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August 15, 2018

Andrew Wheeler,
Acting Administrator
Environmental Protection Agency
William Jefferson Clinton Building, *Mail Code:* 1101A
1200 Pennsylvania Avenue NW
Washington, DC 20460

RE: Docket EPA-HQ-OA-2018-0259-0001

Submitted electronically via <https://www.regulations.gov>

Dear Acting Administrator Wheeler,

Thank you for the opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) proposed "Strengthening Transparency in Regulatory Science" Rule (hereinafter the "Rule"). Public Employees for Environmental Responsibility (PEER) is a Washington D.C.-based non-profit, non-partisan public interest organization concerned with honest and open government. Specifically, PEER serves and protects public employees working on environmental issues, including those at EPA. PEER represents thousands of local, state and federal government employees nationwide.

Background. This proposed rule, issued by former EPA Administrator Scott Pruitt on April 30, 2018, is purportedly designed to "increase transparency in the preparation, identification, and use of science in policymaking."¹ Since Pruitt resigned in July of 2018, you have the opportunity to begin to repair some of the damage that Pruitt has wrought, including rescinding this Rule. As we now know, Pruitt was an enemy of science. There is a plethora of evidence demonstrating his hostility to science, including his false claims that humans are not "a primary contributor to the global warming,"² and even his resignation letter itself, which stated that God's "providence" brought President Trump into power and made Pruitt EPA Administrator.³ In fact, it is worth noting that EPA failed to consult with the Science Advisory Board (SAB) when developing this

¹ 83 FR 18769.

² <https://www.peer.org/news/news-releases/pruitt-had-no-climate-data,-epa-admits.html>

³ <https://www.cnn.com/2018/07/05/politics/scott-pruitt-resignation-letter/index.html>

Rule. In a May 12, 2018 memo from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, the SAB stated, “Members were made aware of the proposed rule via the Federal Register and news articles. The EPA did not provide a description of the planned action.”⁴ Given Pruitt’s obvious animosity toward scientific thought and process, and the scientists themselves, this Rule is suspect. It is therefore incumbent on EPA to rescind this proposal, which is the antithesis of strengthening science. Our specific comments are set forth below.

The proposed Rule limits the science EPA can use. By restricting the types of science EPA can rely on for regulatory decision-making, EPA will be unable to use the best available science as required by law. Despite the fact that the Rule claims “Nothing in the proposed rule compels disclosure of any confidential or private information in a manner that violates applicable legal and ethical protections,”⁵ the actual language appears to require the public release of all data. Specifically, it states:

When promulgating significant regulatory actions, the Agency shall ensure that *dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation. Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered “publicly available in a manner sufficient for independent validation” when it includes the information necessary for the public to understand, assess, and replicate findings.⁶

Therefore, the proposed Rule would disallow the use of studies that rely on confidential patient information from being used in policymaking. Supporters of this Rule have claimed that patients’ names can simply be redacted, but private health data includes more than just a person’s name. For example, in the seminal Six Cities air pollution study conducted by Harvard,⁷ or the American Cancer study on particulate matter and human health,⁸ researchers looked at variants such as places of residence, age, cause of death, occupational histories, and other factors. When all of these factors are looked at together – as they must be to achieve valid study results – the identification of patients can be easily determined. In this case, redaction of names would not be sufficient to protect privacy. And, if the other data regarding things like occupational histories, ages, and cause of death are redacted, they would not meet the transparency requirements of this Rule, therefore creating a catch 22.

⁴[https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/\\$File/WkGrp_memo_2080-AA14_final_05132018.pdf](https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf)

⁵ 83 FR 18771.

⁶ 83 FR 18773-18774.

⁷ Dockery DW, Pope CA 3rd, Xu X, Spengler JD, Ware JH, Fay ME, et al. An association between air pollution and mortality in six U.S. cities. *N Engl J Med.* 1993;329(24):1753–9.

⁸ Pope CA III, Thun MJ, Namboodiri MM, Dockery DW, Evans JS, Speizer FE, et al. Particulate air pollution as a predictor of mortality in a prospective study of U.S. adults. *Am J Respir Crit Care Med.* 1995;151:669–674.

Moreover, other studies - particularly older studies - may have utilized data that legally cannot now be made public. If past study participants were promised confidentiality through legally binding agreements, the researchers cannot now disclose those data. Identifying patient information is crucial to most studies involving impacts of pollutants on human health. The proposed Rule would make these studies less valuable, if not unusable, merely because they contain patient information. This is non-sensical.

EPA's SAB is also opposed to this provision. In its May 12, 2018 memo, the SAB stated:

The proposed rule oversimplifies the argument that 'concerns about access to confidential or private information can, in many cases, be addressed through the application of solutions commonly in use across some parts of the Federal government.' For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential.

The requirement that findings must be able to be replicated is also troublesome. Some scientific findings rely on unintended human exposure to chemicals. Effects from disasters such as massive oil spills also yield data that may be helpful in formulating policy down the road, and yet replicating these events would be impossible – or at the very least, unethical.

Finally, it is unclear who would shoulder both the cost and the burden of making the data sets – some of which are incredibly large and complex – compliant with the proposed Rule. Forcing scientists, many of whom have limited research funds, to do this may be prohibitive for them. Inevitably, this cost will be shifted to the taxpayer, and will decrease the efficiency of the rulemaking process.

The proposed Rule is contrary to existing law. The Clean Air Act, Clean Water Act, Endangered Species Act, the Magnuson-Stevens Fishery Conservation and Management Act, Toxic Substances Control Act; Safe Drinking Water Act; Fungicide, Insecticide, and Rodenticide Act, and other federal laws all require the use of best available science. In fact, EPA itself states that it “works to ensure that...[n]ational efforts to reduce environmental risks are based on the best available scientific information”⁹ in all that it does. Studies that cannot be replicated due to ethical considerations or that contain data that cannot be publicly released are not less valid than other studies. Because the proposed Rule would eliminate many valid studies representing the best available science from consideration, the proposed Rule is contrary to federal law.

Proposal fails to recognize how science works. It is not surprising that the proposed Rule fails to understand how science works. Science contained in peer-reviewed scientific journals is, by definition, based on rigorous scientific standards. When researchers submit findings to a scientific journal, their work is reviewed and critiqued by other scientists in the same field. When a study is published in a peer-reviewed journal, we are assured that it has met the scientific standards of scientists familiar with the research topic at hand. Peer reviewers and readers

⁹ <https://www.epa.gov/aboutepa/our-mission-and-what-we-do>

typically do not ever see the raw data underlying a study. Each study sets out an objective, methods, results, a conclusion, and appropriate citation of relevant studies. Scientists can assess the validity and value of a study based on this information because they are trained to do so. It is not only unnecessary to see the raw data, but in many cases, it would be meaningless. Moreover, scientific knowledge is cumulative; that is, all science builds upon what has already been discovered and proven. Therefore, scientists have a vested interest in seeing valid research published and used as a basis for further study. By excluding relevant and important studies simply because they cannot meet the unrealistic transparency standards in this Rule is counter-intuitive and dangerous to human health and the environment.

Lag time is not addressed. The proposed Rule ignores a critical point about how scientific research is conducted. Specifically, there is an often significant lag time between the hypothesis stage of a scientific study, the data collection and analysis, conclusions, and finally regulatory actions based upon those conclusions. Impacts to the environment and human health are not always immediately obvious, and decades can elapse before those impacts manifest. Despite this, the Rule states: “This proposed regulation is intended to apply prospectively to final regulations that are determined to be ‘significant regulatory actions’... The Agency’s offices should be guided by this policy to the maximum extent practicable during ongoing regulatory action, even where such research has already been generated, solicited, or obtained.”¹⁰ What does this mean for regulated substances where data has already been generated, or older studies where the raw data are no longer available? In a random sample conducted of biomedical literature published between the years 2000 and 2014, not one of 268 papers shared all of their raw data.¹¹ Given the lag time between scientific findings and approval of regulations, it is likely that under this Rule, the best available science could not be used in EPA decision-making.

Proposal is a thinly veiled attempt to hinder science and regulations protective of human health. The proposed Rule appears to show a preference for models that assume chemicals have a threshold below which humans exposure is safe. Specifically, the Background of the proposed Rule states:

...this proposed regulation is designed to increase transparency of the assumptions underlying dose response models. As a case in point, *there is growing empirical evidence of non-linearity in the concentration-response function for specific pollutants and health effects*. The use of default models, without consideration of alternatives or model uncertainty, can obscure the scientific justification for EPA actions. To be even more transparent about these complex relationships, EPA should give appropriate consideration to high quality studies that explore: A broad class of parametric concentration-response models with a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the exposure range; and spatial heterogeneity¹² (emphasis added).

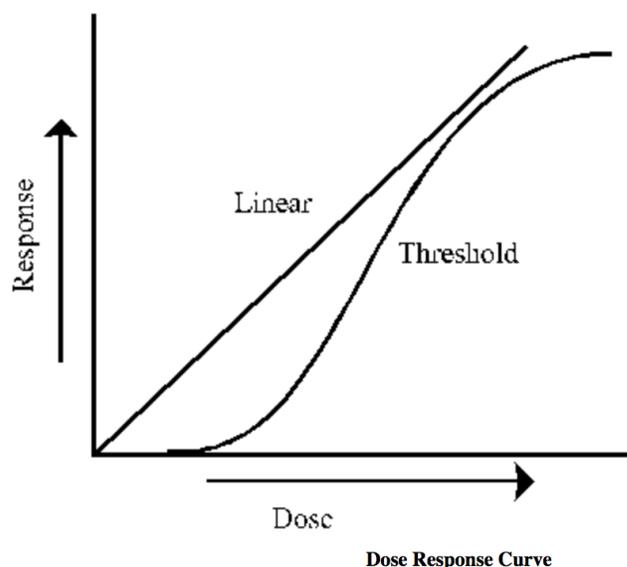
¹⁰ 83 FR 18771

¹¹ Iqbal S, Wallach J, Khoury MJ, Schully S, Ioannidis JPA. Reproducible research practices and transparency across the biomedical literature. PLoS Biol. 2016;14(1):e1002333.

¹² 83 FR 18770

In a dose-response model, the level of exposure, or dose, is compared to the effect on health, or the response. This relationship can be linear or non-linear. If there is a linear relationship between dose and response, we assume there is some response, or impact on health, all the way to zero. If the relationship is non-linear, or a threshold response, there appears to be some safe threshold, below which there is zero risk from exposure. Figure 1, below, illustrates this.

Figure 1: Linear versus non-linear dose-response



The proposed rule claims that scientists are finding non-linear dose responses for certain pollutants – in other words, that pollutants do have a threshold below which exposure is safe. In fact, the science of risk assessment is currently *challenging* the notion that chemicals must have safe thresholds. There is tremendous genetic variation in the human population, and other factors such as disease, age, economic standing, employment, domicile, co-exposures, and other factors that all influence what a safe threshold might be for any one particular individual. Moreover, scientists are discovering that some compounds can be harmful in extremely low doses, and in many instances, a safe threshold has not been identified. By expressing a preference for these non-linear dose-response models, this Rule has the potential to deem certain chemicals safe when, in fact, there is a segment of the population for which they are never safe. In fact, EPA has already taken steps to do exactly this; it is floating the idea of developing a “safe” standard for particulate matter, when science tells us there is no safe level.¹³

In addition, Section 30.6 of the Rule states:

¹³ <http://www.sciencemag.org/news/2018/08/kill-climate-rule-trump-s-epa-wants-redefine-danger-soot>

EPA shall evaluate the appropriateness of using default assumptions, including assumptions of a linear, no-threshold dose response, on a case-by-case basis. EPA shall clearly explain the scientific basis for each model assumption used and present analyses showing the sensitivity of the modeled results to alternative assumptions. When available, EPA shall give explicit consideration to high quality studies that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.¹⁴

Once again, EPA is telling scientists to use assumptions of a linear dose-response on a “case by case basis,” when linear models should be the default. Assuming there is a safe threshold for chemicals is dangerous and reduces protection for human health and the environment.

Finally, while not explicitly stated, the proposed Rule appears to show a preference for dose-response models over other studies, such as epidemiological studies. For example, the Rule defines “Dose response data and models” as:

...the data and models used to characterize the quantitative relationship between the amount of dose or exposure to a pollutant, contaminant, or substance and the magnitude of a predicted health or environmental impact. Such functions typically underlie pivotal regulatory science that drives the size of benefit-cost calculations, the level of a standard, and/or the points of departure from which reference values (reference doses or reference concentrations) are calculated.¹⁵

There are basically two types of studies that are done regarding exposure to chemicals and health effects: 1) toxicological; and 2) epidemiological. The two types differ significantly in how they measure exposure. Toxicological studies involve precise dosing to create a dose-response curve, while epidemiological studies have to rely on exposure information such as environmental monitoring, hospital reports, self-reports, or chemical residue in bodies to measure exposure. Dose-response models typically derive from toxicological studies. Epidemiological studies, like Harvard’s Six Cities study, do not lend themselves to dose-response studies. We cannot ethically dose people with chemicals to obtain a dose-response curve. The language of the proposed Rule makes it unclear what role, if any, epidemiological studies will have in the future. Is EPA going to ignore epidemiological studies that do not rely on dose-response models, or give more weight to toxicological studies over epidemiological ones? If so, this is of grave concern.

Even EPA’s own website admits the limitation of dose-response models:

As with hazard identification, 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, in which case some extrapolation must be done in order to extrapolate to dose levels that are lower than the range of data

¹⁴ 83 FR 18774

¹⁵ 83 FR 18773

obtained from scientific studies. Also, as with hazard identification, animal studies are frequently done to augment the available data.

Studies using animal subjects permit the use of study design to control the number and composition (age, gender, species) of test subjects, the levels of dose tested, and the measurement of specific responses. Use of a designed study typically leads to more meaningful statistical conclusions than does an uncontrolled observational study were additional confounding factors must also be considered for their impact on the conclusions.

However, dose-response relationships observed from animal studies are often at much higher doses that would be anticipated for humans, so must be extrapolated to lower doses, and animal studies must also be extrapolated from that animal species to humans in order to predict the relationship for humans. These extrapolations, among others, introduce uncertainty into the dose-response analysis.¹⁶

Because much of the rule making EPA does is based on human health impacts (particulate matter on asthma, impacts of lead in water on children, oil spills on sea life, etc.), it does it lend itself to dose-response modeling.

The proposed rule improperly injects politics and partisanship into science. First, the proposed Rule gives EPA complete discretion to define what constitutes “pivotal regulatory science.” Pivotal regulatory science is vaguely defined as “the specific scientific studies or analyses that drive the requirements and/or quantitative analysis of EPA final significant regulatory decisions.”¹⁷ In addition, Section 30.9 states:

The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable because: (a) It is not feasible to ensure that all dose response data and models underlying pivotal regulatory science is publicly available in a manner sufficient for independent validation, in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security; or (b) It is not feasible to conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions for reasons outlined in OMB Final Information Quality Bulletin for Peer Review (70 FR 2664), Section IX.¹⁸

Therefore, the EPA Administrator can selectively require disclosure where s/he wishes, and decline to require disclosure where s/he does not. Regardless of what EPA ultimately requires regarding exemptions to these so-called transparency rules, there is no statement describing whether EPA will base a policy decision or take a significant regulatory action on non-disclosed data and models. In other words, under this Rule, the Administrator could waive the requirements for certain industries, or could ignore non-disclosed data in order to reach a pre-

¹⁶ <https://www.epa.gov/risk/conducting-human-health-risk-assessment>

¹⁷ 83 FR 18773

¹⁸ 83 FR 18774

determined outcome. Political appointees should not have this sway over science when it comes to protecting human health and the environment.

Conclusion. This proposed Rule is yet another thinly veiled attempt under the Trump Administration to attack science and insert politics into what should be purely scientific decisions. If this Rule is finalized, it would not only cripple EPA's scientific research, but it would have an adverse impact on human health and the environment. PEER urges you to rescind this Rule, and reach out to the SAB to determine what steps, if any, are necessary to fix the problems you perceive in EPA's scientific processes.

Thank you for the opportunity to comment.

Cordially,

A handwritten signature in black ink that reads "Kyla Bennett" with a long horizontal flourish extending to the right.

Kyla Bennett, PhD, JD
Science Policy Director
Public Employees for Environmental Responsibility