Re: Supplemental Notice of Proposed Rulemaking (SNPRM), Docket No. EPA- HQ-OA- 2018-0259. Federal Register/ Vol. 85, No. 53/ Wednesday March 18, 2020 Proposed Rules on "Strengthening Transparency in Regulatory Science" 40 CFR Part 30

To Administrator Wheeler of the EPA;

The Clean Air Board of Central Pennsylvania is writing to express our opposition to, and concerns with, the proposed rule set forth in the Supplemental Notice of Proposed Rulemaking (SNPRM or Supplemental Notice) , Docket No. EPA- HQ-OA- 2018-0259 on "Strengthening Transparency in Science".

We have several concerns:

1. This rule will work to create barriers to the use of highly respected and valuable epidemiological studies.
2. This rule would inappropriately expand the scope of the rule to apply to influential scientific information and pivotal science, in addition to regulatory science.
3. Given the demands of the COVID crisis, the current comment period does not provide sufficient time for the public to comment on this SNPRM , as scientists are working on the virus, instead of taking time to comment on rules that would minimize the weight given to large public health studies.
4. The breadth and substance of this rule takes this rule beyond the authority used for mere "administrative housekeeping".
5. This rule would make the process of seeking to use well-established studies onerous and lengthy, as persons are forced to re-analyze data and apply for consideration and access.
6. This rule gives too much discretion to the Administrator for granting exemption or non-exemption of studies.

For these reasons, explained more fully below, we believe that the Proposed Rule and the Supplemental Notice proposal should be withdrawn.

First, the Rule inappropriately creates barriers to the use of epidemiological studies.

The 2018 proposal was limited to ensuring that dose response data and models underlying pivotal regulatory science were publicly available in a manner sufficient for independent validation, when promulgating significant regulatory actions. (Much of this has been expanded in the Supplemental Notice amendments.) This provision would restrict the EPA from using studies on health effects for which the data is confidential to comply with privacy safeguards. The April 30, 2018 proposed rule received voluminous comments objecting to the rule, as many scientists commented that this change would exclude important environmental health studies and would discourage people from participating out of the fear that their information would be made public. This concern has not been satisfied by the Supplemental Notice proposal.

In response, the Supplemental Notice proposes to amend the April 2018 proposed rule pursuant to two options – either Option 1: to have EPA only use pivotal regulatory science and /or pivotal science that includes PII if there is tiered access sufficient for independent validation, and studies that do not include restricted data if it is publicly available.

– or Option 2 : that EPA will give greater weight and consideration to studies where the data is publicly available and sufficient for independent validation, and will give greater consideration to data that includes Personally Identifiable Information (PII) if the PII are available through restricted access for independent validation. Where access is limited EPA may still consider them depending on "the other attributes" [which is undefined.]

The problem is that this will exclude studies where the patient information cannot be made public, even where the study is of higher quality than studies with no PII. Independent validation of public health studies is not the only means of determining credibility of studies; the National Academy of Sciences also lists other accepted methods of improving the rigor and credibility of studies , such as peer review, systematic reviews, and meta analyses. The scientific merit of studies is what should be given greatest consideration, and scientific value should be evaluated by scientists.

Environmental and epidemiological studies often consider where people are as they are exposed to pollutants: their residence and their subsequent health issues are germane to the studies. Residence, cause of death on death certificates, older age, are PII. Excluding these studies because they contain PII of the patients' proximity to sources of pollution means that the most relevant studies will not be given appropriate weight. The Supplemental Notice and the Rule seek to resolve a problem that does not exist; researchers already promise to keep participants' personal information confidential.

Under the proposed rule, large epidemiological studies like the effect of air pollution and correlation with public health in regard to respiratory, cardiac, and neurological impacts would be discounted, to the detriment of people living close to polluting sources.

The Supplemental Notice would expand the scope of the rule to apply to influential scientific information and pivotal science, in addition to regulatory science.

In the earlier April 2018 proposal, EPA proposed that: "When promulgating significant regulatory actions, the Agency shall ensure that dose-response data and models underlying pivotal regulatory science are publicly available in a manner sufficient for independent validation."

In the Supplemental Notice, EPA is expanding the scope to apply to influential scientific information, not just regulatory action. It is adding definitions for pivotal science (science which underlies influential scientific information) and influential scientific information which is not regulatory (which impacts public policies or private sector decisions). These changes indicate a broad expansion of the SNPRM's impact on restricting studies considered for policies and influential information that do not undergo the public regulatory process. EPA comments that the Rule and SNPRM provide that access to underlying information that includes PII for pivotal science may be limited to authorized officials and researchers and not provided to the general public. Also, the SNPRM is deleting regulatory text at 40 CFR30.10; the inclusion of Research data would have required the rulemaking to be consistent with the definition of research data.

Option 1 of the Supplemental Notice proposes that: When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/ or pivotal science that includes PII if there is tiered access to these data and models in a manner sufficient for independent validation, and studies that do not include restricted data if it is publicly available.

Option 2 of the Supplemental Notice would have the rule read:

"When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will, other things equal, give greater consideration to studies where the underlying data and models are publicly available in a manner sufficient for independent validation. The Agency will also give greater consideration to studies based on data and models that include confidential business information, proprietary information or personally identifiable information if these data and models were available through restricted access, such as through a secure data enclave, in a manner sufficient for independent validation."

Both Options have major flaws. The Supplemental Notice language expands the rule affecting studies to more than the dose-response data, expands its reach to more than regulatory actions, and expands its application to what information will be used to support influential scientific information. This expansion of the scope of the rule is unnecessary overreach and will restrict much more than what was originally proposed. Such restrictions on studies used for public policies and influential information should not take place outside the public regulatory process.

This substantive expansion is particularly inappropriate when experts in science are unable to comment on the proposal in this period of COVID. **Given the demands of the COVID crisis, the current comment period does not allow sufficient time for the public to comment on this SNPRM , as scientists are working on the virus,** and are not able to take time to comment on rules that would minimize the weight given to large public health studies.

This rule is much broader and more substantive than a mere "housekeeping" measure. EPA is taking comments on its authority to promulgate this rule under its housekeeping authority. In our view, this is not "administrative housekeeping". This rule creates rules to exclude scientific studies and applies to complex and studies with large price tags. This is not an "internal" matter to EPA, but instead affects broad research parameters that impact the scientific and health communities, and the affected public.

This rule would make the process of seeking to use well established studies onerous and lengthy, as persons are forced to re-analyze data and apply for consideration and access.

This rule would likely result in a lengthy, bureaucratic process to use epidemiological studies. Following the suggested model for tiered access, researchers would have to submit a research proposal outlining the need for restricted use data. Government is still developing standard data repositories. Studies would have to be reviewed for meeting the criteria; researchers would need to apply to have the study considered or exempted; interested parties would have to redact information or see if it could be reanalyzed and validated. These are burdensome and time-consuming requirements, that would keep scientists from evaluating and relying on relevant studies. This rule will impede timely actions to protect public and environmental health.

Finally, this rule gives too much discretion to the exemption or non- exemption of studies. It is unwise to leave so much discretion to the Administrator to exempt or not exempt studies. Criteria are too vague and should be explicitly defined.

For all these reasons, the Clean Air Board is concerned with, and opposes, the concepts and proposal of the Supplemental Notice on the Transparency Rule.

Sincerely,

Justina Wasicek, for The Clean Air Board of Central Pennsylvania

May 15, 2020