NACAA
national association of clean air agencies

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U.S. Environmental Protection Agency
EPA Docket Center
Attention: Docket ID No. EPA-HQ-OA-2018-0259
Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

To Whom It May Concern:

The National Association of Clean Air Agencies (NACAA) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) proposed rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018). NACAA is the national, non-partisan, non-profit association of 156 local and state air pollution control agencies in 41 states, the District of Columbia and four territories. The air quality professionals in our member agencies have vast experience dedicated to improving air quality in the U.S. These comments are based upon that experience. The views expressed in these comments do not represent the positions of every state and local air pollution control agency in the country.

NACAA agrees with EPA that "the best available science must serve as the foundation of EPA's regulatory actions."[1] Indeed, reliance on best-available science is a fundamental requirement of the Clean Air Act and other environmental statutes that EPA administers. For example, the Clean Air Act requires EPA to establish National Ambient Air Quality Standards (NAAQS) at levels "requisite to protect the public health" with "an adequate margin of safety."[2] In meeting this obligation, EPA is required to develop air quality criteria that "*accurately reflect the latest scientific knowledge* useful in indicating the kind and extent of all identifiable effects on public health or welfare which may be expected from the presence of such pollutant in the ambient air, in varying quantities."[3] Science-based decision making is at the very core of our shared mission to protect public health and the environment from the harmful effects of air pollution.

[1] 83 Fed. Reg. at 18,769.

[2] 42 U.S.C. § 7409(b)(1).

[3] *Id.* § 7408(a)(2) (emphasis added).

NACAA also recognizes that there is a laudable, long-term trend toward increased transparency in science – in particular, toward providing greater public access to underlying data and analytical techniques after scientific studies are published. There is much to value in this trend toward more "open science," and NACAA supports the continued development of methods that would permit the public disclosure of information on which scientific studies are based without violating, in EPA's words, "confidential or private information in a manner that violates applicable legal and ethical protections."[4] However, at the present time, complete public access to underlying data is not always possible, especially in the case of epidemiological studies based on private health data that must remain confidential. To the extent that techniques are available to anonymize such data, we support their use and we encourage their further development.

Transparency concerns, however, must not override EPA's obligation to consider the full range of peer-reviewed, sound scientific research that is available and relevant to its regulatory decisions. In NACAA's view, the proposal would likely hinder, rather than promote, EPA's use of best-available science and it would tend to diminish public confidence in the integrity of EPA's scientific decision making.

The proposal includes three main components. First, it would require EPA to ensure that the data and models underlying the scientific studies on which its regulatory actions are based are "publicly available in a manner sufficient for independent validation."[5] Second, it would impose upon the agency requirements for the analysis of dose-response models used in scientific studies upon which it relies.[6] Third, it would require EPA to conduct "independent peer review" of scientific studies used to justify its regulatory decisions.[7] Notably absent from the proposal are any details about how, exactly, the agency intends to implement those requirements, or what it might cost.

Our concerns with the proposed rule fall into two main categories: (1) its potential to restrict the scientific studies that EPA will consider in the development of health-based air quality regulations, particularly studies that are based on confidential individual health data, and (2) its vagueness, including its lack of clarity as to how EPA intends to implement the rule in a consistent, clear manner that does not compromise its obligation to protect public health and the environment. We elaborate on these concerns below.

NACAA recommends that EPA withdraw the proposed rule. Prior to proposal, a regulation with such significant ramifications for EPA's science-based decision making should be thoroughly vetted by the scientific community[8] and other key stakeholders, including the state

[4] 83 Fed. Reg. at 18,771.

[5] *Id*. at 18,773-74 (proposed § 30.5).

[6] *Id*. at 18,774 (proposed § 30.6).

[7] *Id*. (proposed § 30.7).

[8] In a memorandum dated May 12, a Science Advisory Board (SAB) Work Group Chair indicated that EPA made no effort to seek the input of its own scientific advisors and that Work Group members were only made aware of the proposal "via the *Federal Register* and news articles." The Work Group concludes that the action warrants further review by the SAB and lays out a number of specific concerns with the proposal, all of with which NACAA concurs

and local air agencies that rely on the scientific integrity of EPA's regulations to protect public health and the environment from the harmful effects of air pollution.

I. EPA Has Not Established that the Proposed Rule Is Necessary or Reasonable

EPA has not adequately explained the purpose and rationale for the proposed rule. The agency suggests that both the "integrity" and "validity" of its decision making will be strengthened by requiring full public disclosure of the data and models underlying the scientific studies on which it relies. The logical implication is that EPA believes those characteristics are currently lacking. The agency does not explain how it reached that conclusion, or what particular "problems" the rule is intended to solve. EPA never explains why, specifically, it believes that existing policies and tools for vetting scientific research are insufficient, why this rule (or any rule) is the best way to address those deficiencies, or why the proposal would better serve and protect the public than its existing policies and practices.

Public access to underlying data and models can be beneficial. However, full public access is not necessary to assure the validity of scientific studies. Rather, the most effective assurance of scientific validity and accuracy is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. There are many steps involved in converting scientific information into policy. Scientists collect data, analyze them, create a model to test theories, compare the model to the data, and then adjust the model. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all these components to establish validity. The process of peer review has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it is incumbent on the agency to explain exactly *why* it believes the process is inadequate and how its proposal specifically addresses those inadequacies.

The proposal does not acknowledge that EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts. The primary function of EPA's Science Advisory Board (SAB) is to review the quality and relevance of scientific and technical information being used by EPA or proposed as the basis for EPA regulations. With respect to the Clean Air Act in particular, EPA's Clean Air Scientific Advisory Committee (CASAC) provides independent advice to the EPA Administrator on the technical bases for the NAAQS. By ignoring the existence of these bodies in the proposed rule, EPA suggests that it does not trust its own scientific advisors. This tends to undermine public confidence in EPA decision making, rather than to bolster it.

The U.S. Court of Appeals for the District Columbia Circuit has affirmed EPA's use of non-public data in support of NAAQS, and in so doing it characterized as "persuasive" EPA's approach to data availability, which the court quoted as follows:

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warrant serious consideration. *See* Memorandum to Members of the Chartered SAB and SAB Liaisons from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration, "Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN" (May 12, 2018).

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment. [S]uch data are often the property of scientific investigators and are often not readily available because of … proprietary interests … or because of [confidentiality] arrangements [with study participants].[9]

Now, EPA indicates that it intends to reverse this policy and adopt one that would expressly preclude it from using studies based on such "non-public data."[10] It is inappropriate for EPA to undertake such a consequential policy change without explaining why it believes the concerns it expressed above are incorrect or no longer valid.

II. The Proposed Rule Could Have Serious, Adverse Effects on the Nation's Air Program

Another concern is that, if enacted, the rule would serve to bar EPA's consideration of relevant scientific literature in the establishment of air regulations designed to protect human health and the environment. Taking one key example, many commenters have opined that the landmark Harvard School of Public Health "Six Cities" epidemiological study, which established the strong association between fine particulate matter pollution and mortality, would not meet the requirements of the proposed rule because it relies on human health data subject to patient confidentiality agreements that were entered into decades ago. EPA should publicly confirm that it would consider existing literature such as the Six Cities Study in future rulemakings, should the proposed rule be enacted.

Unfortunately, EPA suggests in footnote 3 of the proposal that it would exclude such studies from consideration. There, EPA cites two D.C. Circuit cases that upheld its reliance on data that is protected from widespread view by third parties in setting NAAQS for lead and fine particulate matter, respectively, and states, "EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions." NACAA is concerned by the clear implication that EPA will discard rigorously vetted scientific literature such as the Six Cities Study, withdrawing from its legal obligation and stated intention to rely on the best available science.

The proposal would also allow the EPA Administrator to grant exemptions to the rule's requirements on a case-by-case basis if he or she determines it is "not feasible" to make underlying data publicly available or to conduct independent peer review of scientific studies. However, this provision does not alleviate concerns about the potential exclusion of relevant data, because the rule does not include any criteria for how the Administrator would make such a determination. Making the EPA Administrator the ultimate arbiter of what scientific literature should be considered by the agency, based solely on his or her determination of what is or is not "feasible," would have the effect of interjecting the appearance of politics into what should be a

[9] *Am. Trucking Ass'ns., Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

[10] 83 Fed. Reg. at 18,769 n.3.

fair and unbiased scientific assessment. It is an opportunity for arbitrary decision making and is insufficient to protect against the exclusion of relevant, valid scientific studies.

III. Requiring EPA to Conduct "Independent Peer Review" of Scientific Studies Is Unnecessary and Would Be Difficult to Implement

The proposed rule would require EPA to conduct "independent peer review" of scientific studies underlying its significant regulatory decisions, such as the establishment of health-based air quality standards. EPA's in-house peer reviewers would also be tasked with articulating "the strengths and weaknesses of EPA's justification for the assumptions applied and the implications of those assumptions for the results."[11]

It is difficult to provide meaningful comments on this aspect of the proposal because EPA has included no details about how the "independent peer review" requirement would be implemented. The fact that EPA has requested comment on "which parts of the Agency should be responsible for carrying out these requirements" suggests that it has not worked out a plan for this fundamental provision. Peer reviewers must be experts in their fields of scientific study. Would EPA have to hire new experts, and if so, how many and in what fields? How much would this cost? More fundamentally, why should scientific literature that has already undergone peer review and been vetted by EPA's science advisory panels be subjected to an additional layer of government peer review? These key questions should have been considered, and the answers made public, prior to the rule's proposal.

IV. The Proposed Rule Should Not Be Applied Retrospectively

EPA requests comment on whether the requirements of the proposed rule should be applied retrospectively, should the agency decide to adopt it. Specifically, it asks whether for regulatory programs like the NAAQS, in which future significant regulatory actions may be based on the administrative records from previous reviews, the rule should apply to that previous administrative record. This would be inappropriate. To apply such a rule retroactively would create significant regulatory uncertainty by calling into question existing regulatory standards as well as the permits, state implementation plans and other decisions that are based on those standards. Moreover, the rule should not be applied to data and models underlying studies that have already been completed or are currently underway.

V. The Rule Could Be Extremely Costly to Implement

EPA has not estimated the costs of implementing the proposed rule. The preamble states only that "EPA believes the benefits of this proposed rule justify the costs," while providing no information to support that belief. Considering that the rule would require the agency to assemble an in-house group of experts to conduct independent peer review of scientific studies, and to devote staff resources to ensure that data and other information underlying the studies are publicly available in a format sufficient to allow others to replicate their results, it is reasonable to expect those costs could be very high.

[11] 83 Fed. Reg. at 18,774.

The Congressional Budget Office (CBO) was able to estimate the costs of implementing proposed legislation on which we understand the proposed rule to be based, namely, H.R. 1430, the Honest and Open New EPA Science Treatment (HONEST) Act of 2017. CBO estimated that "[i]f EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions," the agency would need to spend at least $100 million dollars per year to upgrade the format and availability of those studies' data to the level required by the bill.[12] Such high costs would reduce the number of scientific studies EPA can consider, which is contrary to the intent and literal language of the Clean Air Act to consider the best available science. We recognize that the proposed rule is somewhat narrower in scope in that its requirements apply to what EPA characterizes as "pivotal regulatory science," but that does not explain why EPA could not provide a cost estimate for the proposed rule when CBO was able to do so for the HONEST Act.

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For all the foregoing reasons, NACAA respectfully requests that EPA withdraw the proposed rule. If the agency intends to update its approach to transparency and reproducibility, it should do so in consultation with the National Academy of Sciences and its own scientific advisors. The implementation details should be worked out in advance, not left to speculation. In the spirit of cooperative federalism, EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation's environmental laws.

If you have any questions about these comments, please do not hesitate to contact me or Karen Mongoven at NACAA. We can be reached by phone at (202) 624-7864 or by email at mkeogh@4cleanair.org and kmongoven@4cleanair.org.

Sincerely,

Miles Keogh
Executive Director
National Association of Clean Air Agencies

[12] Congressional Budget Office, Cost Estimate, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (March 29, 2017).