May 7, 2018

Administrator Scott Pruitt
U.S. Environmental Protection Agency (Mail Code 1101A)
U.S. EPA Headquarters, William Jefferson Clinton Building
1200 Pennsylvania Ave. N.W.
Washington, D.C. 20460
Also via email to docket

Re: Request for a Comment Period Extension, a Hearing, and CASAC Review for EPA's Proposal entitled "Strengthening Transparency in Regulatory Science", 83 Fed. Reg. 18768 (April 30, 2018); Docket No. EPA-HQ-OA-2018-0259

Dear Mr. Pruitt,

I am writing on behalf of the Environmental Protection Network, an organization of former EPA employees and others concerned about the future of the agency, to request an extension of time for public comment, the scheduling of a public hearing or hearings, and other actions.

Our reasons are supported by examples drawn from multiple statutes administered by EPA and will be presented as such.

General concerns supporting an extension of time. The proposal is far too complex, with effects too broad and indeterminate, and requests comment on far too many issues, for a thirty-day response period.

First, although the proposal suggests it will apply to eight environmental statutes, it does not identify any statutory or regulatory provisions requiring the use of science such that the rule will affect their implementation (or effectively amend them). Potential commenters will have to locate and pore through each such provision for themselves in order to assess the proposal's likely effect, *before* they can prepare comments addressing it.

Second, the astonishing breadth of the request for comments also requires extending the comment period. The notice requests comments on a host of general questions, with enough variations or alternatives to bring the total to more than fifty. In many cases, the notice simply identifies the potential comment topics, with no analysis, and no indication which approach the final rule will adopt.

Third, any proposal must meet the obligation to include sufficient, specific information to enable commenters to identify, understand, and respond to the supporting evidence advanced by the agency. This obligation is particularly weighty in a proposal with such sweeping, multi-statutory impact and ambitious, potentially unprecedented scope of change. Yet most of the footnotes are so general and unspecific as to be uninformative (see fn. 8-12, 16-21), or are conclusory without supporting evidence (see fn. 13, part fn. 3).

The amorphousness and breadth of the request for comments, combined with the absence of information about the potential statutory and regulatory provisions the proposal will affect, and the lack of specific information

and supporting evidence in the footnotes, suggest that the proposal should be withdrawn and reissued as an advanced notice of proposed rulemaking (ANPRM). Failing that, EPA should extend the comment period.

Specific Clean Air Act provisions requiring more process.
EPN requests that EPA schedule a public hearing or hearings under the Clean Air Act (CAA) on this proposal, that it extend the public comment period to accommodate that hearing as the CAA requires, and that it submit the proposal for review by the Clean Air Act Scientific Advisory Committee (CASAC) and re-propose it to the extent CASAC directs any changes.

For the following reasons, these steps are legally required:

1. This proposal amends the air quality criteria, adopted under §108 (b) of the CAA, for particulate matter (PM) and lead. See proposed rule fn. 3 final sentence which states that the proposed rule would "preclude" "future regulatory actions" using the Lanphear study which is part of the criteria for the National Ambient Air Quality Standard (NAAQS) for lead, and the Harvard Six Cities and American Cancer Society II study (Dockery and Pope) which are part of the criteria for the PM NAAQS. Air quality criteria cannot be amended without review by CASAC. See CAA §109 (d)(2)(B). EPA consequently must submit its proposal to CASAC for its review, following all procedural requirements for public meeting and deliberations in doing so. CASAC must then submit its recommendations to the Administrator (see §109 (d)(2)(B) final clause), and the Administrator must consider these recommendations and provide a reasonable explanation for any actions that deviate significantly from those recommendations (CAA section 307 (d)(3)). EPA cannot proceed with this action until these requirements are satisfied.

2. Quite apart from the requirement to seek CASAC review, EPA must hold a public hearing on the proposal. The proposal would amend the substantive standards for decision-making for a host of actions covered by §307 (d). It would do so by making in advance a critical part of the regulatory decision in any covered proceeding, namely the decision which scientific evidence to give weight to, and how much – a decision that has previously been made by detailed review in the rulemaking itself. Under the existing approach, such decisions are made after considering the substantive goals of the particular statutory provision involved, are guided by the attitude toward scientific evidence embodied in that provision, and strive for conformity with any applicable procedural requirement. Accordingly, any attempt to make a part of this decision in advance must meet these same standards.

Among the CAA regulatory decisions subject to §307(d) that would be affected in this manner are the NAAQS (§307 (d)(1)(A)), residual risk determinations for hazardous air pollutants (§307 (d) (1)(C)), standards for mobile source air toxics (§307 (d)(1)(K)), and residual risk standards for municipal solid waste combustors (§307 (d)(1)(D)). Therefore, CAA §§307 (d)(5)(ii) and (iv) require the Administrator to hold a public hearing on his proposal and to keep the record open for an additional thirty days "to provide an opportunity for submission of rebuttal and supplementary information".

3. EPA must also submit its proposal to the Science Advisory Board pursuant to the requirements of 42 U.S.C. §4365 (c)(1) (the Environmental Research Development Demonstration Authorization Act), which requires the Administrator to submit to the SAB any "proposed criteria document, standard, limitation, or regulation, together with relevant scientific and technical information in the possession of the (EPA) ... on which the proposed action is based" at the time it provides that proposal to another agency of the government for formal

review. The SAB is then to review and comment on the proposal, which the Administrator is to consider, although the Administrator is not required to obtain SAB approval for any final action. See H. Rep. No. 95-722 (95th Cong. 1st Sess. (1977) (Conference Report).

Further examples of statutory provisions which appear inconsistent with and are not addressed by the proposal

A 30 day comment period is inadequate time to identify and analyze the provisions of multiple statutes administered by EPA with language that will have implications for the actions contemplated by this proposal. Section I.C. of the preamble to this proposal asserts authority for this proposal by identifying, in a very general sense, provisions in several statutes dealing with science and research. The proposal nowhere acknowledges, identifies, or addresses many provisions in these statutes which govern regulatory decision-making and direct how the Administrator is to use science in such decision-making. A couple of illustrative examples drawn from the many relevant provisions raise serious questions as to whether the Administrator has the authority to promulgate such a sweeping, multi-statute rule without addressing the particular, distinctive requirements for regulatory decision-making Congress imposed in each statute. These are issues that would be addressed in an adequate proposal. Because they are not, the proposal in effect tries to shift the burden to commenters to try to make sense of the proposal in the context of statutory language. That is impossible to achieve in 30 days.

Toxic Substances Control Act (TSCA):
While TSCA Section 26 is not identified in the proposal, it includes provisions that raise questions about EPA's authority for and potential application of the proposal. Section 26(h), "Scientific Standards", states that "to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." EPA must consider each of these factors "as applicable." The availability of sufficient underlying data to "validate" or "reproduce" study results is *not* among the relevant factors that EPA must consider.

Similarly, section 26(i) addresses WEIGHT OF SCIENTIFIC EVIDENCE directing that:"—The Administrator shall make decisions under sections 4, 5, and 6 based on the weight of the scientific evidence." This requires the Administrator to evaluate the totality of available scientific evidence and make a judgment about its "weight" – not excluding evidence based solely on the availability of data sufficient for its validation.

These subsections indicate, at a minimum, that this proposal to require that "*dose response data and models* underlying *pivotal regulatory science* are publicly available in a manner sufficient for independent validation.... [w]hen promulgating significant regulatory actions" may not be consistent with the scientific standards and methodology for decision-making Congress prescribed for such actions under TSCA Section 26.

Safe Drinking Water Act (SDWA):
Similarly, although unacknowledged in the proposal including its request for comments, SDWA's standard-setting section, §1412 (42 U.S.C. § 300g–1), addresses the use of science in decisionmaking under that authority:

§1412(b)(3)(A) **Use of science in decisionmaking.—** In carrying out this section, and, to the degree that an Agency action is based on science, the Administrator shall use—

(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and
(ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).

So long as the data used is otherwise collected, assessed, and presented "in accordance with sound and objective scientific practices," Congress did not give the Administrator discretion to ignore the "best available, peer-reviewed science and supporting studies" based on any factor relating to the public availability or unavailability of data, as this proposal would seek to compel. Further, the Report of the Senate Committee on Environment and Public Works – whose language in this provision on the use of science was adopted verbatim in P.L. 104-182 – directs that the "Administrator has a duty to seek and rely upon the best available science and information to support.... [m]any of the most important activities including selecting contaminants for regulation, setting standards, designing analytical methods and structuring waivers, variances and exemptions" (Rpt. 104-169, at 28).

These fundamental omissions illustrate the proposal's inadequacy to identify or address its own implications for the statutory authorities that authorize EPA's programs. These examples, and many more that could be cited, bolster the imperative to withdraw this proposal and grapple meaningfully with these questions in an ANPRM or better fleshed out proposed rule with greater opportunities for exploration and discussion of them via public hearings. Failing that, the agency should at least extend the comment period to 90 days to enable commenters to compile and submit analyses of these questions that EPA has not examined.

The Environmental Protection Network will continue to inventory other statutes and regulations that will be affected by this rulemaking. But even where there are no requirements for a formal hearing or coordination, this proposed rule would change the regulatory framework for determining standards and requirements with no acknowledgement or identification of inconsistencies or conflicts with existing statutory or regulatory requirements or processes, and no opportunity for the public to comment on the specific changes. That makes it imperative to maximize opportunities for the public to review and comment on the regulatory changes being made in this proposal by extending the comment period.

We look forward to your affirmative response to this request.

Respectfully Submitted,

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