NESCAUM
www.nescaum.org

Northeast States for Coordinated Air Use Management
89 South Street, Suite 602 Boston, MA 02111
Phone 617-259-2000 Fax 617-742-9162
Arthur N. Marin, Executive Director

August 9, 2018

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
Attention: Docket ID No. EPA–HQ–OA–2018–0259

Re: *Proposed Rule on Strengthening Transparency in Regulatory Science*

Dear Acting Administrator Wheeler:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on the U.S. Environmental Protection Agency's (EPA's) Proposed Rule, published in the Federal Register April 30, 2018 and entitled "Strengthening Transparency in Regulatory Science" (83 FR 18768-18774). NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont.[1] We submit these comments out of our concern that failure to consider the best available science will endanger public health.

The EPA invokes "strengthening transparency" as a primary driver for the proposal, yet fails to describe how a perceived lack of transparency has hampered past rulemakings. It provides no examples of where "EPA has not previously implemented these policies and guidance in a robust and consistent manner" nor what are the specific "agency culture and practices regarding data access" that require changing. Furthermore, when EPA was legally challenged after setting the 1997 ozone and fine particulate matter ambient air quality standards, the court in *American Trucking Assns. v. EPA* [283 F.3d 355 (D.C.Cir. 2002)] differentiated the substantial difference and administrative hardship between reliance on peer-reviewed scientific studies cited in a rulemaking record rather than on the raw data underlying those studies:

> 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

[1] These comments reflect the majority view of NESCAUM members. Individual member states may hold some views different from the NESCAUM states' majority consensus.

> because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].

In light of the court's holding, and without additional clarity from EPA, we are having difficulty identifying the problem EPA seeks to address with this Proposed Rule. Therefore, as explained below, we request that the Agency withdraw it.

The proposal is too vague as written to provide the public with a meaningful opportunity to comment

The Proposed Rule, as written, lacks credible specificity and is overly vague in its terms and scope. Under the Administrative Procedures Act (APA), a federal regulatory agency must publish notice of either the substance of a proposed rule or a "description of the subjects and issues" covered by a proposed rule (5 U.S.C. § 553(b)(3)). In Fertilizer Institute v. EPA, 935 F.2d 1303 (D.C.Cir. 1991), the court observed that it "has consistently interpreted that requirement to mean that an agency's notice must 'provide sufficient detail and rationale for the rule to permit interested parties to comment meaningfully'" [*citing* Florida Power & Light Co. v. United States, 846 F.2d 765, 771 (D.C.Cir. 1988), cert. denied, 490 U.S. 1045 (1989)]. As such, EPA is required to articulate the specifics of its proposed rulemakings in a manner that provides a valid opportunity for public comment.

In this proposal, EPA solicits comment across a long list of topic areas, but fails to provide the Agency's own "sufficient detail and rationale" on the solicited comment areas, in contravention to APA § 553(b)(3). Commenters are left in the position of speculating on EPA's views and on those of other commenters that would presumably shape EPA's final rule. It is well settled law that this approach fails to provide adequate notice for informed public comment. In Fertilizer Institute v. EPA, the court held "Commenting parties cannot be expected to monitor all other comments submitted to an agency." In commenters' trying to anticipate potential rule revisions in response to comments from others, the court has also stated, "the EPA must *itself* provide notice of a regulatory proposal. Having failed to do so, it cannot bootstrap notice from a comment" [Fertilizer Institute v. EPA, at 1312, *quoting* Small Refiner Lead Phase-Down Task Force v. EPA, 705 F.2d 506, 547 (D.C.Cir. 1983) (emphasis in original)].

EPA must describe how the proposed text in sections 30.5, 30.7, and 30.9 affect current practice

Without clearly articulated and appropriate bounds, the Proposed Rule can restrict the scientific literature that is the basis for reviews of the National Ambient Air Quality Standards (NAAQS). Along with the changes to the NAAQS review process outlined in EPA's May 9, 2018 "Back to Basics" memo[2] and the recent requirement that members of the Clean Air Science Advisory

[2] Memorandum from E. Scott Pruitt, EPA Administrator, to [EPA] Assistant Administrators, *Subject: Back-to-Basics Process for Reviewing National Ambient Air Quality Standards* (May 9, 2018). Available at https://www.epa.gov/sites/production/files/2018-05/documents/image2018-05-09-173219.pdf (accessed May 21, 2018).

Committee and related panel members not receive any current EPA funding,[3] the Proposed Rule would constrain both the range of expertise and body of scientific literature that is available to be considered in these reviews, undermining the NAAQS. This will impede setting NAAQS levels with an adequate margin of safety necessary for public health protection, as required by the Clean Air Act, by preventing EPA from relying on scientific studies previously utilized to set them. Members of EPA's Science Advisory Board (SAB) have recently expressed similar concerns, stating that "The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs."[4]

Sections 30.5 and 30.7 of the Proposed Rule respectively say: "the Agency shall ensure that dose response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation," and "EPA shall conduct independent peer review on all pivotal regulatory science used to justify regulatory decisions[.]" The approaches for "independent validation" and "independent review" are not described. Would EPA's staff scientists conduct these validations and reviews, or would EPA contract this out to third parties? How would EPA determine that third parties have the necessary qualifications and resources to perform these validations and reviews? Would peer reviewers be anonymous, or will their names and reviews be made public?

Without the above listed information elements, commenters are left to guess at the scope and potential impact of EPA's proposal as it applies to "independent validation" and "independent review." For example, a recent study that is likely to be considered "pivotal regulatory science" for the current PM NAAQS review is by Di, *et al.*, "Air pollution and mortality in the Medicare population."[5] This study of chronic effects, along with a complementary study on acute effects,[6] uses 460,310,521 person years of follow-up and has billions of data points. The computational resources necessary to replicate or validate the analysis are available only at large institutions like the Harvard-MIT Data Center.[7] How does EPA's proposal on independent validation and review apply to a study like this?

The Proposed Rule in section 30.5 also includes qualifying language that "The agency shall make all reasonable efforts to explore methodologies, technologies, and institutional arrangements for making such data available before it concludes that doing so in a manner

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[3] U.S. EPA, "Strengthening and Improving Membership on EPA Federal Advisory Committees," (Oct. 31, 2017). Available at https://www.epa.gov/faca/strengthening-and-improving-membership-epa-federal-advisory-committees (accessed May 21, 2018).

[4] Memorandum from Alison Cullen, Chair SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB Liaisons, *Subject: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)* (May 12, 2018). Available at https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf (accessed May 21, 2018).

[5] Di, Q., *et al.* "Air pollution and mortality in the Medicare population." *New England Journal of Medicine* 376.26 (2017): 2513-2522. DOI: 10.1056/NEJMoa1702747.

[6] Di, Q., *et al.* "Association of short-term exposure to air pollution with mortality in older adults." *JAMA* 318.24 (2017): 2446-2456. DOI: 10.1001/jama.2017.17923.

[7] Harvard-MIT Data Center, The Institute for Quantitative Social Science, "Research Computing Environment," https://projects.iq.harvard.edu/hmdc/book/research-computing-environment (accessed May 21, 2018).

consistent with law and protection of privacy, confidentiality, national and homeland security is not possible." If EPA concludes this "is not possible," does EPA then discard the science, or does it proceed in incorporating its consideration in recognition of other legitimate concerns limiting release of some, or even all, the underlying data and methodologies? This is an instance where clear examples of how the proposal applies to "pivotal regulatory science" would be most useful. Possible examples are the Harvard Six Cities Study[8] and the American Cancer Society Study[9] of particulate air pollution and mortality, and their reanalysis sponsored by the Health Effects Institute (HEI).[10] The original two studies are subject to medical history confidentiality requirements of the study subjects. The HEI effort maintained those confidentiality requirements while conducting an independent reanalysis that largely confirmed the original two studies' results. Are these examples in line with EPA's Proposed Rule, or are there other unidentified issues that would lead EPA to discard studies like these if subjected to this Proposed Rule?

Adding to the vagueness of sections 30.5 and 30.7, section 30.9 would provide the Administrator with broad authority to exempt regulatory decisions from the proposed disclosure provisions "on a case-by case basis if he or she determines that compliance is impracticable." The Proposed Rule lists several general considerations, but fails to provide specific criteria for determining when "compliance is impracticable." This creates the potential for inconsistent application, and leaves the public with no salient points upon which to provide comments. In addition to lacking specific criteria for evaluating what is "impracticable," the Proposed Rule does not describe the process that will be used to determine whether or not a regulatory decision is eligible for such an exemption, nor whether the basis of the Administrator's decision for such an exemption will be publicly disclosed. Lacking clear guidelines for transparent decision-making, the Administrator's discretion would appear to be unbounded and haphazard in application, with an undisclosed rationale.

EPA has provided no meaningful cost estimate for the Proposed Rule

Should EPA impose additional undefined peer review requirements on "pivotal regulatory science," EPA has failed to provide a regulatory impact assessment of costs from imposing such requirements. The costs are likely quite significant, however, based on a Congressional Budget Office (CBO) cost estimate[11] of a similar legislative proposal in H.R. 1430 "Honest and Open New EPA Science Treatment (HONEST) Act of 2017" passed in the House on March 29, 2017. Depending on the scope of "peer review" under this Proposed Rule, costs can be inferred from the CBO analysis to range "between a few million dollars per year to more than one hundred million dollars per year over the 2018-2022 period to ensure that data and other information

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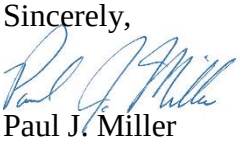
[8] Dockery, D.W. *et al.*, "An Association between Air Pollution and Mortality in Six U.S. Cities," *New England Journal of Medicine*, 329 (1993) 1753-1759.
[9] Pope, C.A. *et al.*, "Particulate Air Pollution as a Predictor of Mortality in a Prospective Study of U.S. Adults," *Am. J. Respir. Crit. Care Med.*, 151 (1995) 669-674.
[10] Health Effects Institute, "Special Report: Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality," July 2000, https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air (accessed May 14, 2018).
[11] Congressional Budget Office, "Cost Estimate: H.R. 1430 Honest and Open New EPA Science Treatment (HONEST) Act of 2017" (March 29, 2017), at https://www.cbo.gov/publication/52545 (accessed May 14, 2018).

underlying studies are publicly available in a format sufficient to allow others to substantially reproduce the results of studies." EPA has provided no relevant information specific to this proposed rulemaking in order to evaluate the value of the additional costs this rule imposes beyond current practice, nor can we weigh potential foregone benefits should an overly broad application of this proposal limit the use of the best available science in setting public health standards and preventing adverse health outcomes.

Conclusion

EPA's proposal has far-reaching consequences on the future use of science by the agency. These consequences, however significant they may be, are indeterminate in light of the proposal's vagueness. The proposal fails to clearly articulate the problem EPA seeks to address, the specific Proposed Rule requirements, and the rule's potential benefits and costs. These are well understood and basic elements that federal regulatory agencies must include to ensure informed public comment. Given these elements are completely missing from this proposal, EPA should withdraw it.

Sincerely,



Paul J. Miller
Deputy Director and Chief Scientist

cc: NESCAUM state directors
Dave Conroy, EPA R1
Richard Ruvo, EPA R2