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U.S. Environmental Protection Agency  
EPA Docket Center  
Office of Research and Development Docket  
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) offers the following comments on the U.S. Environmental Protection Agency's (EPA's) Supplemental Notice of Proposed Rulemaking (SNPRM), "Strengthening Transparency in Regulatory Science," which was published in the *Federal Register* on March 18, 2020 (85 Fed. Reg. 15,396). NACAA is the national, non-partisan, non-profit association of air pollution control agencies in 41 states, including 115 local air agencies, 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.

The SNPRM amends EPA's 2018 "Strengthening Transparency in Regulatory Science" proposal, 83 Fed. Reg. 18,768 (Apr. 30, 2018). The original proposal would have required 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." It also included proposed requirements for the agency's analysis of dose-response models used in scientific studies upon which it relies. Finally, it would require EPA to conduct "independent peer review" of scientific studies used to justify its regulatory decisions.

On July 26, 2018, NACAA submitted written comments on the original proposed rule. We emphasized in those comments that transparency concerns, while important, must not override EPA's obligation to consider the full range of peer-reviewed, sound scientific research that is available and relevant to it

regulatory decisions. In our view, the rule as originally proposed would hinder EPA's use of best-available science and would likely diminish public understanding and confidence in the integrity of EPA's scientific decision-making. NACAA recommended that EPA withdraw the April 2018 proposed rule, based in particular on the following serious concerns:

1. **Full public access to underlying data and models is not necessary to assure the validity of scientific studies.** The vast majority of scientific information on which EPA relies has already been subject to peer review; this is the most effective assurance of scientific validity and accuracy. Furthermore:
  - a. EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts, including the Science Advisory Board and the Clean Air Scientific Advisory Committee; and
  - b. EPA provided no compelling reason for the agency to require an additional layer of "independent peer review" on the scientific studies on which it relies. Nor did it explain how this requirement would be implemented (including which parts of the agency would be responsible for carrying it out).
2. **The proposal would restrict EPA from considering relevant scientific literature in the establishment of health-based air quality regulations.** In particular, the original proposal could bar EPA from considering rigorously vetted scientific literature based on confidential health data that is not publicly available, such as the landmark Harvard School of Public Health "Six Cities" epidemiological study.
3. **The proposal should not apply retrospectively.** The rule should not be applied to data and models underlying studies that have already been completed or are currently underway. For regulatory programs like the National Ambient Air Quality Standards (NAAQS), in which future regulatory actions may be based on the administrative records from previous reviews, it would be wholly inappropriate to apply the public availability requirements to those earlier records.
4. **The provision allowing the EPA Administrator to grant "exemptions" to the rule when compliance is "impracticable" invites arbitrary decision-making.** Moreover, the provision could interject political overtones into what should be an unbiased scientific assessment.
5. **The rule could be extremely expensive to implement.** EPA has not estimated the costs of implementing the proposed rule. Based on a Congressional Budget Office review of a legislative proposal with similar provisions, it appears those costs could be extremely high.

Unfortunately, the SNPRM is largely unresponsive to NACAA's concerns and does not allay them. In some respects, EPA is proposing to *expand* the applicability of problematic provisions that are neither necessary nor desirable. Although the agency has proposed to moderate, to some extent, the rule's provisions governing EPA's ability to consider studies that offer limited or no public access to

underlying data and models, EPA’s proposed “modified” and “alternative” approaches to data and model availability are both unsound.

In sum, nothing in the SNPRM has caused NACAA to change its original assessment: EPA should not finalize this proposal. We elaborate on our specific concerns with the SNPRM below.

**1. Underlying Data and Model Availability Should Not Be Conflated with Scientific Rigor.**

NACAA’s overriding concern with EPA’s science transparency proposal – now packaged with the SNPRM – remains the same: it inherently assumes, incorrectly, that some peer-reviewed scientific studies are “better” or more “valid” than others, based on whether (or the degree to which) their underlying data and models are available to the public. This assumption is fundamentally untrue and conflates two separate issues: transparency and scientific rigor.

As we stated in our earlier comments, transparency in and of itself is a commendable goal, and NACAA supports the continued development of methods to anonymize personal health data and other confidential information. But this issue is distinct and separate from EPA’s obligation to consider the complete range of published, peer-reviewed scientific research that is relevant to its regulatory decisions. The proposal package calls for underlying data and models to be “publicly available in a manner sufficient for independent validation.” However, additional “independent validation” that goes above and beyond the peer review process and EPA existing science advisory infrastructure is not necessary to assure scientific validity and accuracy. All that this new procedural hurdle can accomplish is to limit the universe of scientific studies that EPA may consider. Creating such an impediment undermines EPA’s legal obligation to use the best-available science to guide its decision-making processes and portends a weakening of the scientific underpinnings of health-based environmental regulations.

**2. The SNPRM’s Proposals Governing EPA’s Ability to Consider Scientific Studies Where Public Availability of Underlying Data and Models Is Limited Are Misguided and Overly Subjective.**

EPA’s original proposal would have required the agency to “ensure” that data and models underlying significant regulatory decisions are “publicly available in a manner sufficient for independent validation.” In the SNPRM, EPA acknowledges that many commenters (NACAA among them) contended that this will have the effect of precluding the agency from considering relevant scientific studies that are older and/or rely on confidential or proprietary data. Attempting to address this critical flaw, EPA now offers two options to replace the data and model availability provisions as originally proposed: a “modified” approach (Option 1) and an “alternative” approach (Option 2). Under Option 1, EPA would only consider studies containing confidential business information, proprietary data or personally identifiable information if there is “tiered access” to the data or if the data can be sufficiently de-identified. Option 2 would allow EPA to consider all relevant studies, regardless of their transparency, but the agency would give “greater consideration” to studies where the underlying data and models are publicly available in a manner sufficient for independent validation.

These options represent a marginal improvement over EPA’s original proposal, in that they would appear to restrict fewer scientific studies from EPA’s consideration. However, as with the

original proposal, both of these alternative provisions are unsound. Again, both options rest on a premise with which NACAA fundamentally disagrees: that scientific studies should be “graded” by EPA based on the transparency of their underlying data and models, and that more “transparent” science is more worthy of EPA’s consideration than studies based on confidential data that cannot be made publicly available. The public availability of underlying data and models is not relevant to whether a scientific study is useful, relevant or valuable.

Both options presented in the SNPRM are overly vague and opaque. Option 1 does not explain what framework or level of “tiered access” would be deemed acceptable to EPA. It is questionable whether a tiered approach is feasible or could be managed to the extent that confidentiality could be maintained. Option 2 would impose a wholly subjective framework by which EPA would determine the weight that should be afforded to scientific studies based on their transparency. What is meant by “greater” consideration? How much “greater”? The proposed regulation states, “Where there is no access to data and models, or access is limited, the Agency may still consider these studies, depending on the other attributes of the studies.” What “other attributes” will EPA consider, and how much weight will it place on such attributes? With no criteria to make these determinations, it would be extremely difficult to apply this provision uniformly or objectively. The entire provision is an invitation for arbitrary decision-making. EPA should not serve as an “arbiter” of scientific studies in this manner.

### **3. EPA Should Not Expand the Proposed Rule’s Applicability.**

In the SNPRM, EPA proposes to expand the applicability of the rule to cover not just EPA’s “significant regulatory actions,” but also “influential scientific information.” EPA defines “influential scientific information” broadly, as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important policies or private sector decisions.” The definition does little to clarify the meaning of “influential scientific information,” which is troubling in an SNPRM concerned with transparency. In addition, EPA is now proposing to expand the applicability of certain provisions from “dose-response” data and “dose-response” models to all types of data and models. Subjectively restricting the use of data and models does little to strengthen transparency in science.

NACAA is very concerned that these proposed changes will greatly expand the coverage of a proposal whose precepts we fundamentally disagree with. Thus, we do not support either of these expansions to the proposed regulatory language.

### **4. The EPA Administrator’s Proposed “Exemption” Power Remains Highly Problematic.**

NACAA remains deeply concerned with the provision in the proposal that would allow the EPA Administrator to exempt certain studies from the rule’s requirements on a case-by-case basis, if he or she determines that compliance with the public availability requirements is “impracticable.” In the original proposal, EPA provided no criteria for how the Administrator would make such a determination. EPA now attempts to remedy this shortcoming by describing the factors the Administrator would consider in determining whether to grant an exemption: 1) “technological barriers render sharing of the data or models infeasible,” 2) “the development of the data or model was completed or updated before [effective date of final rule],” or 3) “making the data and models publicly

available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.” 85 Fed. Reg. 15,406.

These proposed criteria do not allay our concerns with the exemption power, because they do not speak to a fundamental issue: what policies or procedures would guide when and how the Administrator would exercise this discretion? Would there be a procedure for persons to request an exemption, and who does EPA anticipate making such requests? How will EPA protect against bias in these exemptions? Will there be an appeal mechanism? These questions are critically important and must be addressed by the agency.

More fundamentally, such exemption authority is not appropriately wielded by a political appointee, but – if it exists at all – by independent science advisors. Placing this authority in the hands of the EPA Administrator would tend to undermine public trust in agency decision-making, because it gives the appearance of allowing the Administrator to pick and choose among scientific studies to obtain the outcome he or she desires. The exemption authority, as proposed, appears to subvert the principles and empirical process of discovery and demonstration that are characteristic of decision-making based on sound science and seems to be at odds with increasing transparency in these matters.

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In conclusion, NACAA is deeply concerned that the science transparency proposal and its supplement could potentially preclude or greatly limit EPA’s reliance on foundational scientific studies underlying the NAAQS and other critical programs that protect the health of millions of Americans. The proposed rule would undercut well-established and validated scientific procedures and principles and further obscure the process that it is intended to strengthen. We also find it unfortunate that EPA appears to be rushing to finalize this deeply controversial proposal at a time when the nation faces an unprecedented health crisis in the COVID-19 pandemic which requires the full attention of our public health and scientific communities. We urge EPA to withdraw the original proposal and the SNPRM.

Thank you for your consideration of these comments. If you have any questions, please feel free to contact me at (571) 970-6678 or [mkeogh@4cleanair.org](mailto:mkeogh@4cleanair.org).

Sincerely,



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