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May 18, 2020

Andrew Wheeler, Administrator
USEPA Headquarters
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N.W.
Mail Code: 1101A
Washington, DC 20460

Re: EPA-HQ-OA-2018-0259, Strengthening Transparency in Regulatory Science Supplemental Notice of Proposed Rulemaking

Honorable Administrator Wheeler:

The National Tribal Air Association (NTAA) submits these comments regarding the supplemental notice of proposed rulemaking titled “Strengthening Transparency in Regulatory Science” (SNPRM).¹

The NTAA is a member-based organization with 151 principle member Tribes. The organization’s mission is to advance air quality management policies and programs, consistent with the needs, interests, and unique legal status of Indian Tribes. As such, the NTAA uses its resources to support the efforts of all federally recognized Tribes in protecting and improving the air quality within their respective jurisdictions. Although the organization always seeks to represent consensus perspectives on any given issue, it is important to note that the views expressed by the NTAA may not be agreed upon by all Tribes. Further, it is important to understand interactions with the organization do not substitute for government-to-government consultation, which can only be achieved through direct communication between the federal government and Indian Tribes.

On April 30, 2018, the United States Environmental Protection Agency (EPA) published a notice of proposed rulemaking that would drastically reduce the types of scientific studies that can be used to inform EPA regulations protecting public health under the guise of improving transparency.² On August 13, 2018, the NTAA submitted comments opposing the proposed rule, explaining, among other things, that the rule would undermine EPA’s mission to protect human health and the environment.³ The NTAA explained that the proposed rule was vague, purported to address a non-existent and unsubstantiated problem, and would result in EPA failing to rely on the best available science in its important regulatory decision making. The NTAA was particularly concerned about the proposed rule because of its apparent exclusion of

¹ 85 Fed. Reg. 15396 (Mar. 18, 2020).

² Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18768 (Apr. 30, 2018).

³ NTAA’s comments are available in the docket and at <https://www.ntaatribalair.org/wp-content/uploads/2020/03/8.13.18.NTAA-comment-letter-on-transparency-in-science-proposed-rule.EPA-HQ-OAR-2018-0259.pdf>.

studies, that have since been replicated and supported many times, linking air pollution to mortality and disease, and which serve as the basis for important air protections from EPA that Tribes rely on.

Despite the objection from the NTAA and the hundreds of thousands of other comments urging EPA to withdraw the proposal, on March 18, 2020, EPA published a SNPRM that contained a more expansive version of the proposed rule and that does not address any of the NTAA's concerns. In fact, it further heightens those concerns. The NTAA opposes the SNPRM for the following reasons, as well as for the reasons outlined in the 2018 comments. The NTAA urges EPA to withdraw the proposed rule and SNPRM and focus its efforts on protecting human health and the environment based on the best available science.

The NTAA appreciates that EPA extended the 30-day comment period to 60 days for the SNPRM and EPA's stated commitment to giving the public ample time to participate in the rulemaking process. But the NTAA disagrees with EPA's refusal to extend the SNPRM's comment period beyond the additional 30-day extension, as the NTAA and many other organizations' reasonable requests explained was required in order to provide meaningful public participation. By EPA's own description, the SNPRM changes the scope of the original proposed rule to apply to new information, proposes two new approaches to the availability of data, and seeks comment on a new source of proposed authority. The SNPRM would significantly impact every facet of EPA's work. EPA is required to provide the public with notice of a proposed rule, followed by a meaningful opportunity to comment on the rule's content. 5 U.S.C. § 553(b)-(c). Executive Order 12,866 directs EPA to "afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days."⁴ The opportunity to comment must be meaningful under the APA, which "means enough time with enough information to comment."⁵

Conventionally, 60 days would be insufficient for Tribes and the public to meaningfully review and comment on the SNRPRM with such wide-ranging proposed changes and impacts. But this is not a normal time: The national emergency declaration by the Administration due to the COVID-19 pandemic necessitates additional time by the NTAA, Tribes, and the public to review and evaluate the potential impacts of the SNPRM. EPA recognizes the unprecedented situation, but apparently only with respect to the regulated industry, by providing waivers and rule amendments⁶ for, among other things, civil violation enforcement (including settlement agreement and consent decree violations) and gasoline grade requirements.⁷ Yet, EPA ignores the pandemic's impacts to

⁴ Executive Order 12,866, 58 Fed. Reg. 51735 (Sep. 30, 1993).

⁵ *Prometheus Radio Project v. FCC*, 652 F.3d 431, 450 (3d Cir. 2011) (citing *Rural Cellular Ass'n v. FCC*, 588 F.3d 1095, 1101 (D.C. Cir. 2009)).

⁶ It should be noted that on Friday, May 15, 2020, EPA proposed amendments to the March 2020 final action for the 2015 New Source Performance Standards for New Residential Wood Heaters, New Hydronic Heaters and Forced-Air Furnaces. Due to the nation-wide spread of the COVID-19 virus, the proposed amendments, if finalized, would provide retailers additional time to sell Step 1-certified residential wood heating devices. The proposal would change the deadline to November 30, 2020: <https://www.epa.gov/residential-wood-heaters>.

⁷ Susan Park Bodine, COVID-19 Implications for EPA's Enforcement and Compliance Assurance Program, U.S. EPA (Mar. 26, 2020), <https://www.epa.gov/sites/production/files/2020->

Tribes and the public's abilities to meaningfully participate in important regulatory changes: in a March 23 article in *The Hill* an EPA spokesperson is quoted, "We're open and continuing our regulatory work business as usual. As regulations.gov is fully functioning, there is no barrier to the public providing comment during the established periods."⁸ Why is EPA willing to allow industry to violate environmental laws because of the COVID-19 pandemic but won't even provide Tribes consultation and the public more than 60 days to comment on an important proposal that has no statutory or court ordered deadline? Please respond.

Many Tribes, state, and local governments, as well as Tribal agencies are shut down or at severely decreased levels of operation, with many policy support personnel ordered to work from their homes.⁹ Significant sources of Tribal government funds are shut down and Tribes have to focus on protecting their communities with already strained essential services.¹⁰ Many Tribes are now responding to cases of COVID-19 and re-directing staff to respond to the crisis. The SNPRM involves the EPA's consideration of health-related studies, but many health care professionals in and around Tribal communities are busy responding to the national health crisis and do not have the capacity to review, analyze, and respond within 60 days. EPA must re-open and extend the comment period.

I. The NTAA Opposes Both Versions of Proposed 40 C.F.R. § 30.5 As They Would Cause EPA to Arbitrarily Exclude Consideration of the Best Available Science

The NTAA opposes the SNPRM's proposed 40 C.F.R. § 30.5 that would preclude EPA's consideration of scientific information unless all data and models are available, including through tiered access, in a manner sufficient for independent validation. 85 Fed. Reg. at 15405. The NTAA also opposes the alternative proposed 40 C.F.R. § 30.5, that allows consideration but requires the agency to give greater weight to scientific information where all data and models are available in a manner sufficient for independent validation. 85 Fed. Reg. at 15405-06. Finally, the NTAA opposes the SNPRM's explanation that the proposal would apply regardless of when the data and models were generated, even to those collected decades ago. 85 Fed. Reg. at 15405-06.

As a baseline, whether working on "significant regulatory actions," "influential scientific information," or anything requiring the consideration of science, EPA must base its decisions on

[03/documents/oecamemooncovid19implications.pdf](#) ("At the EPA, we are cognizant of potential worker shortages due to the COVID-19 pandemic as well as the travel and social distancing restrictions imposed by both governments and corporations or recommended by the Centers for Disease Control and Prevention to limit the spread of COVID-19."); EPA Press Office, *EPA Announces Steps to Protect the Availability of Gasoline during COVID-19 Pandemic* (Mar. 27, 2020), <https://www.epa.gov/newsreleases/epa-announces-steps-protect-availability-gasoline-during-covid-19-pandemic>.

⁸ Rachel Frazin, *Advocacy Groups Push Back on 'Business as Usual' at EPA During Coronavirus*, *The Hill* (Mar. 23, 2020), <https://thehill.com/policy/energy-environment/488753-advocacy-groups-push-back-on-business-as-usual-at-epa-during>.

⁹ See, e.g., Turtle Talk, *COVID-19 Tribal Documents*, <https://turtletalk.blog/covid-19-tribal-documents/> (last visited Mar. 30, 2020) (collecting Tribal government and court declarations and orders, as well as other resources related to the pandemic).

¹⁰ Bryan Newland, *Indigenous Americans Must Not Once Again Pay the Price for the Mistakes of Others*, *Washington Post* (Mar. 25, 2020), <https://www.washingtonpost.com/opinions/2020/03/25/coronavirus-social-distancing-could-devastate-tribal-communities/> (describing impact, including the closure of casinos, on Tribes).

the best available science. Anything less is nonsensical, arbitrary, and in violation of the environmental laws EPA is charged with implementing. The SNPRM does not maintain this baseline, rather provides for ways EPA would exclude and lessen consideration of the best available science. Therefore, the SNPRM, along with the proposed rule, must be withdrawn. *See, e.g.*, 42 U.S.C. § 300g-1(b)(1)(B)(ii), (3)(A) (Safe Drinking Water Act provisions requiring regulation of contaminants based on best available science); 15 U.S.C. § 2625(h) (Toxic Substances Control Act provision requiring the use of best available science); *see also* 83 Fed. Reg. at 18,769 (“The best available science must serve as the foundation of EPA’s regulatory actions.”).

The SNPRM does not address the fact that many past and ongoing public health studies simply cannot lawfully, ethically, or efficiently publicly release the underlying data. Tellingly, the SNPRM does not claim that such studies are invalid or reached incorrect conclusions. Furthermore, some of these past studies have been reviewed, replicated, and validated by additional independent studies. Even if applied only to future research, the SNPRM would limit participation, limit the information that can be collected, and waste limited resources. Proposed 40 C.F.R. § 30.5 remains a poorly formed scheme in search of a problem that would ultimately force EPA to arbitrarily make public health and environmental decisions based on incomplete or improperly weighted information.

Many environmental statutes require EPA to promulgate standards and protections based on the best available science, and then reanalyze those decisions at set points in the future. The SNPRM, and its proposal to apply regardless of when the data and models were generated, suggests that as EPA reexamines standards and protections, the agency would potentially exclude from consideration studies that led it to enact those standards and protections in the first place. It would be nonsensical and unlawful for EPA to overturn or weaken a standard or protection not based on any new science, or on a concern that the results were invalid, but rather because that study has not publicly released all its underlying data.

Relatedly, the SNPRM’s proposal for tiered access to confidential business information, proprietary data, or Personally Identifiable Information (PII) remains vague and unworkable. The SNPRM’s preamble states, “A model of tiered access for data involving PII is the Research Data Center (RDC), National Center for Health Statistics (NCHS), Centers for Disease Control (CDC).” 85 Fed. Reg. at 15402. The SNPRM states, “EPA is currently conducting a pilot study using the RDC’s secure data enclave to host EPA datasets in a restricted use environment,” and later states, “[d]evelopment of standard data repositories is still ongoing.” *Id.* The SNPRM explains that, “[i]nformation received during this public comment period will, among other things, help inform improved guidance and best practices related to preserving and providing access to data.” *Id.*

This vague aspiration—saying a tiered approach to accessing data is possible, without details—is insufficient and unacceptable. In August 2018, the NTAA expressed concerns about EPA’s belief that confidential or private information could be dealt with by the application of solutions in use across other parts of the federal government. The NTAA also expressed concerns about the cost of doing so and the reduction in studies this would cause EPA to consider. Eighteen months later the SNPRM did not address any of these concerns or analyze the costs or impacts. Before EPA can finalize a rule that relies on certain approaches to provide, yet protect data, it must lay out and analyze those approaches for public review and comment.

Beyond the outstanding problems with the SNPRM’s requirement that underlying data be made publicly available in a manner sufficient for independent replication, the SNPRM also expands the requirement to all data and models rather than just dose-response models and when EPA finalizes “influential scientific information,” in addition to promulgating “significant regulatory actions.” 85 Fed. Reg. at 15398. And, based on an Office of Management and Budget Bulletin, the SNPRM defines “influential scientific information” as “scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions.” *Id.* at 15405.

The NTAA opposes these expansions; the SNPRM takes a bad proposal and makes it worse. These changes do nothing to address the crux of the problem: there are many valid and important scientific studies that cannot legally, ethically, or efficiently publicly release all their data. This cannot be a basis to exclude consideration of those studies. The expansion of scope would also create an even higher burden on scientists or the agency to publicly release and maintain depositories of more data. Although EPA purports to define it, the term “influential scientific information” remains vague and it remains unclear to which actions the SNPRM’s requirements would apply. Finally, the expansion would lead to *less* transparency: if EPA refuses to consider a valid scientific study when finalizing “influential scientific information,” the public might never be informed, have the opportunity to comment, or bring a legal challenge.

EPA should withdraw the proposed rule, SNPRM, and consider the best available science in all its activities.

II. The NTAA Opposes the SNPRM’s Provision That Allows a Political Appointee Unbridled Discretion to Exempt Science from the Proposal’s Requirements

The NTAA opposes the proposed exemption that the Administrator may grant in 40 C.F.R. § 30.9. 85 Fed. Reg. at 15403. The NTAA explained in its 2018 comments that the potential for abuse of this exemption by a political appointee is high and unbounded. The SNPRM now includes factors the Administrator would consider when granting an exemption, which on its face is an improvement. But the SNPRM still leaves the decision to exempt or not exempt, even if based on these factors, completely up to the Administrator. The science should be left to the scientists not political appointees. This unbounded exemption ensures that the proposal can be applied unevenly—for certain actions the “rules” of the SNPRM can be discarded or ignored without any basis in the law. *See* 5 U.S.C. § 706(2)(A) (requiring a reviewing court to hold unlawful agency actions that are arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law).

If EPA moves forward with the SNPRM, it should include a nondiscretionary, mandatory exemption from the rule for all studies which have data that cannot legally, ethically, or efficiently be publicly released, including a mandatory exemption for all studies began prior to the date the proposal is finalized.

III. EPA Lacks Authority for the Proposed Rule and SNPRM

The SNPRM changes the authority EPA claims to rely on for the proposal, however either way, the proposal remains unlawful. The text of the SNPRM proposes to rely solely on 5 U.S.C. § 301. 85 Fed. Reg. at 15404. The preamble says EPA is taking comment on whether to use 5 U.S.C.

§ 301, which the SNPRM calls EPA’s housekeeping authority, independently or in conjunction with statutory provisions cited in the proposed rule and corrected in the SNPRM’s preamble. 85 Fed. Reg. at 15398. The fact that EPA is still considering and asking what authority it can rely on for the proposed rule, twenty-two months after the initial proposed rule, shows that EPA does not have such authority. The SNPRM’s statements on authority continues EPA’s pattern of making rules first and searching for a justification later (which it still has not provided for this rulemaking). As the NTAA explained in its 2018 comments: In order to protect human health and environment, EPA must have a solid foundation before it proposes rules and rulemaking as such portrays the agency’s naiveté in seeking answers for questions about its own authority.

First, none of the initial or corrected environmental statutes provide EPA authority for the proposed rulemaking. In most cases, EPA simply cites its general authority for rulemaking under the statutes. Still that general authority alone cannot provide a basis for the rule, especially when, as here, the rule would conflict with the requirements of each of the statutes. Courts have made clear that “EPA cannot rely on its gap-filling authority to supplement [a statute’s] provisions when Congress has not left the agency a gap to fill.” *NRDC v. EPA*, 749 F.3d 1055, 1064 (D.C. Cir. 2014); *see also New York v. U.S. EPA*, 413 F.3d 3, 40-42 (D.C. Cir. 2005). EPA otherwise cites to statutes describing research programs established by the agency, with no relation to or authorization for the requirements the SNPRM seeks to create. The NTAA also disagrees with EPA’s reliance on 5 U.S.C. § 301 as:

- 1) It is questionable whether § 301 applies to EPA as EPA is not one of the fifteen “Executive Departments” listed at 5 U.S.C. § 101, and
- 2) The proposed rule and SNPRM are not merely internal rules of agency procedure—they would significantly impact every aspect of EPA’s scientific and regulatory work, the individuals who contribute to that work, and the Tribes and communities who rely on it.

The NTAA appreciates the SNPRM’s recognition that “in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control.” 85 Fed. Reg. at 15398. This statement alone should lead EPA to withdraw the proposed rule and SNPRM; the requirements conflict with every statute EPA administers and would cause EPA to unlawfully exclude valid scientific research from its work.

By way of example, in Clean Air Act Section 108(a)(2), Congress requires EPA to issue air quality criteria for air pollutants to “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.” 42 U.S.C. § 7408(a)(2). The SNPRM does not claim that studies that have not publicly released all their underlying data, such as those linking air pollution to mortality and disease, do not 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. If EPA were to exclude such studies from consideration when issuing air quality criteria, it would be in violation of the Clean Air Act.

IV. EPA Neglects its Responsibilities to Tribes and Environmental Justice Communities in the SNPRM

The NTAA is disheartened by the SNPRM's lack of consideration and analysis relating to the proposal's impact on Indian Tribes and Environmental Justice communities: the SNPRM merely states, without further explanation, that "this action does not have tribal implications as specified in Executive Order 13175," and "EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard." 85 Fed. Reg. at 15,404.

It is well established that Tribal communities are likely to experience disproportionate exposure to harmful pollutants and chemicals.¹¹ The Proposal seeks to preclude the use of scientific research critical to establishing safeguards against this disproportionate exposure. Further the Proposal will reduce research and data collection needed to protect the health of Tribal communities as individuals are deterred from participation based on the fear their personal information will be released and researchers avoid seeking such information. EPA has not addressed this issue. Before finalizing any version of the proposed rule and/or SNPRM, EPA must listen to, analyze, and address Tribal concerns with appropriate government-to-government consultations.

The NTAA has recently learned that the EPA is refusing Tribal consultation on this rulemaking. One reason given is that this rule is being proposed under the EPA's housekeeping authority, and is an internal rule. As explained above this authority is not an appropriate vehicle to address a rule of this importance. This proposal will change the way scientific analyses are performed at the EPA. It is wholly insufficient for EPA to force Tribes to save our comments for future rulemakings, which will be constrained by these problematic rules. Proposed new rules will cite back to this Proposed Rule and will not have any recourse. Another reason given by EPA for refusing consultation is the claim that this proposal does not have Tribal implications. While this proposal may not impose direct regulatory requirements on Tribes, it will most certainly have implications on the ability of Tribes to protect the health of their citizens and therefore it has Tribal implications. If the EPA moves forward with this rulemaking, it must reverse its ill-conceived refusal to undertake the necessary and essential government-to-government Tribal consultations on this rulemaking. EPA's refusal to offer Tribal consultation is a failure to uphold the 1984 Indian Policy.

V. Conclusion

The NTAA opposes the finalization of the original proposed rule and this SNPRM for the reasons outlined above. This rule would preclude EPA from considering important and pertinent scientific health studies that contain personal medical information which cannot be publicly released. The proposed rule would create barriers to regulations and arbitrarily deny consideration of important findings, thereby restricting EPA's ability to protect human health and the environment. Moreover, its provisions would result in less, rather than more, transparency. EPA must withdraw the proposed rule and SNPRM.

¹¹ See, e.g., EPA, Tribal Air and Climate Resources <https://www.epa.gov/tribal-air> ("Tribal citizens are often disproportionately affected by air pollution, while their governments play an increasingly valuable role in controlling and reducing pollution and its adverse health effects. Tribes are also particularly vulnerable to the impacts of climate change and are taking steps to prepare for and become more resilient to these changes.").



If you have any questions or require clarification from the NTAA please do not hesitate to contact the NTAA's Project Director Andy Bessler at 928-523-0526 or Andy.Bessler@nau.edu.

Sincerely,

A handwritten signature in blue ink, appearing to read "Wilfred J. Nabahe". The signature is written in a cursive style with a long horizontal stroke at the top and a large loop at the bottom.

Wilfred J. Nabahe
Chairman
National Tribal Air Association
Executive Committee

Cc: Anne Idsal, Office of Air and Radiation Acting Assistant Administrator
Pat Childers, Office of Air and Radiation Tribal Program Manager
Cheryl A. Hawkins, Office of Science Advisor, Policy and Engagement