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DAQ-054-18

NOTICE UTAH AIR QUALITY BOARD TELECONFERENCE MEETING

Tuesday, August 7, 2018 - 1:30 p.m.
195 North 1950 West, Room 1015
Salt Lake City, Utah 84116

I. Discussion on Comment Letter to EPA, "Strengthening Transparency in Regulatory Science."

Dial in Number: 1-877-820-7831, Participant Passcode: 915298#

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Primer on EPA "Strengthening Transparency in Regulatory Science"

Prepared by Kevin Cromar for the Utah Air Quality Board

August 1, 2018

Proposed Rule

The US EPA announced a proposed rulemaking "Strengthening Transparency in Regulatory Science" on April 25, 2018 and subsequently published the proposed rule in the *Federal Register* on April 30, 2018 which originally had a 30-day public comment period (available at: <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>). Subsequently, the EPA extended the comment period on the proposed rule until August 16, 2018.

"The proposed regulation provides that, for the science pivotal to its significant regulatory actions, EPA will ensure that the data and models underlying the science is publicly available in a manner sufficient for validation and analysis."

"Where the Agency is making data or models publicly available, it shall do so in a fashion that is consistent with law, protects privacy, confidentiality, confidential business information, and is sensitive to national and homeland security. Information is considered 'publicly available in a manner sufficient for independent validation' when it includes the information necessary for the public to understand, assess, and replicate findings."

"The Administrator may grant an exemption to this subpart on a case-by-case basis if he or she determines that compliance is impracticable."

Legal Basis

There is no clear statutory basis for the proposal rule and instead "solicits comment on...how it can best be implemented in light of existing law." The sections of the Clean Air Act that are cited in the rule as the statutory basis of proposed action are generic rulemaking provisions

that do not mention how science should be considered as a part of rule making. In particular, the proposed rule does not cite section 307(d) of the Clean Air Act even though that section deals directly with the issue of data disclosure. This is likely due to established case law on section 307 that is contrary to the rule being proposed.

The U.S. Court of Appeals for the D.C. Circuit in *American Trucking Associations v Environmental Protection Agency* found that the Clean Air Act imposes no obligation to obtain and make public the data underlying certain "key studies" and similarly reject arguments that a general requirement be imposed for EPA to obtain and publicize the data underlying published studies on which the agency relies. The court also found that "requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary.'" Subsequent legal challenges that EPA should be required to obtain and make public the underlying data from studies used as the basis of regulatory action have similarly been rejected even if it is requested for a single study as opposed to all studies on which the agencies relies (see 2010 U.S. Court of Appeals for the D.C. Circuit ruling in *Coalition of Battery Recyclers Association v Environmental Protection Agency*, 604 F.3d 613, 623 (D.C. Circuit 2010)).

It is not clearly explained what problem this proposed rule is trying to solve

EPA does not provide any rationale for how public disclosure of underlying data used in scientific research improves the "validity" or "integrity" of scientific information used to inform regulatory decisions. It also provides no evidence or explanation of deficiencies in the scientific research that has informed any previous rule promulgated by EPA. If the EPA believes that the existing procedures and safeguards for the conduct, dissemination, and synthesis of scientific research are lacking in some way, it is not mentioned in the proposed rule. A general summary of some of the existing procedures used to ensure the validity and integrity of scientific findings is described in the next paragraph.

Most scientific research is competitively funded through review procedures that are designed to enhance reproducibility and transparency which includes evaluating the scientific premise of the proposed research, ensuring rigorous experimental design for unbiased results, consideration of relevant biological variables, and authentication of key biological and chemical

resources (see NIH notice: NOT-OD-16-011). Research results are published only after rigorous peer-review in which reviewers can be provided confidential access to key data if necessary and are skilled at judging the merits of the research based on the logic of the research design, the appropriateness of methods utilized, and the appropriate citation of previous research results (see J. Berg., P. Campbell, V. Kiermer, N. Raikhel, D. Sweet, *Science* 10.1126/science.aau0116 (2018)). Finally, judgments regarding potential clinical and policy interventions are made based on the entire body of scientific evidence, not individual studies; consistent results observed across multiple studies is the best guarantee of the validity and integrity of scientific findings.

Many air pollution studies already use publically available data

Much of the epidemiology research evaluating the human health impacts of air pollution are based on datasets that are already publically available (e.g., Medicare datasets, NHANES, administrative claims records, etc.). Asking researchers to make the data they used in their studies publically available would violate institutional review board guidelines and data use agreements that are intended to protect patient confidentiality and is not needed given that anyone can access the data as long as they abide by similar data use agreements.

It is impossible to de-identify publically available health data and still allow replication of epidemiology studies

It is not possible to make the data from air pollution epidemiology studies publically available in a way that allows for replication while simultaneously maintaining the privacy of protected health information. Air pollution exposures are assigned based on location and time of the relevant health event. Controlling for potential confounders also typically requires identifying and protected information. Even within a research team, this data is generally not put together in the same place; the analysis is done in parts so that the individuals on the research team do not have access to identifying information. It is incorrect to assert that the requirements of the proposed rule can be met while still maintaining the privacy of medical information.

Draft Comments on the Proposed "Strengthening Transparency in Regulatory Science" Rule

1 The Utah Air Quality Board is the primary air quality policy maker for the State of Utah and is
2 responsible for enacting rules pertaining to air quality activities including the development of
3 state implementation plans to attain and maintain National Ambient Air Quality Standards.
4 Board members are appointed by the governor and confirmed by the senate. By statute, board
5 members must be knowledgeable of air pollution matters and represent a variety of interests,
6 industries, and professions.

7 We concur with the expert opinions of numerous medical societies, scientific organizations,
8 and state air quality agencies in opposing the proposed "Strengthening Transparency in
9 Regulatory Science" and recommend that EPA withdraw the proposed rule.

10 Regulatory decisions made by the EPA should be based on the best available science. For air
11 quality regulations this includes scientific studies that seek to identify pollutants that are
12 responsible for adverse health effects, the health impacts short-term and long-term exposure
13 to air pollution, and the identification of patient subpopulations with increased susceptibility to
14 ambient air pollution. In answering these and other critical questions, the results of any
15 individual study is relatively unimportant compared to the composite body of evidence
16 synthesized across multiple independent studies.

17 We find the existing procedures and safeguards commonly used to conduct, disseminated,
18 and synthesize scientific research more than adequate in ensuring the validity and integrity of
19 the science used to inform EPA decision-making. The proposed rule does not identify any
20 deficiencies in the long established approach of using scientific studies to inform agency
21 decisions nor does it provide any rationale for how the proposed rule, if promulgated, would
22 remedy these deficiencies.

23 While the background of the proposed rule does mention a general concern regarding the
24 reproducibility of scientific studies, it fails to acknowledge the extensive efforts that have
25 already been enacted by funding agencies, scientific journals, and scientific societies to ensure
26 the transparency and reproducibility of biomedical research. The proposed rule also fails to

27 provide any evidence of a replication crisis among the types of studies that have traditionally
28 been used as the basis for air quality regulations.

29 We oppose asking scientific researchers to make publically available administrative claims
30 datasets (e.g., hospital admission and emergency department records, Medicare records, etc.)
31 or other population datasets (e.g., National Health and Nutritional Examination Survey, NIH-
32 AARP Diet and Health Study, etc.) which would not only violate data use and institutional
33 review board agreements but is wholly unnecessary given that these records are already
34 openly available to any individual or group that adheres to data privacy requirements.

35 We also oppose any effort by EPA, under the guise of transparency, to disregard the findings
36 of scientific studies assessing the health impacts of air pollution when making regulatory
37 decisions. We find it disingenuous that the proposed rule suggests that health datasets can be
38 sufficiently de-identified in the public domain in a way that would simultaneously allow for
39 reanalysis while also preventing the illegal disclosure of protected information.ⁱ Since there is
40 no way to provide de-identified data in the public domain that would allow for secondary
41 reanalysis of both the exposure assessment and health analysis in studies assessing the
42 health impacts of air pollution, the EPA should instead continue to focus on assessing results
43 across multiple studies to evaluate the veracity and general applicability of scientific findings.

44 In cases where a scientific study is the first of its kind, and as such has not yet been replicated
45 using independent study populations, we suggest that the EPA follow the example of past EPA
46 administrators in waiting for additional studies to be completed (except in the case of
47 exceptional circumstances) before taking regulatory action based on its study findings.ⁱⁱ While
48 this situation may appear to provide the best argument for reanalysis of individual studies
49 provides little value in informing policy decisions and is not a replacement for replication of
50 study findings in multiple distinct health studies.

51 We specifically oppose any proposed or future action that would disregard the well established
52 effects of particle air pollution on mortality risk in the United States, either as part of future
53 regulatory decisions or in cost benefit analyses included in mandated regulatory impact
54 assessments. These adverse risks have been confirmed and verified both through extensive
55 reanalysis of individual studiesⁱⁱⁱ and more importantly through additional studies that have

56 been completed using numerous independent study populations in the US, Canada, and many
57 other parts of the world.^{iv} Regardless of whether these effects are reported by the EPA as
58 ranges or as combined estimates of mortality risk, the continued inclusion of mortality impacts
59 in regulatory analysis is critical for federal regulatory decisions that impact air quality in Utah. If
60 the proposed transparency rule is promulgated, we ask that the associations of particle
61 pollution and mortality risk are specifically and preemptively excluded from the judgment of the
62 EPA Administrator in adhering to data availability requirements.

63 We strongly oppose the proposal to grant the EPA administrator with authority to consider "on
64 a case-by-case basis" which studies will be used to inform significant regulatory decisions.
65 Picking and choosing which studies to use as the basis of agency actions is antithetical to both
66 sound scientific analysis and evidence-based rulemaking.

67 In summary we agree with the findings of the U.S. Court of Appeals for the D.C. Circuit in
68 *American Trucking Associations v Environmental Protection Agency* that the Clean Air Act
69 imposes no obligation to obtain and make public the data underlying certain "key studies" and
70 similarly reject arguments that a general requirement be imposed for EPA to obtain and
71 publicize the data underlying published studies on which the agency relies. We also agree
72 with the court's finding that "requiring agencies to obtain and publicize the data underlying all
73 studies on which they rely 'would be impractical and unnecessary.'"^v

Footnotes:

ⁱ Assessing the health impacts of air pollution at the individual level requires information about the location of patients, the time when health events occur, and personal information that is used to account for potential confounding effects (smoking status, income, insurance status, education level, etc.). At best, publically available de-identified patient datasets would need to have the assessment of air pollution exposures already assigned (which requires precise location information and is matched to the time of health events) which would effectively preclude the type of secondary verification sought for in the proposed rule.

ⁱⁱ Former Administrator Johnson provides an effective example in how he considered the results of the California Children's Health Study, which at the time was the first of its kind, as part of the 2006 review of the PM NAAQS.

ⁱⁱⁱ See 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. Available at: <https://www.healtheffects.org/system/files/Reanalysis-ExecSumm.pdf>.

^{iv} Additional studies are too numerous too exhaustively list here but the recent paper by Di et. al., (2018) "Air Pollution and Mortality in the Medicare Population" lists at least 11 studies that have found positive associations between long-term pollution exposure and mortality, all of which have been published since the 2009 EPA ISA that determined long-term exposure to PM_{2.5} to be causal for premature mortality risk. See N Engl J Med. 2017 Jun 29; 376(26): 2513–2522.

^v See *American Trucking Associations v EPA*, 283 F.3d 355, 372 (D.C. Circuit 2002). Subsequent legal challenges that EPA should be required to obtain and make public the underlying data from studies used as the basis of regulatory action have similarly been rejected even if it is requested for a single study as opposed to all studies on which the agencies relies. See 2010 U.S. Court of Appeals for the D.C. Circuit ruling in *Coalition of Battery Recyclers Association v Environmental Protection Agency*, 604 F.3d 613, 623 (D.C. Circuit 2010).

MEMORANDUM

TO: Members of the Chartered SAB and SAB Liaisons

FROM: Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science */signed/*

DATE: May 12, 2018

SUBJECT: Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)

The Chartered Science Advisory Board convened Work Groups to discuss whether to review the adequacy of the science supporting planned regulatory actions identified by the EPA as major actions in the Spring and Fall 2017 semi-annual regulatory agenda at its May 31, 2018 meeting. To support this discussion a SAB Work Group was charged with identifying actions for further consideration by the Chartered SAB.

The Environmental Protection Agency announced the proposed rulemaking entitled Strengthening Transparency in Regulatory Science RIN (2080-AA14) on April 25, 2018 at a press event and published a *Federal Register* notice on April 30, 2018 with a 30-day public comments period. The Work Group notes that this planned action was not identified as a major action in either of the Spring 2017 nor Fall 2017 semi-annual Regulatory Agendas.

This memorandum summarizes the charge to the Work Group, their discussion regarding the planned action and issues and questions for the SAB to discuss at its May 31, 2018 meeting.

Background

The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other Federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then make available to the Administrator, within the time specified by the Administrator, its advice and comments on the adequacy of the scientific and technical basis of the proposed action.

EPA's current process is to provide the SAB with information about the publication of the semi-annual regulatory agenda and to provide descriptions of major planned actions that are not yet proposed but appear in the semi-annual regulatory agenda. These descriptions provide available information regarding the science informing agency actions. This process for engaging the SAB supplements the EPA's process for program and regional offices to request science advice from the SAB.

The SAB Work Group then follows a [process adopted by the Chartered SAB](#) in 2013¹ to initiate its review of major planned actions identified in the Unified Regulatory Agenda by EPA. This semi-annual regulatory agenda is available at <https://www.reginfo.gov/public/do/eAgendaMain>. The current SAB

¹ Available at [http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/\\$File/SABProtocol2017.pdf](http://yosemite.epa.gov/sab/sabproduct.nsf/WebSABSO/ProcScreen2017/$File/SABProtocol2017.pdf)

Work Group was formed in December 2017 to review the Fall 2017 semi-annual Regulatory Agenda and includes SAB members with broad expertise in scientific and technological issues related to the proposed actions.

The Work Group met by teleconference on May 3, 2018 to discuss its recommendations on considered actions in the Fall 2017 semi-annual regulatory agenda and included the proposed rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14)² as part of the discussions. Members were made aware of the proposed rule via the *Federal Register* and news articles. The EPA did not provide a description of the planned action. SAB members on the Work Group teleconference include Drs. Alison Cullen (Work Group chair), Robert Blanz, Otto Doering, H. Christopher Frey, John Graham, Michael Honeycutt (SAB chair) Merl Lindstrom, Jay Turner, and Messers. Richard Poirot and Robert Merritt.

Work Group Discussions Regarding Strengthening Transparency in Regulatory Science RIN (2080-AA14)

Table 1: Summary of Proposed Actions that the SAB Work Group Considered for Additional SAB Comment on the Supporting Science		
RIN	Planned Action Title	Workgroup Recommendation
2080-AA14	Proposed Rule: Strengthening Transparency in Regulatory Science RIN	Merits review by the SAB.
¹ There is no additional information available on the planned action provided in the Unified Regulatory Agenda on the OMB website http://www.reginfo.gov/ . The OMB review was completed on April 23, 2018. The hyperlink is to the FR notice for the proposed rule.		

Recommendation: This action merits further review by the SAB. The proposed rule deals with issues of scientific practice and proposes constraints that the agency may apply to the use of scientific studies in particular contexts. As such, this rule deals with a myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board.

Rationale: In reviewing the Federal Register, Work Group members noted that EPA published a proposed rule that would limit the use of science based on human subject data and would impose requirements for the analysis of dose-response relationships widely used in risk assessments across a wide range of agency programs.

The Work Group recognizes that the long-term trend in most scientific fields is for authors to supply public access to data and analytic methods after scientific findings are published. Such transparency may help to detect and discourage scientific fraud, facilitate various forms of robustness analysis, and allow supplementary lines of knowledge to be developed from the same data. Some fields of science are moving faster than others in the direction of transparency.

² Available at: <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

For studies published many years ago, it may not be feasible to deliver public access to data and analytic methods. There are also sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate. In addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available within Institutional Review Board requirements, including the issue of who would be responsible for shouldering this burden. Thus, the development of guidelines and rules in this arena requires careful collaboration between the government and the scientific community.

Although the proposed rule cites several valuable publications that support enhanced transparency, the precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community. Nor does the preamble to the rule describe precisely how the proposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines.

The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. Without access to the restricted data, regulatory programs could become more or less stringent than they otherwise would be, with consequences for both regulatory costs and benefits. The Work Group also found that the rule is highly controversial (indeed a similar legislative effort in the House has been stalled in Congress for several years) and could have long-term implications. Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts. The proposed rule does not acknowledge that the epidemiologic science community, for example, has been making significant efforts to make data available where possible and to develop studies based on publicly available data where appropriate. On the other hand, the rule might stimulate researchers to make stronger efforts toward transparency so that their work may be considered in regulatory deliberations. It might be easier to accomplish the rule's objectives if the focus were on future studies rather than on studies that are already designed and published with terms that make complete transparency difficult or impossible to accomplish. It might also be easier if the rule took into account reasonable areas for accommodation or exception in situations for which it is not possible to release a dataset publicly either entirely, or without revision, for legitimate reasons pertaining to the use, for example, of human subject data.

Among the key science issues that the rule touches upon are the following:

- Restrictions on the use of epidemiologic studies that are based on confidential human subject data. Although the epidemiologic community recognizes the need to make data public to the extent possible, in some cases it is not possible to make public full datasets. These include, but are not limited to, cases in which studies are subject to prior Institutional Review Board (IRB) conditions or in which prospective cohort studies include extensive personal data from which it would be possible to identify individual persons.

- The proposed rule fails to mention that there are various ways to assess the validity of prior epidemiologic studies without public access to data and analytic methods. For example, the Health Effects Institute (HEI) conducted a re-analysis of the influential Harvard Six Cities and American Cancer Society (ACS) epidemiologic studies and was able to replicate its findings and to assess the robustness of the findings via sensitivity analysis³. HEI did uncover some sensitivities in the original ACS cohort findings associated with multiple pollutants and with interactions of pollution with socio-economic status (SES) variables such as educational attainment. Furthermore, over time, additional studies have confirmed the basic findings. Thus, in this particular case, an unusually rigorous form of peer review and independent reanalysis, coupled with many follow-up studies, has accomplished a measure of confidence in findings without public access to data and analytic methods. And we note that some of the recent confirmation studies have used publicly available data.
- The proposed rule oversimplifies the argument that “concerns about access to confidential or private information can, in many case, be addressed through the application of solutions commonly in use across some parts of the Federal government.” For studies already completed or underway, the participation of human subjects is undertaken according to terms approved by the cognizant IRB. These terms can vary from study to study. In some cases, the data cannot be released simply by redacting portions of it. For example, data may have been collected with an assurance to the participating individuals that their data would be kept confidential⁴.
- The requirement of the consideration of multiple dose-response models should explicitly state that this consideration is based on information relevant to the selection of the most scientifically-appropriate model(s) such as biological plausibility, mode of action, or mechanism of action. Deviations from the use of default models should be evaluated on a case-by-case basis and have adequate scientific justification for use of an alternative model better supported by the chemical-specific data. Concepts such as “replication” and “validation”, although they are surely crucial in sound science, are not clearly defined in the rule.
- The proposed rule fails to mention that EPA has mechanisms for vetting science through several expert panels, including the EPA Science Advisory Board, the EPA Clean Air Scientific Advisory Committee, and the EPA FIFRA Scientific Advisory Panel (FIFRA is the Federal Insecticide, Fungicide, and Rodenticide Act). For example, the EPA CASAC routinely reviews and evaluates epidemiologic and toxicological studies that are the basis for dose-response relationships used in risk and exposure assessments for air pollutants regulated under the National Ambient Air Quality Standards. Although such mechanisms do not typically engage in reanalysis of original data using the same methods as the original investigators, they do entail a rigorous review process that goes beyond the typical journal peer review procedures.

³ Health Effects Institute, 2000. Reanalysis of the Harvard Six Cities Study and the American Cancer Society Study of Particulate Air Pollution and Mortality. Daniel Krewski, Richard T. Burnett, Mark S. Goldberg, Kristin Hoover, Jack Siemiatycki, Michael Jerrett, Michal Abrahamowicz, and Warren H. White.

<https://www.healtheffects.org/publication/reanalysis-harvard-six-cities-study-and-american-cancer-society-study-particulate-air>

⁴ Ibid.

Work Group Recommendations Regarding Improvements to the Process for Identifying EPA Planned Actions for SAB Consideration

The Work Group notes that the Proposed Rule on Strengthening Transparency in Regulatory Science was not included in previous semi-annual regulatory agendas, is not available on the OMB website www.reginfo.gov and that the EPA did not provide a description of the action. The Work Group continues to urge the EPA to improve the process for future review of the semi-annual regulatory agenda and strongly recommends that EPA enhance descriptions of future planned actions by providing specific information on the peer review associated with the scientific basis for actions and more description of the scientific and technological bases for actions. EPA should provide such information in the initial descriptions provided to the work group.

Effective SAB evaluation of planned actions requires the agency to characterize the following.

- All relevant key information associated with the planned action.
- The science supporting the regulatory action. If there is new science to be used, provide a description of what is being developed. If the agency is relying on existing science, provide a short description.
- The nature of the planned or completed peer review. To the extent possible, provide information about the type of peer review, the charge questions provided to the reviewers, how relevant peer review comments are/were integrated into the planned action, and information about the qualifications of the reviewer(s).

This SAB made several of these recommendations in previous reviews⁵. We request that the chartered SAB highlight to the Administrator the need for the Agency to provide more complete information to support future SAB decisions about the adequacy of the science supporting actions in future regulatory agendas.

References: Proposed Rule: Strengthening Transparency in Regulatory Science (RIN 2080-AA14) FR Vol 83, Num. 83, pages 18768-18774. Available at: <https://www.federalregister.gov/documents/2018/04/30/2018-09078/strengthening-transparency-in-regulatory-science>

⁵ [SAB Discussions about EPA Planned Actions in the Fall 2012 Unified \(Regulatory\) Agenda and their Supporting Science \(see page 5 of the Work Group memorandum\)](#)
[SAB Discussions about EPA Planned Actions in the Spring 2013 Unified Agenda and their Supporting Science \(Letter to the Administrator and Work Group memorandum \[see page 5\]\)](#)
[SAB Discussions about EPA Planned Actions in the Spring 2017 Unified Agenda and their Supporting Science \(see page 7\)](#)

Cite as: J. Berg., P. Campbell, V. Kiermer,
N. Raikhel, D. Sweet, *Science*
10.1126/science.aau0116 (2018).

Joint statement on EPA proposed rule and public availability of data

Jeremy Berg,^{1*} Philip Campbell,² Veronique Kiermer,³ Natasha Raikhel,^{4,5} Deborah Sweet⁶

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We are writing in response to a proposed rule announced by the Environmental Protection Agency (EPA) in a 24 April 2018 press release (1). The release reads, “The rule will ensure that the regulatory science underlying Agency actions is fully transparent, and that underlying scientific information is publicly available in a manner sufficient for independent validation.”

Data sharing is a feature that contributes to the robustness of published scientific results. Many peer-reviewed scientific journals have recently adopted policies that support data sharing, consistent with the Transparency and Openness Promotion (TOP) standards. These standards, however, recognize the array of workflows across scientific fields and make the case for data sharing at different levels of stringency; in not every case can all data be fully shared. Exceptional circumstances, where data cannot be shared openly with all, include data sets featuring personal identifiers.

We support maintaining the rigor of research published in our journals and increasing transparency regarding the evidence on which conclusions are based. As part of these goals, we require that all data used in the analysis must be available to any researcher for purposes of reproducing or extending the analysis. Importantly, the merits of studies relying on data that cannot be made publicly available can still be judged. Reviewers can have confidential access to key data and as a core skill, scientists are trained in assessing research publications by judging the articulation and logic of the research design, the clarity of the description of the methods used for data collection and analysis, and appropriate citation of previous results.

It does not strengthen policies based on scientific evidence to limit the scientific evidence that can inform them; rather, it is paramount that the full suite of relevant science vetted through peer review, which includes ever more rigorous features, inform the landscape of decision making. Excluding relevant studies simply because they do not meet rigid transparency standards will adversely affect decision-making processes.

REFERENCE

1. U.S. Environmental Protection Agency, News Releases, “EPA Administrator Pruitt proposes rule to strengthen science used in EPA regulations” (2018); www.epa.gov/newsreleases/epa-administrator-pruitt-proposes-rule-strengthen-science-used-epa-regulations.

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Joint statement on EPA proposed rule and public availability of data

Jeremy Berg, Philip Campbell, Veronique Kiermer, Natasha Raikhel and Deborah Sweet

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July 26, 2018

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Attention: 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) appreciates this opportunity to comment on the U.S. Environmental Protection Agency's (EPA's) proposed rule, "Strengthening Transparency in Regulatory Science," 83 Fed. Reg. 18,768 (Apr. 30, 2018). NACAA is the national, non-partisan, non-profit association of 156 local and state air pollution control agencies in 41 states, 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.

NACAA agrees with EPA that "the best available science must serve as the foundation of EPA's regulatory actions."¹ Indeed, reliance on best-available science is a fundamental requirement of the Clean Air Act and other environmental statutes that EPA administers. For example, the Clean Air Act requires EPA to establish National Ambient Air Quality Standards (NAAQS) at levels "requisite to protect the public health" with "an adequate margin of safety."² In meeting this obligation, EPA is required to develop air quality criteria that "*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, in varying quantities."³ Science-based decision making is at the very core of our shared mission to protect public health and the environment from the harmful effects of air pollution.

¹ 83 Fed. Reg. at 18,769.

² 42 U.S.C. § 7409(b)(1).

³ *Id.* § 7408(a)(2) (emphasis added).

NACAA also recognizes that there is a laudable, long-term trend toward increased transparency in science – in particular, toward providing greater public access to underlying data and analytical techniques after scientific studies are published. There is much to value in this trend toward more “open science,” and NACAA supports the continued development of methods that would permit the public disclosure of information on which scientific studies are based without violating, in EPA’s words, “confidential or private information in a manner that violates applicable legal and ethical protections.”⁴ However, at the present time, complete public access to underlying data is not always possible, especially in the case of epidemiological studies based on private health data that must remain confidential. To the extent that techniques are available to anonymize such data, we support their use and we encourage their further development.

Transparency concerns, however, must not override EPA’s obligation to consider the full range of peer-reviewed, sound scientific research that is available and relevant to its regulatory decisions. In NACAA’s view, the proposal would likely hinder, rather than promote, EPA’s use of best-available science and it would tend to diminish public confidence in the integrity of EPA’s scientific decision making.

The proposal includes three main components. First, it would require 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.”⁵ Second, it would impose upon the agency requirements for the analysis of dose-response models used in scientific studies upon which it relies.⁶ Third, it would require EPA to conduct “independent peer review” of scientific studies used to justify its regulatory decisions.⁷ Notably absent from the proposal are any details about how, exactly, the agency intends to implement those requirements, or what it might cost.

Our concerns with the proposed rule fall into two main categories: (1) its potential to restrict the scientific studies that EPA will consider in the development of health-based air quality regulations, particularly studies that are based on confidential individual health data, and (2) its vagueness, including its lack of clarity as to how EPA intends to implement the rule in a consistent, clear manner that does not compromise its obligation to protect public health and the environment. We elaborate on these concerns below.

NACAA recommends that EPA withdraw the proposed rule. Prior to proposal, a regulation with such significant ramifications for EPA’s science-based decision making should be thoroughly vetted by the scientific community⁸ and other key stakeholders, including the state

⁴ 83 Fed. Reg. at 18,771.

⁵ *Id.* at 18,773-74 (proposed § 30.5).

⁶ *Id.* at 18,774 (proposed § 30.6).

⁷ *Id.* (proposed § 30.7).

⁸ In a memorandum dated May 12, a Science Advisory Board (SAB) Work Group Chair indicated that EPA made no effort to seek the input of its own scientific advisors and that Work Group members were only made aware of the proposal “via the *Federal Register* and news articles.” The Work Group concludes that the action warrants further review by the SAB and lays out a number of specific concerns with the proposal, all of which NACAA concurs

and local air agencies that rely on the scientific integrity of EPA's regulations to protect public health and the environment from the harmful effects of air pollution.

I. EPA Has Not Established that the Proposed Rule Is Necessary or Reasonable

EPA has not adequately explained the purpose and rationale for the proposed rule. The agency suggests that both the “integrity” and “validity” of its decision making will be strengthened by requiring full public disclosure of the data and models underlying the scientific studies on which it relies. The logical implication is that EPA believes those characteristics are currently lacking. The agency does not explain how it reached that conclusion, or what particular “problems” the rule is intended to solve. EPA never explains why, specifically, it believes that existing policies and tools for vetting scientific research are insufficient, why this rule (or any rule) is the best way to address those deficiencies, or why the proposal would better serve and protect the public than its existing policies and practices.

Public access to underlying data and models can be beneficial. However, full public access is not necessary to assure the validity of scientific studies. Rather, the most effective assurance of scientific validity and accuracy is the process of peer review itself, a process to which the vast majority of scientific information on which EPA relies has already been subject. There are many steps involved in converting scientific information into policy. Scientists collect data, analyze them, create a model to test theories, compare the model to the data, and then adjust the model. When the results of a scientific study are submitted for publication, the uncertainties, assumptions, parameters and theories utilized by the scientists are laid out in the publication. Peer review analyzes all these components to establish validity. The process of peer review has been rigorously developed over centuries. If EPA believes the peer review process is flawed, it is incumbent on the agency to explain exactly *why* it believes the process is inadequate and how its proposal specifically addresses those inadequacies.

The proposal does not acknowledge that EPA already has institutional mechanisms to review and vet scientific information through panels of scientific experts. The primary function of EPA's Science Advisory Board (SAB) is to review the quality and relevance of scientific and technical information being used by EPA or proposed as the basis for EPA regulations. With respect to the Clean Air Act in particular, EPA's Clean Air Scientific Advisory Committee (CASAC) provides independent advice to the EPA Administrator on the technical bases for the NAAQS. By ignoring the existence of these bodies in the proposed rule, EPA suggests that it does not trust its own scientific advisors. This tends to undermine public confidence in EPA decision making, rather than to bolster it.

The U.S. Court of Appeals for the District Columbia Circuit has affirmed EPA's use of non-public data in support of NAAQS, and in so doing it characterized as “persuasive” EPA's approach to data availability, which the court quoted as follows:

warrant serious consideration. *See* Memorandum to Members of the Chartered SAB and SAB Liaisons from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration, “Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN” (May 12, 2018).

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 because of ... proprietary interests ... or because of [confidentiality] arrangements [with study participants].⁹

Now, EPA indicates that it intends to reverse this policy and adopt one that would expressly preclude it from using studies based on such “non-public data.”¹⁰ It is inappropriate for EPA to undertake such a consequential policy change without explaining why it believes the concerns it expressed above are incorrect or no longer valid.

II. The Proposed Rule Could Have Serious, Adverse Effects on the Nation’s Air Program

Another concern is that, if enacted, the rule would serve to bar EPA’s consideration of relevant scientific literature in the establishment of air regulations designed to protect human health and the environment. Taking one key example, many commenters have opined that the landmark Harvard School of Public Health “Six Cities” epidemiological study, which established the strong association between fine particulate matter pollution and mortality, would not meet the requirements of the proposed rule because it relies on human health data subject to patient confidentiality agreements that were entered into decades ago. EPA should publicly confirm that it would consider existing literature such as the Six Cities Study in future rulemakings, should the proposed rule be enacted.

Unfortunately, EPA suggests in footnote 3 of the proposal that it would exclude such studies from consideration. There, EPA cites two D.C. Circuit cases that upheld its reliance on data that is protected from widespread view by third parties in setting NAAQS for lead and fine particulate matter, respectively, and states, “EPA is proposing to exercise its discretionary authority to establish a policy that would preclude it from using such data in future regulatory actions.” NACAA is concerned by the clear implication that EPA will discard rigorously vetted scientific literature such as the Six Cities Study, withdrawing from its legal obligation and stated intention to rely on the best available science.

The proposal would also allow the EPA Administrator to grant exemptions to the rule’s requirements on a case-by-case basis if he or she determines it is “not feasible” to make underlying data publicly available or to conduct independent peer review of scientific studies. However, this provision does not alleviate concerns about the potential exclusion of relevant data, because the rule does not include any criteria for how the Administrator would make such a determination. Making the EPA Administrator the ultimate arbiter of what scientific literature should be considered by the agency, based solely on his or her determination of what is or is not “feasible,” would have the effect of interjecting the appearance of politics into what should be a

⁹ *Am. Trucking Ass’n, Inc. v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002).

¹⁰ 83 Fed. Reg. at 18,769 n.3.

fair and unbiased scientific assessment. It is an opportunity for arbitrary decision making and is insufficient to protect against the exclusion of relevant, valid scientific studies.

III. Requiring EPA to Conduct “Independent Peer Review” of Scientific Studies Is Unnecessary and Would Be Difficult to Implement

The proposed rule would require EPA to conduct “independent peer review” of scientific studies underlying its significant regulatory decisions, such as the establishment of health-based air quality standards. EPA’s in-house peer reviewers would also be tasked with articulating “the strengths and weaknesses of EPA’s justification for the assumptions applied and the implications of those assumptions for the results.”¹¹

It is difficult to provide meaningful comments on this aspect of the proposal because EPA has included no details about how the “independent peer review” requirement would be implemented. The fact that EPA has requested comment on “which parts of the Agency should be responsible for carrying out these requirements” suggests that it has not worked out a plan for this fundamental provision. Peer reviewers must be experts in their fields of scientific study. Would EPA have to hire new experts, and if so, how many and in what fields? How much would this cost? More fundamentally, why should scientific literature that has already undergone peer review and been vetted by EPA’s science advisory panels be subjected to an additional layer of government peer review? These key questions should have been considered, and the answers made public, prior to the rule’s proposal.

IV. The Proposed Rule Should Not Be Applied Retrospectively

EPA requests comment on whether the requirements of the proposed rule should be applied retrospectively, should the agency decide to adopt it. Specifically, it asks whether for regulatory programs like the NAAQS, in which future significant regulatory actions may be based on the administrative records from previous reviews, the rule should apply to that previous administrative record. This would be inappropriate. To apply such a rule retroactively would create significant regulatory uncertainty by calling into question existing regulatory standards as well as the permits, state implementation plans and other decisions that are based on those standards. Moreover, the rule should not be applied to data and models underlying studies that have already been completed or are currently underway.

V. The Rule Could Be Extremely Costly to Implement

EPA has not estimated the costs of implementing the proposed rule. The preamble states only that “EPA believes the benefits of this proposed rule justify the costs,” while providing no information to support that belief. Considering that the rule would require the agency to assemble an in-house group of experts to conduct independent peer review of scientific studies, and to devote staff resources to ensure that data and other information underlying the studies are publicly available in a format sufficient to allow others to replicate their results, it is reasonable to expect those costs could be very high.

¹¹ 83 Fed. Reg. at 18,774.

The Congressional Budget Office (CBO) was able to estimate the costs of implementing proposed legislation on which we understand the proposed rule to be based, namely, H.R. 1430, the Honest and Open New EPA Science Treatment (HONEST) Act of 2017. CBO estimated that “[i]f EPA continued to rely on as many scientific studies as it has used in recent years to support its covered actions,” the agency would need to spend at least \$100 million dollars per year to upgrade the format and availability of those studies’ data to the level required by the bill.¹² Such high costs would reduce the number of scientific studies EPA can consider, which is contrary to the intent and literal language of the Clean Air Act to consider the best available science. We recognize that the proposed rule is somewhat narrower in scope in that its requirements apply to what EPA characterizes as “pivotal regulatory science,” but that does not explain why EPA could not provide a cost estimate for the proposed rule when CBO was able to do so for the HONEST Act.

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For all the foregoing reasons, NACAA respectfully requests that EPA withdraw the proposed rule. If the agency intends to update its approach to transparency and reproducibility, it should do so in consultation with the National Academy of Sciences and its own scientific advisors. The implementation details should be worked out in advance, not left to speculation. In the spirit of cooperative federalism, EPA should also consult from the earliest stages with the state and local agencies that are responsible for implementing our nation’s environmental laws.

If you have any questions about these comments, please do not hesitate to contact me or Karen Mongoven at NACAA. We can be reached by phone at (202) 624-7864 or by email at mkeogh@4cleanair.org and kmongoven@4cleanair.org.

Sincerely,

A handwritten signature in black ink, appearing to read 'Miles Keogh', is written over a horizontal line. The signature is fluid and cursive, with a large loop at the end.

Miles Keogh
Executive Director
National Association of Clean Air Agencies

¹² Congressional Budget Office, Cost Estimate, H.R. 1430, Honest and Open New EPA Science Treatment (HONEST) Act of 2017 (March 29, 2017).