



**Environmental Defense Fund Comments on
Environmental Protection Agency (EPA) Science Advisory Board (SAB) Draft Report;
Consideration of the Scientific and Technical Basis of EPA’s Proposed Rule Titled
Strengthening Transparency in Regulatory Science (10/16/19)
Submitted January 10, 2020**

The draft report developed by a working group of the U.S. Environmental Protection Agency (EPA) Science Advisory Board (SAB) on the agency’s proposed rule, *Strengthening Transparency in Regulatory Science* (proposal)¹ correctly identifies significant problems with the premise, intent, and mechanics of the proposal. These issues range from definitional ambiguity of critical terms and concepts to the feasibility and real-world implications of implementation—the full scope of which is impossible to determine given the limited amount of information and analysis the agency has developed. More fundamentally, the draft SAB report appropriately raises concern that the proposal could impede EPA’s ability to protect public health and environment by limiting the science available to set strong, science-based regulatory standards. As discussed in the draft SAB report, the exclusion of studies based solely on constraints associated with data availability and reanalysis is not good scientific practice and represents a superficial understanding of study validation.

EDF agrees with the draft SAB report that EPA has failed to articulate “why...existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner” and further that, “[i]t is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity...” (draft report p. 17) It is not only unclear what theoretical “problem” the agency is seeking to remedy through the proposed regulation; the draft report properly recognizes that the proposal could “easily undercut the integrity of environmental laws” by introducing ‘systematic bias’ in the consideration of science.” (draft report p. 9)

¹<https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

The SAB working group correctly notes that public disclosure of data, and the theoretical reanalysis that could then occur, does not constitute validation. As noted in the draft SAB report, “The scientific community uses numerous tools to validate studies without access to all underlying ‘raw data,’ including rigorous peer review, replication of a study using the same methodology but with different data sources, or reproduction of a study’s conclusions using different methodologies and data. The EPA’s proposed policy of excluding from consideration any study for which underlying data are not made publicly available is not consistent with sound scientific practice.” (draft report p. 16) As with failing to articulate the purported problem it seeks to resolve, EPA fails to describe and demonstrate any benefit from its proposal – much less demonstrate that it bolsters the existing repertoire of validation approaches to an extent that justifies the costs and harmful repercussions of its implementation.

The proposed rule also raises several troubling concepts in dose response modeling that are contrary to scientific best practices as discussed extensively in the seminal National Academies report, *Science and Decisions*.² Specifically, the proposed rule ignores the National Academies report’s conclusion that thresholds of effects for chemical exposures are the exception rather than the rule given biological and exposure variability across the population. Additionally, the proposal intends to give more value to studies that employ a variety of dose response models, an approach that can be misleading. Multiple analyses do not necessarily make a study more credible. The draft SAB report should better represent the proposal’s clear departures from accepted, public-health oriented approaches to dose response modeling that reflect known biological and exposure variability across the population.

The draft SAB report would benefit from further addressing other major deficits in EPA’s proposal including 1) the agency’s failure to assess and characterize the proposal’s impact on the conduct of research, 2) the discordance between EPA’s responsibility to use the best available science and the almost certain exclusion of such science the proposal would entail, and more broadly, 3) the practice of codifying scientific practice into regulation—a consistently frowned upon approach given the continuously evolving nature of science.

² <https://www.nap.edu/catalog/12209/science-and-decisions-advancing-risk-assessment>



At points, the SAB's draft report provides general descriptions of potential mechanisms for implementing the proposed rule, from developing various guidance documents to establishing a data sharing office among others. These possibilities, however, do not address the fundamental conceptual flaws in the proposal and are not developed in sufficient detail for the public, the SAB, or EPA to evaluate them. Instead, EDF believes the identification of these mechanisms distracts from the core scientific deficiencies of the proposal and respectfully recommends to the SAB that they do not merit consideration at this time.

EDF supports meaningful transparency in science, and the ongoing efforts in the scientific community to provide that transparency. But this proposal is not about transparency, it is about restricting EPA's ability to rely on sound science in a manner that hobbles the agency's ability to inform and establish public health and environmental protections. Comments submitted by EDF on the proposed rule³ provide multiple examples of how EPA's proposal threatens specific existing and future potential regulatory actions designed to protect human health and the environment from harmful exposures.

EDF fully agrees with the draft SAB report's statement "that exclusion of segments of the scientific literature with the possibility of inclusion of selected elements based on non-scientific considerations represents a significant shift in science-based decision making. Such a change could easily undercut the integrity of environmental laws, as it will allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data. Such a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research." (draft report p. 9). Likewise, the proposal is also likely to discourage investigators from participating in the development of critical information that ensures regulatory activities are scientifically robust and health protective.

³ <https://www.regulations.gov/document?D=EPA-HQ-OA-2018-0259-9227>



EDF, alongside numerous other public health organizations and scientific institutions, believes the proposal undermines the agency's scientific integrity and ability to fulfill its mission of protecting public health and the environment, and should be withdrawn immediately.