March 25, 2020

SUBMITTED VIA REGULATIONS.GOV

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


Dear Administrator Wheeler:

In the midst of an unprecedented pandemic that demands the full attention of scientists and health professionals across the globe, the U.S. Environmental Protection Agency has published a second proposal aimed at limiting its use of science—a proposal that threatens to undermine critical protections for human health and the environment.\(^1\) Remarkably, the agency has also granted members of the public a mere thirty days to submit their comments on the rule—an inadequate amount of time given the scope of the rulemaking and the constraints imposed by the current crisis.\(^2\) On behalf of 36 environmental and public-health organizations, we ask the EPA to withdraw the proposed rule and renew its commitment to protecting the wellbeing of all Americans. If the EPA insists, however, on moving forward with this rulemaking, it must ensure that members of the public—including the scientists and health professionals whose work would be directly impacted by the proposal—are afforded a meaningful opportunity to comment. To do this, the agency must hold the comment period open for at least sixty days after the national emergency has been lifted and provide opportunities for comments to be presented at public hearings on the rule.

This is an extraordinary moment. As a result of the widening coronavirus pandemic, most Americans have been told to isolate themselves in their homes—for


\(^{2}\) Id. at 15,397.
weeks, if not longer—while medical professionals, first responders, and others who provide essential services work tirelessly to reduce the harms wrought by this virus. Across the country, schools and offices have been closed, grocery-store shelves have been emptied, gatherings of all kinds have been cancelled, and many families have been left to care for the ill or tend to children or parents whose usual caretakers are not available. Under such circumstances, the public cannot be asked to respond to an unessential and ill-advised proposal in only thirty days. And given the need for isolation, they cannot be invited to public hearings—which are essential to ensuring that everyone has a meaningful chance to be heard.

The unreasonableness of the EPA’s thirty-day comment period is particularly pronounced given the nature of both the current crisis and the proposed rule. Under the proposal, the agency would in many cases be precluded from relying on scientific studies as the basis for establishing public-health protections. In order for the EPA to understand the implications of such a regulation, it must hear from the nation’s scientists and health experts—the very people who are now on the frontlines of a pandemic where studies of the sort the EPA seeks to exclude are a critical source of life-saving information about COVID-19. If the agency refuses to extend the comment period, in other words, it will deny itself much-needed information—and increase the risk of making an arbitrary decision. Indeed, under these circumstances, a thirty-day comment period would not fulfill the requirements of the Administrative Procedure Act—which require agencies to “give interested persons an opportunity to participate in … [a] rule making through [the] submission” of comments—insofar as the national emergency and its consequences would prevent critically impacted constituencies, such as scientists and health professionals, from participating and being heard.³

Even in the absence of an unprecedented pandemic, the proposed rule wouldn’t be one that could be adequately addressed in only thirty days. This fact is evident in the reach and complexity of the EPA’s significantly revised proposal:

First, while the agency’s proposed restrictions on the use of science were originally limited to “dose response data and models[,]” they have now been “broadly” expanded to include “data and models” of every kind.⁴ As a result of this expansion, members of the public will be required to address the implications of limiting the agency’s reliance on “environmental fate studies, bioaccumulation data, water-solubility studies, environmental fate models, engineering models, data on

³ 5 U.S.C. § 553(c).

environmental releases, exposure estimates, quantitative structure activity relationship data, and environmental studies”—to name only a few examples.\footnote{Supplemental Proposal, 85 Fed. Reg. at 15,400 (acknowledging that the agency has identified “[s]ome, but not the only, examples of information that would be considered to be data and models” under its new proposal).}

Second, the new proposal also pushes the rule’s restrictions well beyond the “significant regulatory decisions” that were targeted in the original notice, extending them to reach every piece of “influential scientific information” that is prepared by the EPA.\footnote{Original Proposal, 83 Fed. Reg. at 18,773; Supplemental Proposal, 85 Fed. Reg. at 15,398.} According to the agency’s most recent Peer Review Agenda, “influential scientific information” includes a sprawling set of documents that play critical roles in protecting human health and the environment.\footnote{Peer Review Agenda, available at https://cfpub.epa.gov/si/si_public_pr_agenda.cfm (noting that “influential scientific information” includes the agency’s integrated review plans, integrated science assessments, risk and exposure assessments, policy assessments, peer reviews, health models, economic models, and other important materials).} The public’s comments will have to address all of these materials.

Third, with its new proposal, the EPA has introduced the concept of “tiered access” to scientific models and data—one that would allow the agency to rely on “studies with restricted data and models … if there is tiered access to these data and models in a manner sufficient for independent validation.”\footnote{Supplemental Proposal, 85 Fed. Reg. at 15,399.} As the EPA’s proposal itself acknowledges, a “tiered access” requirement would raise a host of complicated legal and technical issues—issues that will need to be addressed by members of the public.\footnote{Id. at 15,402 (noting that access to personally identifiable information would have to be “consistent with the requirements of the Common Rule, the Health Insurance Portability and Accountability Act (HIPPA), the 21st Century Cures Act, the Privacy Act, and other relevant laws and regulations,” and that “[d]evelopment of standard data repositories is still ongoing”).}

Fourth, in addition to making significant changes to its original proposal, the EPA has now floated a second option: giving more weight to studies for which the underlying data has been released.\footnote{Id. at 15,399, 15,402, 15,405.} This new alternative will require careful consideration and comment.
Fifth, the EPA’s new proposal appears to rest on a new theory for why the agency is even authorized to promulgate such a rule. According to the notice, the EPA is now attempting to rely on a “housekeeping authority” rooted in the Federal Housekeeping Statute, Reorganization Plan No. 3, or both, maybe.\(^\text{11}\) While the EPA mentioned the housekeeping statute when it extended the first comment period, it now seems to be relying on a more amorphous “housekeeping authority.”\(^\text{12}\) It is also unclear whether the EPA is relying on this asserted authority exclusively, or whether it intends to include a host of environmental statutes as additional authority for the rule. As the EPA has acknowledged in its notice, reliance on this new theory of authority calls for additional consideration and comment.

Sixth, the proposed rule offers new definitions for a number of key terms: “capable of being substantially reproduced,” “data,” “independent validation,” “influential scientific information,” “model,” “pivotal science,” “publicly available,” and “reanalyze.”\(^\text{13}\) Each of these definitions raise complex scientific and technical questions—and each deserves the attention of the nation’s scientists and public-health experts.

Finally, the EPA’s notice presents a number of challenging policy questions that should also be addressed by medical experts and scientists. For example, the agency has “request[ed] comment on how to ensure that, over time, more of the data and models underlying the science that informs significant regulatory decisions and influential scientific information are available to the public for independent validation in a manner that honors legal and ethical obligations to reduce the risks of unauthorized disclosure and re-identification.”\(^\text{14}\) And the agency has asked how it might “provide sufficient incentives and support to researchers to increase access to the data that may be used as pivotal regulatory science or pivotal science.”\(^\text{15}\)

In short, given the scope of the proposed rule and the agency’s requests for comments, the comment period cannot reasonably be limited to only thirty days.

The inadequacy of the agency’s thirty-day comment period shouldn’t come as a surprise. Under Executive Order 12,866, each federal agency has been directed to “afford the public a meaningful opportunity to comment on any proposed regulation,

\(^{11}\) Id. at 15,397-98.

\(^{12}\) Id.

\(^{13}\) Id. at 15,398, 15,405.

\(^{14}\) Id. at 15,403.

\(^{15}\) Id.
which in most cases should include a comment period of not less than 60 days.”

The EPA recognized the appropriateness of an even lengthier comment period when it granted members of the public additional time and a hearing on the agency’s original proposal. There is no basis for placing more restrictions on public comment during a pandemic.

Again, in the face of the current public-health crisis, the EPA should abandon the proposed rule and the limits it would place on public-health protections. If the agency elects to move forward with this rulemaking, however, it must ensure that scientists, health experts, and other members of the public have a meaningful opportunity to be heard by holding the comment period open for at least sixty days after the national emergency has been lifted. And once the restrictions on gatherings are no longer in place, the agency should provide members of the public with opportunities to present their comments at hearings on the proposed rule.

Thank you for your consideration. Given the short time you have provided for public comment, we would appreciate a reply to this request by Friday, March 27.

Sincerely,

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Clean and Healthy New York
Clean Water Action California
Clean Water Action/Clean Water Fund
Commonweal Biomonitoring Resources
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Huntington Breast Cancer Action Coalition, Inc.
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RH White Consultants
Safer Chemicals Healthy Families
Safer States
Science and Environmental Health Network
Seventh Generation
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Vermont Conservation Voters
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