May 18, 2020

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

Subject: Comments on Supplemental Notice of Proposed Rulemaking to the Rule "Strengthening Transparency in Regulatory Science," Docket ID No. EPA-HQ-OA-2018-0259

Dear Administrator Wheeler:

As leading scientific, engineering, and higher education organizations – which together represent hundreds of thousands of scientists, engineers, and educators – we are writing to submit our comments on EPA's Supplemental Notice of Proposed Rulemaking ("supplemental") to the Strengthening Transparency in Regulatory Science Proposed Rulemaking that was originally published on April 30, 2018.

As the scientific community has stated throughout consideration of this proposal, both when it appeared in legislation and now as a proposed rule, transparency is an essential ingredient of science and the scientific process. Scientists welcome transparency and encourage scrutiny of their work. However, this rule and supplemental are not about strengthening science, but about undermining the ability of the EPA to use the best available science in setting policies and regulations.

While the supplemental attempts to clarify the original proposed rule and address concerns previously raised by the scientific community, the changes proposed by EPA add yet another set of issues and concerns that will negatively impact the use of science at EPA and do not resolve many of our original concerns. We strongly believe the proposed rule and supplemental would diminish the critical role of scientific evidence in decisions that impact the health of Americans. Simply put, excluding the best available science, as this proposed rule would do, puts public health and the environment at risk. We strongly request the EPA rescind this proposal in its entirety for reasons outlined below.

The preeminent concern with the original rule was that by mandating all raw data be publicly available before a study can be utilized, the EPA would cut off foundational research that could best inform the agency. The supplemental offers two approaches to dealing with data that cannot or should not be made public. However, both approaches still maintain our concerns of the original rule and create more of their own.

The first proposed approach in the supplemental is a tiered access model. If a study that cannot be made public because it contains proprietary data, confidential business or personally identifiable information that cannot be deidentified, it could be considered for use by EPA only if restricted access is provided to the underlying data and models for independent validation by "authorized researchers." This approach, however, presupposes permission and participation from the

scientists doing the research. Since EPA does not have the authority to grant access to confidential and private research data, this approach would depend on the consent and approval of the scientists and institutions who conducted the research. It is unclear if this is at all possible, as researchers and institutions, in the example of many groundbreaking epidemiological studies, enter into contracts with participants to keep their health and other sensitive information private. It is improbable the researchers would or could alter these legal contracts after studies are concluded to allow individuals selected by EPA to gain access to such protected information, even in a tiered scheme. Thus, this approach would likely exclude many credible and valuable studies, including ones containing private information that EPA has benefited from in the past. It reinforces our ongoing serious concern that this proposal threatens the use of the best available science in its decision-making.

The second proposed tactic is a weighted approach model, i.e., if a study's data cannot be made publicly available for independent validation, it would be down-weighted in comparison to studies where data are publicly available. While incrementally better, the underlying concern remains. Saved from complete exclusion, this approach would still devalue research that is considered scientifically rigorous and could fundamentally benefit and shape public policy.

This model of down-weighting research maintains the major flaw in deeming data that cannot be made completely public – for legitimate and legal reasons to protect the privacy of health and confidential business information – less scientifically valid or valuable. It mischaracterizes the scientific process and the range of mechanisms for disclosing and protecting scientific research results for decision-making, implying that peer-reviewed scientific research data that are not available in its raw form is not rigorous enough for use in policy. This is simply not true.

We must emphasize that access to raw data is not determinative of the quality of the research. As has been stated by the scientific community repeatedly in response to this rule and now this supplemental, there are credible procedures for testing results and verifying outcomes with methodologies that do not require access to raw data. The original proposed rule and now this supplemental are de facto rejecting credible practices used by the scientific community and replacing them with a non-scientific metric in the evaluation of a study beyond its immediate quality. As the EPA's own Scientific Advisory Board has stated, this decision risks politicizing science by using an unscientific standard to assess the validity of science.

Moreover, we are deeply concerned that the supplemental expands the scope of the original rule to affecting not just studies underlying EPA's regulatory decisions but to all "influential scientific information." The supplemental defines this as any science the agency reasonably can determine will, or does have, a clear and substantial impact on important public policies or private sector decisions. This widening of the scope means that the rule won't just limit EPA's use of science underpinning regulation, but also EPA's use of science underpinning other significant outputs of the agency. The supplemental also expands the scope of studies that would be impacted by the revised rule, from the original proposed focus on only dose-response data and models to all data and models. With this expansion, the supplemental now risks limiting a massive breadth of scientific information because not all scientific data and models can be made public, as explained above.

For example, this drastic change means EPA will likely be unable to cite important studies on topics relating to the levels of contaminants in water, air and land; epidemiological studies that describe clinical markers of exposure or effect; and many other studies that are fundamental in understanding and protecting human health. That EPA would risk prohibiting or severely limiting such evidence and research sends a chilling message to the scientific community and risks breaching the confidence of the American public on whether they can trust EPA decisions to protect their health.

Lastly, the supplemental retains the troublesome provision that the EPA Administrator has sole authority to grant exceptions to the rule should he or she want to include a study that cannot meet the rule's standards. This kind of authority does not provide for proper checks and balances with appropriate scientific oversight bodies. Since EPA addresses a wide range of scientific disciplines that intersect environmental and public health policies, this exemption would eliminate the important role that scientific advisors play in the decision-making process.

Given the gravity of these concerns, which are echoed by a chorus of other scientific societies, health advocacy groups, universities, stakeholders, and member scientists of EPA's own Scientific Advisory Board, we urge the EPA to rescind this rule. This proposal would diminish the critical role of scientific evidence in helping to make decisions that impact the health of Americans. Excluding the best available science, as this proposal would, puts public health at risk.

Sincerely,

American Anthropological Association
American Association for the Advancement of Science
American Association of Geographers
American Chemical Society
American Economic Association Committee on Government Relations, Committee on Economic Statistics, and Office of the Data Editor
American Geophysical Union
American Institute of Biological Sciences
American Meteorological Society
American Physiological Society
American Psychological Association
American Society for Microbiology
American Society of Agronomy
American Sociological Association
American Statistical Association
Association of American Universities
Association of Public and Land-grant Universities
Bigelow Laboratory for Ocean Sciences
Brown University
Coalition for the Life Sciences
Coastal and Estuarine Research Federation
Consortium for Ocean Leadership
Council of Scientific Society Presidents

Crop Science Society of America
Ecological Society of America
Entomological Society of America
Geological Society of America
Harvard University
International Society for Environmental Epidemiology, North American Chapter
Massachusetts Institute of Technology
Mathematical Association of America
Research!America
Society for Freshwater Science
Society for Industrial and Applied Mathematics
Society of Wetland Scientists
Soil Science Society of America
Stony Brook University
University of California, Los Angeles
University of Colorado Boulder
Washington University in St. Louis