



May 18, 2020

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, DC 20460

Re: Strengthening Transparency in Regulatory Science, Supplemental Notice of Proposed Rulemaking, Docket No. EPA-HQ-OA-2018-0259

Dear Administrator Wheeler:

Thank you for moving forward with the important rulemaking on *Strengthening Transparency in Regulatory Science*. Western Energy Alliance supports the original, unmodified transparency requirements, but recognizes that option 1 in the supplemental rule is a reasonable accommodation to include sound studies that are based on confidential business information (CBI), proprietary data, and personally identifiable information (PII) with tiered access. The rulemaking advances much needed standards to ensure that significant regulatory decisions and influential scientific information made and used by EPA are based on science that meet high standards of data transparency.

Western Energy Alliance represents 300 companies engaged in all aspects of environmentally responsible exploration and production of oil and natural gas across the West. The Alliance represents independents, the majority of which are small businesses with an average of fourteen employees.

We do understand why EPA felt it necessary to supplement the rulemaking, as the proposed rulemaking was mischaracterized as an effort to block science by those who wish to impose no limits on the ability of EPA to regulate and are willing to sacrifice scientific standards to that end. However, EPA is well within its authority to determine that transparent and reproducible science is of higher quality than opaque and irreproducible science. The agency is similarly well within its authority to accord greater weight to studies that are transparent and hence, independently verifiable by designating them as pivotal regulatory science. EPA's rulemaking effort is laudable, as holding itself to scientific standards is only right and equitable as it holds companies and citizens to strict environmental standards that cost society billions of dollars every year.

The Alliance supports EPA's efforts to give greater weight to transparency and reproducibility, two basic components of sound science. There is extensive evidence about the lack of reproducibility in science today, and how much published research is flawed if

not outright wrong.¹ Peer review is not always an indication that a scientific report has been properly critiqued, and rarely includes independent verification of reproducibility.² The Federal Government's own Information Quality Act guidelines recognize that "there is a significant scholarly literature documenting quality problems with articles published in peer-reviewed research."³ Flowing from that well-documented problem is the risk that regulations are based on faulty science.

Ensuring EPA holds itself to the highest standards of transparency and reproducibility help to mitigate that risk, and this rulemaking is important in that regard. We realize that EPA heard extensively from some who are invested in a system that enables them to receive grant money and publish research without having to subject their research to the rigors of reproducibility. However, EPA should understand the interests behind those comments when evaluating them. Science, like every human endeavor, is subject to human foibles. In the oil and natural gas industry, we have seen clearly biased scientists publish studies that are fatally flawed, funded by activists, purposefully misleading, even containing falsified results. Even when debunked through the peer review process, erroneous studies persist in the public domain and influence rulemaking at every level of government. The final rule is an opportunity to ensure that EPA regulation is not unduly influenced by poor science. Below are our specific comments.

Option 1: We support option one, which requires regulatory actions or influential scientific information to be based on studies either with publicly available data; or when using those with CBI, proprietary data or PII, to require tiered access in a manner sufficient for independent validation. It is reasonable that certain data "may be limited to authorized officials and researchers and not provided to the general public" (15403) as long as EPA is scrupulous about ensuring the researchers and officials have the necessary qualifications, and maintain high standards of objectivity and professionalism.

Option 2: Although Option 1 is preferred, if EPA does go with Option 2, there should be a better definition of what "give greater consideration to" means. Should EPA choose option 2 for the final rule, we suggest that "greater consideration to" should be defined more precisely. We suggest that "give greater consideration to" should be clearly defined to mean whether the studies can or cannot be used primarily as the basis of a regulatory action, based on their level of transparency. A simple "short description of why greater consideration was given" to some studies over others is not sufficient assurance.

¹ [The Irreproducibility Crisis of Modern Science: Causes, Consequences, and the Road to Reform](#), David Randall and Christopher Welsler, April 9, 2018; [Why Most Published Research Findings are False](#), John P. Ioannidis, August 30, 2005; [1,500 scientists lift the lid on reproducibility: Survey sheds light on the 'crisis' rocking research](#), Monya Baker, July 28, 2016.

² [Peer review: a flawed process at the heart of science and journals](#), Richard Smith, "Journal of the Royal Society of Medicine," April 2006; [Reproducibility](#), Marcia McNutt, "Science," Vol. 343, Issue 6168, January 17, 2014.

³ [Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies](#), Office of Management and Budget, Fed. Register Vol. 67, No. 36, February 22, 2002, p. 8455.

We recommend that any study which has fully open public data can be considered the basis of a regulatory action, assuming of course, that the study supports the action that EPA wishes to take. Secondly, studies based on “CBI, proprietary data or PII with tiered access in a manner sufficient for independent validation” could likewise be considered foundational as a basis for regulatory action, but require more oversight and assurance that the system for allowing tiered access is robust. We recommend that EPA, in conjunction with this rulemaking, review its program for ensuring rigorous oversight of CBI, proprietary data or PII program.

For those studies that are not either fully transparent or transparent with tiered access, EPA should determine that they cannot be used solely as the basis for a regulatory action or when finalizing influential scientific information. Such studies may be considered, but alone cannot form the basis of a regulatory action without the inclusion of a fully transparent or transparent with tiered access study.

Effective Date of the Rule: EPA is requesting comment on whether these standards should apply only to data and models generated after the effective date of this rulemaking. (15403) While it is reasonable not to apply the new standard to existing rules, it would be a mistake to perpetuate outdated, substandard scientific studies into the future. These standards should apply to any science that a new rulemaking is using, regardless of when the science was generated. Perpetuating non-transparent, irreproducible studies potentially in perpetuity should not be the goal of this rulemaking.

Applying the new standard to existing studies would also encourage researchers to make their underlying data more transparent in accordance with the tiered approach, thereby benefiting not just EPA rulemakings, but scientific knowledge to the broader society. Encouraging researchers to release data for existing studies also addresses EPA’s question in the supplemental rule on “how to provide sufficient incentive...to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science.” (15403) Allowing their existing, nontransparent studies to be used in the future would discourage greater openness and hinder the contribution to better science.

Housekeeping Authority: Like criticisms of EPA’s attempts to hold itself to high scientific standards, criticisms about the use of the housekeeping authority are misplaced. The criticism extends from the fact that the Federal Housekeeping Statute should be internally focused, but that’s exactly what’s laudable about this proposed rule. EPA is aiming to regulate itself by holding itself to high standards in ensuring the best science is used. Some argue that it would limit EPA’s ability to regulate, but EPA should be limited to only regulate when backed by sound science. Regulated communities have to meet strict standards imposed by EPA. It is only right that EPA is held to high standards itself. However, statutory authority from substantive statutes should be used in conjunction with this housekeeping authority.

Expansion of Scope: Western Energy Alliance supports the broadening of the rule to all data and models and not just those related to dose response. We believe all scientific

information used by EPA should adhere to the highest scientific standards. EPA is also proposing to expand the scope of this rulemaking to apply to influential scientific information as well as significant regulatory actions. We also support the broadening of the scope to apply to influential scientific information.

Definitions: We support the clarity achieved by defining “Capable of being substantially reproduced”, “Data”, “Independent validation”, “Influential scientific information” “Model”, “Pivotal science”, “Publicly available” and “Reanalyze”.

Thank you for considering our input. We appreciate the opportunity to comment, and EPA’s leadership on advancing sound pivotal regulatory science.

Sincerely,

A handwritten signature in blue ink, appearing to read 'K M Sgamma', with a long horizontal flourish extending to the right.

Kathleen M. Sgamma
President