is almost certainly describing the latter, but the language is drafted in a manner that could potentially lead to confusion. Further, if “developed in the future” is supposed to be describing “data and models,” this would render the data and models exemption language in §30.9 superfluous. If the EPA is actually trying to describe “data and models” or “studies,” this would create a blanket and excessive exception to the rule for previously developed data, models, or studies. The problem of creating exceptions for “old data” will be discussed later in this comment.

2) “The provisions of this part apply to data and models, underlying pivotal science supporting influential scientific information and/or underlying pivotal regulatory science used to justify significant regulatory decisions regardless of the source of funding or identity of the party conducting the science.”

This language come from §30.3. The comma after “data and models” appears to be communicating that the provisions apply to data and models, underlying pivotal science, and/or

\textsuperscript{22} Id.
\textsuperscript{24} Id.
underlying pivotal regulatory science. Unfortunately, this language could also create confusion by giving the impression that the provisions only apply to data and models. Since this is unlikely what the EPA intends, it should make § 30.3 clearer.

If in fact the EPA does only intend to cover data and models, then this would make little sense and beg the question why it would not cover pivotal science and pivotal regulatory science. Both are critical in practice and for purposes of this rule. The EPA would be creating a transparency rule to help the public evaluate the science, and then arbitrarily only allow the public to evaluate a subset of what informs influential scientific information and significant regulatory actions.

Privacy, Confidentiality, and Confidential Business Information

The EPA should respect genuine privacy, confidentiality, and confidential business information (CBI) concerns. It should not respect fake concerns. Critics of this rule have often talked about the merits of transparency and then criticized the rule because there might be some instances where these concerns might be genuine. These exceptions are not an argument against the promulgation of the transparency rule (or for inappropriately watering down the rule), but they are an argument for being cognizant of any legitimate concerns and taking appropriate action to address them.

A 2013 ACUS-published report seems especially relevant to help put these concerns in proper context. The report discussed overclaiming CBI concerns:

‘Confidential Business Information (CBI) claims can . . . make it difficult for the interested public to evaluate studies that contribute to regulatory policy.’ Agencies that provide CBI protections for studies or data that inform regulation should ensure that the CBI claims are justified. Given the strong incentives to regulated parties for overclaiming CBI protection and the resultant costs from this overclaiming to public health protection and research, it is important that the agencies’ CBI programs not provide a safe haven for unjustified suppression of relevant regulatory research. To that end and as a first step, the agencies should review their CBI programs to ensure that there is rigorous oversight of CBI and related trade secret claims on health and environmental research. Agencies should, where possible, penalize those CBI claims that, upon review, appear unjustified.

This overclaiming problem applies to the privacy, confidentiality, and CBI arguments against the EPA rule. The EPA should be skeptical of such claims and do what is needed so that underlying information is provided to the greatest extent possible.

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25 For simplicity purposes in the comment, the full language describing the pivotal science and pivotal regulatory science from the quoted language was excluded: “underlying pivotal science supporting influential scientific information and/or underlying pivotal regulatory science used to justify significant regulatory decisions…”

Revising § 30.5

The EPA proposes two alternatives in how to address situations when underlying data and models for studies are unavailable. The EPA should take elements of both proposals and make some critical changes.

As an initial matter, it is unclear why the EPA only mentions “data and models” at the start of § 30.5. This is just a subset of information that underlies pivotal regulatory science and pivotal science. In fact, the EPA appears to recognize this in both versions of § 30.5, when it states, “information is considered ‘available in a manner sufficient for independent validation’ when it includes the information necessary to understand, assess, and reanalyze findings.” The EPA then goes on to list some examples. The EPA should be focusing § 30.5 on all information necessary to understand, assess, and reanalyze findings (basically, in plain English, as a general rule, the public should have access to whatever information is necessary to evaluate a study). The list of examples in § 30.5 includes some of the additional information that is necessary, including computer codes and “associated protocols necessary to understand, assess, and extend conclusions.”

When there are genuine privacy, confidentiality, and CBI concerns, the EPA should not exclude studies, but give lesser weight to the studies when underlying information is unavailable. Determining the genuineness of these concerns will be explained below when discussing exclusion of such studies. By allowing these studies to be considered when there are genuine concerns, this should make the exemption for “old data and models” in § 30.9 unnecessary. If adopted, studies with genuine privacy (and related) concerns could be considered. As a result, there is no reason for the EPA to include such a sweeping exemption in § 30.9. This exemption, if maintained, would also likely have the unintended consequence of encouraging the EPA to use old data/exclude new data when disseminating influential scientific information and developing significant regulatory actions.

The EPA should develop objective criteria to determine when a study should be excluded. These criteria are in effect a means to determine when there are not genuine privacy, confidentiality, and CBI concerns. These criteria should include:

- The authors simply do not want to provide the underlying information
- The authors have already disclosed the underlying information to third parties. This should be prima facie evidence that the information can be made available to the public.
- The EPA has disclosed the underlying information to a third party. This too should be prima facie evidence the information should be made available to the public. If the disclosure was only made because the third party is an agent (e.g. contractor) of the EPA, then the EPA should make comparable arrangements for other third parties to review the underlying information.

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27 There might be some unlikely situation where the disclosure to the third party or third parties was legally authorized but future disclosures are not authorized.
The study authors or the EPA have not exhausted all available commonly used practices to de-identify information (if such de-identification is required). When the EPA provides a legal justification to not disclose underlying information, there should be clear documentation provided to the public in support of the legal justification. When there are subjective privacy or confidentiality concerns unrelated to law, this can be tricky to ensure the authors or agency are stating a genuine concern. The EPA should view and treat such assertions with skepticism, and deem the concern to be genuine only when disclosure would violate widely accepted practices or norms.

If the concerns are deemed genuine, then the study should not be excluded. However, it still should be provided less weight than comparable studies. It should be rare for the EPA to solely rely upon studies without underlying data, and the EPA should clarify in the rule that the agency shall take all reasonable steps to avoid such an outcome. Further, the EPA should certify in the administrative record of a rulemaking that it did a full literature review and no legitimate studies without such problems exist that could have been used in their place.

Finally, limiting the release of underlying information, if required, should be narrowly tailored to cover only the specific information that is unable to be disclosed. Through a tiered approach, researchers signing non-disclosure requirements should be able to gain access to the restricted information.

Conclusion

I want to commend the EPA for trying to address the transparency of science used and disseminated by the agency. As the agency’s efforts get close to the finish line, I want to strongly encourage the agency to not let overstated privacy and related concerns divert the agency’s attention away from creating a strong transparency rule with clear requirements and limited discretion. Some flexibility may be needed, but this does not mean the final rule should fail to create some real binding requirements on the agency.

28 The EPA in part has addressed this issue in § 30.5: “The agency shall make reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data and models available before it concludes that doing so in a manner consistent with law and protection of privacy, confidentiality, national and homeland security is not possible. Where data and models are controlled by third parties, EPA may work with those parties to endeavor to make the data and models available in a manner that complies with this section.”

29 This would include a legal justification by statute or contract.

30 There may be instances when a study author has passed away or the underlying information is no longer available. The EPA should take reasonable steps to secure whatever information can be obtained. If such steps are taken, then the study should not be excluded but given less weight than comparable studies.

31 The supplemental notice uses “other things equal” when comparing studies. This minimizes the severe problem of underlying information not being available. A better measure would be to studies that are “comparable,” which to this author, means something slightly less than “other things equal.”

32 One exception would be if there was a genuine concern (as described this comment) for access to be provided even to researchers signing non-disclosure agreements or who have been subject to other privacy and related requirements.
The underlying information requirements, despite claim by critics, are not a way to exclude or devalue the best available science. In fact, the opposite is true. They are a way to ensure that the best available science is used. If the underlying information is not made available to the public, then there is no way to know whether the science is credible. This is a big problem for academic journals and the academic community. This is a much bigger problem for the EPA and all federal agencies. These studies are not academic exercises when used by the EPA, they are the justifications for public policy that impacts the lives of all Americans.

Sincerely,

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