

January 10, 2020

Written Statement for the Teleconference of the Executive Committee of the EPA Science Advisory Board, 1/17/20

Thank you for the opportunity to comment on the SAB workgroup's draft letter on the scientific and technical basis of EPA's *Strengthening Transparency in Regulatory Science* proposed rule. We appreciate the amount of work and thoughtful consideration that went into this detailed report in such a short time period.

We support the SAB workgroup's comments that the strengthening transparency rule ignores key considerations and that EPA has not articulated a problem that would be solved with this rule. We also believe that this rule is a solution in search of a problem that simply does not exist. As the SAB points out, the requirements imposed by the proposed rule may actually make scientific research, internal and external to the Agency, "more difficult."¹ The proposal could allow EPA to exclude vast amounts of reliable, valid, and critically important scientific information from consideration as it makes decisions. Broad implementation of the proposal "would be enormously expensive and time consuming at best and can be expected to result in the exclusion of much of the scientific literature from consideration."² This includes studies that have been proven to be reliable. Moreover, the authority given to the administrator to exclude studies from the requirements of the rule on a case-by-case basis would further politicize science, as the SAB notes.³ The proposed rule as drafted, and the supplemental rule as reported by the *New York Times*, would waste enormous resources, make data more vulnerable to misuse and exploitation, and make it nearly impossible for the EPA to use the best available science to inform mission-critical decisions.⁴ And that is not merely an incidental consequence of the proposal, but rather is its intended purpose.

In addition to the issues raised by the SAB in its critical report, the SAB should also highlight in its final letter to EPA the following issues with the rule:

- The proposed transparency rule is unlawful for a number of reasons, not the least of which its precluding the Agency from meeting the Agency's statutory requirement to use the "best available science" under laws like the Toxic Substances Control Act and the Safe Drinking Water Act, as well as permitting the Agency to arbitrarily and capriciously select which information to use in decisionmaking.
- The proposed rule offers no information on where the raw data collected would reside, how the resources to manage the data would be obtained, or how the Agency would protect data that is confidential or sensitive as it is legally and ethically obligated to do. While EPA has suggested models at other agencies, it has not articulated how EPA would feasibly implement and run similar data protection systems.
- It is problematic that the proposal demands additional consideration of non-linear concentration-response models. Inclusion of such models beyond what is already in established epidemiologic and toxicologic literature is not scientifically justified.

¹ EPA Science Advisory Board (SAB). 2019. Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled *Strengthening Transparency in Regulatory Science*, October 16, [https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/8a4dabc3b78f4106852584e100541a03/\\$FILE/Science%20and%20Transparency%20Draft%20Review_10_16_19_.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/ea5d9a9b55cc319285256cbd005a472e/8a4dabc3b78f4106852584e100541a03/$FILE/Science%20and%20Transparency%20Draft%20Review_10_16_19_.pdf), page 6.

² *Ibid.*, page 8.

³ *Ibid.*, page 8.

⁴ Friedman, Lisa. 2019. E.P.A. to Limit Science Used to Write Public Health Rules. *New York Times*, November 11. <https://www.nytimes.com/2019/11/11/climate/epa-science-trump.html>.

- EPA’s intention to apply this rule retroactively to studies conducted prior to implementation of the rule is entirely unreasonable as established scientific practice does not require indefinite retention of underlying data. Such a measure would mean the exclusion of peer-reviewed, valid studies that underlie established EPA regulations that are physically incapable of being made public because of age or because the data contains legally protected sensitive information.

EPA should have involved SAB far earlier in the development of this rule. Perhaps if it had, the rule would not blatantly violate best scientific practices and be the target of opposition throughout the scientific community.⁵ EPA submitted a supplemental rule to the OMB before receiving recommendations from the SAB on the full proposal, hearing only member consultations related to a narrow question about confidential business information and personally identifiable information and doing that only after SAB raised concerns that it had not reviewed the proposed rule prior to its publication. It is almost certain that, at this stage, the SAB’s review and recommendations will come too late to adequately inform the rule’s development.

We appreciate the time and effort that has gone into the SAB’s review of this proposed rule and urge the Board to include in its final letter a recommendation that EPA not finalize a rule that has received substantial and well-reasoned pushback from its science advisors and the broader scientific community.

Sincerely,

Michael Halpern
Deputy Director
Center for Science and Democracy, Union of Concerned Scientists

Carrie Apfel
Staff Attorney
Earthjustice

⁵ See McNutt, M., C.D.Mote, Jr., and V.J. Dzau. 2018. Comment Re: Strengthening Transparency in Regulatory Science (Docket ID No. EPA-HQ-OA-2018-0259), July 16. <http://www.nationalacademies.org/includes/EPA%20Proposed%20Rule%20Docket%20EPA-HQ-OA-2018-0259%20NASEM%20Comment.pdf>; The American Association for the Advancement of Science. 2018. AAAS Statement on EPA Administrator’s Plan to Disallow Use of Scientific Evidence in Decision-Making, April 20. https://mcmprodaas.s3.amazonaws.com/s3fs-public/AAAS%20Statement%20on%20EPA%20Administrators%20Plan%20to%20Disallow%20Use%20of%20Scientific%20Evidence%20in%20Decision-Making.pdf?8VbTPspoSi_h9OpYeyea_dw4jeYph9x8; Thorp, Holden et al. 2019. Joint statement on EPA proposed rule and public availability of data (2019). *Science*, Vol. 366, Issue 6470. DOI: 10.1126/science.aba3197, <https://science.sciencemag.org/content/366/6470/eaba3197>.