



PUBLIC EMPLOYEES FOR ENVIRONMENTAL RESPONSIBILITY

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April 18, 2020

U.S. Environmental Protection Agency
EPA Docket Center
Office of Research and Development Docket
Mail Code 28221T
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Docket ID No. EPA-HQ-OA-2018-0259, Supplemental notice of proposed rulemaking, Strengthening Transparency in Regulatory Science; Submitted electronically via <https://www.regulations.gov>

To Whom It May Concern:

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) Supplemental Notice of Proposed Rulemaking on its "Strengthening Transparency in Regulatory Science" Rule (hereinafter the "Supplemental Rule"). Public Employees for Environmental Responsibility (PEER) commented on the original "Strengthening Transparency in Regulatory Science" Proposed Rule in August of 2018.¹ The Supplemental Rule does not alleviate the concerns we had about the original Rule; in fact, it has only served to increase these concerns.

Background. Both the original Rule and the Supplemental Rule are an unacceptable solution searching for a problem that does not exist. The Supplemental Rule expands the scope of the original Proposed Rule to cover all EPA "influential science," not just dose-response models. The Rule will impede both the speed and accuracy of EPA decision-making, something that is particularly important during a pandemic. EPA's core mission is to protect human health and the environment; this Supplemental Rule will do the opposite.

The Federal Housekeeping Statute does not give authority for this Rule: According to legislative history, the Federal Housekeeping Statute² was never intended by Congress to authorize an agency to use for substantive regulations. EPA cannot now use §301 of the Federal Housekeeping Statute to give itself authority to create substantive regulations, because it expressly contradicts the purpose of the code it is invoking.

¹ See https://www.peer.org/wp-content/uploads/attachments/8_15_18_PEER_Sci_Censorship_Comments.pdf

² 5 U.S.C. § 301

Expansion of the Rule to cover all data and models, not only dose-response models, and to cover studies informing agency rules and internal scientific assessments that are not part of rulemaking, is far too broad. The Supplemental Rule modifies the regulatory text originally proposed in the 2018 rulemaking such that the “transparency requirements” would cover all research used to support agency rules, not *only* dose-response data and dose-response models. PEER’s 2018 letter laid out in detail why restrictions on the use of dose-response data would be detrimental to EPA’s core mission of protecting human health and the environment; expansion of this to all data and models simply means that EPA will now have the ability to ignore far more science/research than it originally proposed.

Consideration of studies only if the underlying data is publicly available in a tiered access approach is still indefensible. It is unconscionable to only use studies where all underlying data are available, because too many important studies will be dismissed. The tiered-access approach, by which data that cannot be made public can be shared with a few for independent validation, is still unworkable. It is illegal to share personal health data with anyone, so sharing it with one or a handful of people is just as illegal as sharing it with the general public. The alternative offered by EPA is to “down-weight” studies relying on data that cannot be made public. This approach arbitrarily devalues scientific work that relies on health data containing personal identification. As a reminder, EPA is charged with protecting public health and the environment, and as such, studies that involve health data are critical. Specifically, giving less consideration, or no consideration, to studies where underlying data are not publicly available is a political decision that has nothing to do with science. This is contrary to EPA’s mission to protect human health and the environment based on best-available science.

EPA does not have the resources to re-analyze all data used in decision-making. The Supplemental Rule clarified that by saying all studies had to be reproduceable, it meant re-analyzed. EPA does not have the necessary statisticians and data analysts to do such work. Moreover, this will delay all EPA decision-making. When studies are sent to the U.S. Food and Drug Administration (FDA), statisticians do re-analyze all the data, and sometimes run new analyses. Expedited FDA review takes roughly 6 months; but some normal reviews can take up to two years. How will EPA deal with the lack of resources within the agency, and the timing? How much will this cost, and what will delays mean in terms of impacts to human health and the environment? Here in the United States, chemicals are innocent until proven guilty – in other words, new chemicals, such as novel PFAS, can be used unless and until they are proven to adversely affect human health and the environment. Delays imposed as a result of this Supplemental Rule are not ethical, particularly when impacts to individual health may be severe.

EPA continues to assign greater value to dose-response studies, which by definition reduce the use/value of epidemiological studies. Section 30.6 of the Supplemental Rule has been revised, but continues to give “explicit consideration to ... parametric dose-response or concentration-response models.” As PEER stated in its 2018 comments, EPA itself admits that, “there is frequently a lack of dose-response data available for human subjects. When data are

available, they often cover only a portion of the possible range of the dose-response relationship.”³ This gives more weight to toxicological studies as opposed to epidemiological studies, which form the basis of many human health exposure studies. EPA must continue to use epidemiological studies; to do otherwise is to compromise the health of all Americans.

Terms are ill-defined and lack guidance. EPA provides no guidance for what the term “greater consideration” means when weighing one study against that of another. The use of meta-analysis (when results from pertinent, multiple studies are combined) is becoming increasingly common, and they are crucial to understanding epidemiology and public health issues. In fact, EPA scientists themselves use meta-analysis. The Supplemental Rule requires a brief description of why one study is given “greater consideration” over another, but does not give any direction as to how to weigh these different studies. Failure of the Supplemental Rule to address basic questions such as these is indicative that the authors have no understanding of scientific analysis.

This Supplemental Rule is simply a continuation of this Administration’s war on science. Peer-review of scientific articles should be enough to establish the strength of a study. Scientists are able to evaluate the strength of a study by looking at the data transformation (if any), the sample size, the assumptions, and the model. In other words, these safeguards already exist in peer-review. This Supplemental Rule invents a new, arbitrary and political standard by which a study is judged, unrelated to scientific merit. Moreover, it gives the EPA Administrator, a political appointee who may not be a scientist, the authority to grant an exemption to the Rule, which is further illustrative of how this rule is designed to corrupt the scientific principles that should govern EPA decision-making.

Conclusion. This Rule purports to increase transparency and good science, but it does exactly the opposite. It allows the agency to substitute its political will in place of science, and there is no justification for the Rule. EPA should withdraw both the Strengthening Transparency in Regulatory Science Rule and the Supplemental Rule.

Thank you for the opportunity to provide these comments.

Sincerely,

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³ <https://www.epa.gov/risk/conducting-human-health-risk-assessment>