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May 18, 2020

Andrew Wheeler, Administrator
U.S. Environmental Protection Agency
EPA Docket Center,
Office of Research and Development Docket, Mail Code 28221T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attention: Docket ID No. EPA–HQ–OA–2018–0259

Re: *Strengthening Transparency in Regulatory Science (Supplemental Notice of Proposed Rulemaking)*

Dear Administrator Wheeler:

The Northeast States for Coordinated Air Use Management (NESCAUM) offer the following comments on EPA's Supplemental Notice of Proposed Rulemaking (SNPRM) for "Strengthening Transparency in Regulatory Science" [85 Fed. Reg. 1539615406 (March 18, 2020)]. The SNPRM clarifies and modifies provisions in the proposed rule [83 FR 18768-18774 (April 30, 2018)].

NESCAUM is the regional association of air pollution control agencies representing Connecticut, Maine, Massachusetts, New Hampshire, New Jersey, New York, Rhode Island, and Vermont. Our member agencies have the primary responsibility in their states for implementing clean air programs that achieve the public health and environmental protection goals of the federal Clean Air Act (CAA). We are submitting these comments out of concern that, by restricting the science that will be considered in important Agency decisions, this rule will endanger public health and the environment.

Like many others member of the scientific, public health and environmental communities, NESCAUM submitted comments in 2018 asking EPA to withdraw the proposed rule. That request was based on a number of concerns, including EPA's failure to articulate a need for the requirements; the vagueness of the proposal, which precluded an evaluation of the potential impacts of the rule on regulatory programs and the use of science by the Agency; and the absence of a meaningful assessment of the costs associated with implementation of the requirements.[1]

[1]NESCAUM Comments on EPA's Proposed Rule on Strengthening Transparency in Regulatory Science (August 9, 2018), Available at: https://www.nescaum.org/activities/comments-and-testimonies

While the SNPRM provides some additional clarity, e.g., by defining certain terms used in the proposed rule, the major issues raised by NESCAUM and others in the earlier comments continue to be pertinent. In fact, the SNPRM expands the scope of the applicability of the requirements without providing a demonstration of the necessity of the regulation and without providing an assessment of the costs and regulatory implications of implementation of the rule. As discussed below, the EPA Science Advisory Board expressed concern about these issues in its recently report on this rule, which considered aspects of the SNPRM along with the original proposal.[2] As such, NESCAUM is again requesting that EPA withdraw the proposed rule.

A discussion of NESCAUM's continuing concerns about the rule and responses to EPA requests for comments in the SNPRM follows. Those comments address the following issues:

1. The Federal Housekeeping Statute is not an appropriate legal authority for this action. The proposal is also inconsistent with provisions in the Toxic Substances Control Act (TSCA) and Safe Drinking Water Act (SDWA) and would hamper implementation of CAA requirements.
2. The proposed rule and the SNPRM do not demonstrate why this regulation is needed or how it would improve the transparency and scientific integrity of regulatory outcomes.
3. The proposed rule and the SNPRM do not provide meaningful assessments of the cost of implementing the rule or of the impact of the rule on existing regulations and programs.
4. The tiered structure presented in the SNPRM does not adequately address concerns about re-identification of study participants, disclosure of private health data, and negative effects on future study participation.
5. The rule would compromise EPA's decision-making by excluding from consideration or devaluing well-conducted peer reviewed studies that cannot comport with data availability requirements.
6. Due to the rapid development of scientific knowledge, risk-related models and methodologies should be addressed in guidelines, rather than in fixed regulations. In particular, the SNPRM's identification of specific dose-response modeling techniques that would be given "explicit consideration" is inappropriate.
7. The SNRPM continues to allow the Administrator to include or exclude studies from consideration on a case-by-case basis. This may result in exclusion of important studies and invites politicization of the process.
8. 40 CFR 30.5 in the SNPRM specifies that the rule would apply to all data and models evaluated in conjunction with a significant regulatory action or development of influential scientific information, regardless of when the data or models were developed, but asks for comment about whether the requirements

[2] Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science (April 24, 2020). Available: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf

should be limited to studies conducted after the rule is adopted. NESCAUM strongly opposes adoption of the rule; however, if it is adopted, the provisions should not apply to past studies.

9. Of the two versions of 40 CFR 30.5 included in the SNPRM, NESCAUM strongly prefers the second alternative, which allows some consideration of studies without public accessible data. However, NESCAUM does not agree that data accessibility should be the primary factor used to determine how a study is weighted relative to other studies.
10. EPA asks whether age of data and models should be considered in determining the feasibility of making underlying data and models publicly available and asks whether additional factors should also be considered in this determination. NESCAUM strongly supports the consideration of age of data, as well as where and by whom the study was conducted and funded, the nature of confidentiality agreements, and other factors that may preclude data accessibility, in any feasibility determination.

1. The Federal Housekeeping Statute is not an appropriate legal authority for this action. The proposal is also inconsistent with provisions in the TSCA and SDWA and would hamper implementation of CAA requirements.

In the SNPRM, EPA requests comments on whether the Federal Housekeeping Statute [5 CFR U.S.C. 301] should be used independently or in conjunction with environmental statutory provisions as the authority for promulgating this regulation. Authorizing environmental statutory provisions cited include: the Clean Air Act (CAA); the Clean Water Act (CWA); the Safe Drinking Water Act (SDWA); the Resource Conservation and Recovery Act (RCRA); the Comprehensive Environmental Response, Compensation, and Liability Act CERCLA); the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA); the Emergency Planning and Community Right-To-Know Act (EPCRA) and the Toxic Substances Control Act (TSCA).

As EPA acknowledges in the SNPRM, the Supreme Court ruled in *Chrysler Corp. v. Brown*, [441 U.S. 281, 309 (1979)]. that the intended purpose of the Housekeeping Statute is "to govern internal departmental affairs" and, as such, authorizes "what the [Administrative Procedure Act] terms 'rules of agency organization, procedure or practice' as opposed to substantive rules." Because the proposed Strengthening Transparency rule would have far reaching substantive impacts on a wide range of EPA programs and activities, it is clearly inappropriate to invoke the Housekeeping Statute as authority applicable to this proposed rule.

The proposed rule is also inconsistent with provisions in environmental statutes cited by EPA. For instance, TSCA specifies that "(h)azard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science and weight of scientific evidence" (40 CFR 702.41(d)(2)).The TSCA definition of "best available science" goes on to list five criteria that should be considered, as

applicable, one of which is "(t)he extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models." While this definition acknowledges the merit of independent verification, that criterion is only one of several listed and peer review is identified as another method of review of data quality. This is inconsistent with the SNPRM, which stipulates that studies for which data cannot be made available for reanalysis will not be considered or will be considered as less valid, even when the validity of those studies is supported by other avenues, including peer review.

Similarly, the SDWA stipulates that, in risk assessment, management and communication actions that are based on science, "the Administrator shall use the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices" and defines "best available science," as "science that is reliable and unbiased ... conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods." (40 CFR 300g-1) Again, a rule that precludes that use of high-quality peer reviewed studies in significant actions would contradict the SDWA language.

While similar language does not specifically appear in the CAA, *American Trucking Assns. v. EPA* [283 F.3d 355 (D.C. Cir. 2002)] supported EPA's reliance on peer-reviewed scientific studies, without conducting an independent analysis of the raw data underlying those studies, in setting the 1997 ozone and fine particulate matter ambient air quality standards as follows:

> 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].

Therefore, the requirements in the proposed regulation are inconsistent with specifications in several of the environmental statues cited in the SNRPM. In addressing this issue, the SNRPM says, "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." However, there is no attempt to delineate those conflicts or to explain how an environmental statute can serve as legal authority for a regulation that conflicts with important provisions of that statute. NESCAUM also strongly disagrees with the application of the Housekeeping Statue as an authority for a regulation with significant, far-reaching implications.

2. The proposed rule and the SNPRM do not demonstrate why this regulation is needed or how it would improve the transparency and scientific integrity of regulatory outcomes.

In the proposed rule, EPA invoked "strengthening transparency" as the primary driver of the regulation, but did not provide evidence of how a perceived lack of transparency has hampered past rulemakings. In addition, the proposal did not provide evidence to support the claim that "EPA has not previously implemented these policies and guidance in a robust and consistent manner."

The recent Science Advisory Board (SAB) report on the proposal highlighted this issue, pointing out that:

> There is minimal justification provided in the Proposed Rule for why existing procedures and norms utilized across the U.S. scientific community, including the federal government, are inadequate, and how the Proposed Rule will improve transparency and the scientific integrity of the regulatory outcomes in an effective and efficient manner. It is plausible that in some situations, the Proposed Rule will decrease efficiency and reduce scientific integrity, determining if in fact that will be the case requires a thorough and thoughtful examination that is currently absent in the Proposed Rule. Moving forward with altered transparency requirements beyond those already in use, in the absence of such a robust analysis, risks serious and perverse outcomes. [3]

Despite EPA's receipt of extensive comments on this issue, the SNPRM does not address the need for the regulation and does not provide evidence that implementation of the proposed rule would improve regulatory outcomes. Instead, the SNPRM expands the scope of the rule to include all data and models used in influential scientific information and significant regulatory actions, rather than to just dose-response data and dose-response models.

The proposed rulemaking does not provide additional transparency and, by limiting the studies that can be considered, will compromise crucial decisions by the Agency. Appropriate data sharing mechanisms already exist and major funding sources, including the National Institutes of Health (NIH) and EPA, require scientists to establish a data sharing plan as part of the scientific granting process. The NIH currently operates multiple data repositories. Major journals, including Lancet, the Journal of the American Medical Association, and the New England Journal of Medicine, require researchers to specify a mechanism for sharing data with other scientists consistent with NIH policies and the FAIR (findable, accessible, interoperable, re-usable) principles as part of their manuscript submission to facilitate replication of findings, or pooling of data from multiple studies. EPA should focus on implementing existing initiatives and guidelines for improving data sharing and transparency at federal agencies rather than

[3] Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled Strengthening Transparency in Regulatory Science (April 24, 2020), page 18. Available: https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/2DB3986BB8390B308525855800630FCB/$File/EPA-SAB-20-005.pdf.

promulgating a regulation that requires additional data sharing as a condition for consideration of a study.

Further, reanalysis of data is only one of several mechanisms available for validating studies. The scientific community uses numerous tools to validate studies, many of which do not require access to all underlying study data. Those tools include rigorous peer review, replication of a study using the same methodology but with different data sources, or reproduction of a study's conclusions using different methodologies and data. Under the proposed rule, a peer reviewed study that has been replicated many times by different investigators using different data may be excluded from consideration, while one that uses an inferior database that is publicly available would be included.

In the absence of the demonstration of the benefits of requirements that will have significant negative consequences, as discussed below, NESCAUM requests that EPA withdraw the proposed rule from further consideration.

3. The proposed rule and the SNPRM do not provide meaningful assessments of the cost of implementing the rule or of the impact of the rule on existing regulations and programs.

The costs associated with implementing this rule are not well-articulated in the proposal and are not addressed in the SNPRM. The SAB report identifies a number of costly activities that implementation would require, including establishing an office for data-sharing, funding replication studies, promulgating guidance on methods and analysis, developing tiers of public access, and conducting data reanalysis. These costs should be thoroughly assessed prior to finalization of the rule. Note that the Congressional Budget Office estimated the costs to the Agency of a similar proposal at $100-250 million a year.[4] A thorough cost-benefit analysis of the proposed rule is essential because implementation of these requirements would likely reduce the resources available for other important activities, including the development of advanced risk assessment methodologies.

The proposed regulation would also impose significant costs on research scientists. Formatting, preparing and de-identifying datasets and associated materials to be publicly available or to conform with EPA's proposed tiers of data availability would be extremely time and resource intensive. Further, according to a 2002 report from the National Academy of Sciences, re-

[4] Congressional Budget Office. Cost Estimate: H.R. 1030 Secret Science Reform Act of 2015. March 11, 2015. Available: https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

analyses of studies almost always require the participation of the original researchers to provide additional information and support, at an additional cost of personnel time and resources.[5]

As discussed above, the SNPRM cites a wide range of environmental statutes - the CAA, CWA, SDWA, RCRA, CERCLA, FIFRA, EPCRA and TSCA - as authorities for this action. However, EPA did not evaluate the impact of the proposed rule on the existing regulations and programs that have been adopted to implement those laws. For example, EPA has not provided an analysis of how the requirements in this regulation would affect key studies that support the periodically updated Integrated Risk Information System (IRIS) risk assessments, which are used to support regulations adopted pursuant to several of those statutes. It is irresponsible to proceed with adopting this rule without such an analysis.

4. The tiered structure presented in the SNPRM does not adequately address concerns about re-identification of study participants, disclosure of private health data, and negative effects on future study participation.

The SNPRM allows for tiered access to data that contain confidential business information (CBI), proprietary data, or personally identifiable information (PII) in order "to reduce the risk of re-identification and, therefore, mitigate certain disclosure privacy risks associated with providing such access." (page 15399). According to the SNPRM, "(t)he benefit of tiered access is that data users who wish to conduct activities with a statistical purpose without first obtaining special authorization have access to the versions of the data in the least restricted tiers, allowing them to conduct research while protecting confidentiality." (page 15402)

While the tiered access structure presented in the SNPRM is preferable to the requirement in the proposed rule that all data used in decision-making must be publicly available, NESCAUM continues to be concerned about the potential for re-identification of study participants. Because environmental studies by necessity need to use location data to establish exposures, a very significant percentage of study participants can be identified unless the data are masked to a degree that would not allow reanalysis. Recently, a peer reviewed study examined the identifiability of records from an environmental health study in northern California. Using data considered by the Health Insurance Portability and Accountability Act (HIPAA) to be sufficiently de-identified to be made public and which involved far fewer variables than would be required for the reanalysis proposed by EPA, the researchers were able to correctly identify over 25% of the study participants.[6]

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[5] National Research Council. 2002. *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of a Workshop*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10302.

[6] Sweeney L, Yoo JS, Perovich L, Boronow KE, Brown P and JG B. Re-identification Risks in HIPAA Safe Harbor Data: A study of data from one environmental health study. Technology Science. 2017.

This issue has been well recognized. The 2002 National Academy of Sciences reports states that:

> In an experiment to discover whether confidentiality could be preserved while opening the data for public review, the study investigators attempted to disguise the identity of the study participants. They deleted as many features as possible from the questionnaires, such as the name, the state file number, the mother's maiden name, and the name of the person providing the information. However, they needed to retain a minimum set of features if other scientists were to be able to replicate the basic findings of the study… They found that even this minimum set of features could allow for identification of research participants.[7]

Risking re-identification by increasing access to study data is not necessary, given the availability of data to other scientists through NIH repositories and peer-review journals, and the alternative techniques available to verify conclusions of scientific studies, as discussed above. Further, identification of participants in studies could have consequences for future studies. People will be much less likely to agree to participate in long term epidemiological studies if they have seen that people in prior studies have been identified, which will hamper future research efforts.

5. The rule would compromise EPA's decision-making by excluding from consideration or devaluing well-conducted peer reviewed studies that cannot comport with data availability requirements.

The SNRPM presents two alternatives to 40 CFR 30.5; the first would exclude and the second would devalue EPA's consideration of any studies that cannot comport to the data availability requirements in the proposed rule. Those alternatives would exclude or devalue many well-conducted, peer reviewed studies, including a number of studies conducted outside of the United States. In comments on the proposed rule, the International Society for Environmental Epidemiology documented stringent European and Canadian privacy laws which would preclude making data from studies conducted in those jurisdictions available.[8] As an example, those comments cite the following international air pollution studies, which would be excluded or devalued in EPA's proposed protocol:

- The Canadian Community Health Survey Cohort, which followed a cohort of 300,000 people to study the association of PM2.5 with mortality. The participants were linked to their tax records to obtain individual level information on income, which was a variable

[7] National Research Council. 2002. *Access to Research Data in the 21st Century: An Ongoing Dialogue Among Interested Parties: Report of a Workshop*. Washington, DC: The National Academies Press. https://doi.org/10.17226/10302.

[8] Comments of the International Society for Environmental Epidemiology on EPA's Proposed Rule on Strengthening Transparency in Regulatory Science (EPA-HQ-OA2018-0259-0001) Available at: http://www.youreventinfo.org/ISEE/Documents/ISEE_Comments_on_EPA-HQ-OA-2018-0259-0001FINAL_ISEE_submitted.pdf.

in the analysis. Analyses were performed on computers at Statistics Canada and, because of the highly confidential nature of the data, even the investigators did not have possession of the data.[9]

- The ESCAPE study combined 22 cohorts across Europe, estimating address-specific concentrations of multiple air pollutants for each participant, and examined the association of air pollution with mortality in these participants. European data privacy laws would prevent the data from these people being available to EPA as specified in the SNPRM.[10]

The failure to consider these and similar studies, solely on the basis of data availability, would clearly limit the breadth and quality of the information available to EPA for critical decisions, such as the setting and review of environmental standards.

6. Due to the rapid development of scientific knowledge, risk-related models and methodologies should be addressed in guidelines, rather than in fixed regulations. In particular, the SNPRM's identification of specific dose-response modeling techniques that would be given "explicit consideration" is inappropriate.

The scientific information, techniques and models used in risk assessments are developing rapidly. Therefore, risk assessment methodology should be addressed in guidelines, which can be adjusted as more information becomes available, rather than with fixed regulations. Instead of establishing inflexible regulatory requirements, the Agency should focus on continuing to improve its existing guidelines, in concert with other federal agencies.

In particular, NESCAUM regards the following language in Section 30.6 of the SNPRM as highly inappropriate for inclusion in a regulation:

> When available, EPA shall give explicit consideration to high quality studies, including but not limited to those that explore: A broad class of parametric dose-response or concentration-response models; a robust set of potential confounding variables; nonparametric models that incorporate fewer assumptions; various threshold models across the dose or exposure range; and models that investigate factors that might account for spatial heterogeneity.

The specific identification of modeling considerations in a regulation is inappropriate, as discussed above. Further, because multiple analyses using a variety of models do not necessarily

[9] Pinault L, et al. Risk estimates of mortality attributed to low concentrations of ambient fine particulate matter in the Canadian community health survey cohort. Environmental Health. 2016;15:18. https://ehjournal.biomedcentral.com/articles/10.1186/s12940-019-0518-y.

[10] Beelen R, et al. Effects of long-term exposure to air pollution on natural-cause mortality: an analysis of 22 European cohorts within the multicentre ESCAPE project. Lancet. 2014;383:785-95. https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(13)62158-3/fulltext.

make a study more credible, there is no scientific justification for this stipulation. Model choices consider such factors as biological plausibility and the degree of protection to human health. An evaluation of a study that uses modeling should assess model assumptions, the fit of the model to the dataset, the goal of the analysis, and other issues. Use of a greater number of models does not in itself improve results or make a study more plausible. Therefore, giving priority to studies based on the number or range of models used is scientifically inappropriate and may create an incentive for using inappropriate models without scientific justification, which may generate inaccurate outputs.

7. The SNRPM continues to allow the Administrator to include or exclude studies from consideration on a case-by-case basis. This may result in exclusion of important studies and invites politicization of the process.

Section 30.9 of the SNPRM states the following:

> The Administrator may grant an exemption to this subpart on a case-by case basis if he or she determines that compliance is impracticable because technological barriers render sharing of the data or models infeasible, the development of the data or model was completed or updated before [*EFFECTIVE DATE OF FINAL RULE*] or making the data and models publicly available would conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security.

NESCAUM agrees that the criteria listed are important considerations in decisions about data availability. However, providing the Administrator with the authority to make case-by-case exemption determinations will exacerbate concerns about inappropriate exclusion of scientifically important studies, raise questions about a transparent ethical process, and invite politicization of the process. As discussed above, data sharing and other study assessment methodologies should be addressed in guidelines rather than in a fixed regulation, and criteria for how the above considerations are evaluated should be delineated in those guidelines.

8. NESCAUM strongly opposes adoption of the rule. If it is adopted, the provisions should not apply to past studies.

The SNPRM specifies in 40 CFR 30.5 that the rule would apply to all data and models that are considered in conjunction with a significant regulatory action or development of influential scientific information, regardless of when the data or models were developed, but asks for comment about whether the requirements should be limited to studies conducted after the rule is adopted. NESCAUM strongly opposes adoption of the rule. If it is adopted over our objections, the provisions should not apply to past studies.

Data requirements should not be applied retroactively to past studies. Data may no longer be available or may be restricted by use agreements in place at the time the study was conducted. Note that although the requirements in this rule do not apply to past regulatory decisions, many regulatory decisions, including NAAQS derivations, are subject to periodic statute-mandated reviews and discounting the studies that are the basis of those derivations would have disastrous consequences for public health and the environment.

9. Of the two versions of 40 CFR 30.5 included in the SNPRM, NESCAUM strongly prefers the second alternative, which allows some consideration of studies without public accessible data. However, NESCAUM does not agree that data accessibility should be the primary factor used to determine how a study is weighted relative to other studies.

The SNPRM asks for comments on "how much consideration should be given to studies when there is limited or no access to the underlying data and models." Specifically, the SNPRM includes two versions of Section 30.5. The primary version of that section states that EPA would consider studies without publicly available data and models only when there is "tiered access to these data and models in a manner sufficient for independent validation" of those studies. Studies that do not meet these criteria, including older studies, would not be considered. The alternative 30.5 allows consideration of studies that do not meet the above criteria, but specifies that such studies will be given less weight.

Of these two alternatives, clearly NESCAUM would prefer the second, because it does not automatically eliminate a wide range of well-conducted studies that cannot comport with the data availability specifications. However, it is inappropriate to elevate consideration of data availability above all other factors in establishing the weight or quality of a study. As discussed above, there are a number of reasons why underlying data may not be available and well-conducted studies should not be given a lower weight based solely on that criterion.

As discussed in comments on the proposed rule submitted by a large group of scientists[11] in August 2018, representatives of academia, medical scientists, industry and publishers have developed protocols and guidelines specifically designed to improve reporting and evaluation of studies to improve the quality and transparency of the interpretation of findings. These protocols and guidelines are designed to improve the scientific basis of data evaluations without requiring public access to all study data. EPA should utilize these existing tools to evaluate study quality and should build on the work already done by the scientific community.

[11] Comments from Academics, Scientists and Clinicians on the EPA Proposed Rule "Strengthening Transparency in Regulatory Science" (August 2018). Submitted online via *Regulations.gov* to docket EPA-HQ-OA-2018-0259 https://prhe.ucsf.edu/sites/g/files/tkssra341/f/wysiwyg/2018%2008%2016%20Transparency%20in%20Science%20UCSF-PRHE%20comments%20EPA.pdf.

10. The SNPRM asks whether age of data and models should be considered in determining the feasibility of making underlying data and models publicly available and whether additional factors should also be considered in this determination. NESCAUM strongly supports the consideration of age of data, as well as privacy laws, technology barriers, the nature of confidentiality agreements, and other factors that may preclude data accessibility, in any feasibility determination.

As discussed above, NESCAUM strongly supports the consideration of the date that the study was conducted in any evaluation of data accessibility. An older study should not be excluded or devalued solely because raw data are no longer available or because accessibility to those data are restricted by use agreements in place at the time the study was conducted. In addition, any other factor that precludes or limits data accessibility, including, as listed in Section 30.9 of the SNPRM, technological barriers and conflicts with "laws governing privacy, confidentiality, confidential business information, or national and homeland security," should be considered. The criteria should be specified in guidelines, and data availability should be considered as only one factor in weighing the quality of studies.

Conclusion

The proposed Strengthening Transparency in Regulatory Science regulation has far-reaching implications for the future use of science in critical Agency decisions. In the SNPRM, EPA responded to some of the concerns raised in the vast number of comments submitted on the proposed rule by allowing tiered levels of data accessibility and by providing definitions of previously undefined terms. However, without addressing the need, cost, or regulatory implications of the regulation, and without providing evidence that implementation of the rule would improve regulatory outcomes, the SNPRM expands the reach of the proposed regulation to include all data and models used in influential scientific information and significant regulatory actions.

The proposed rulemaking provides no additional transparency and addresses no identified problem. Rather, it compromises the integrity of the Agency actions, including regulatory decisions, without clear benefits. This places the public's health and welfare at unnecessary risk. EPA should withdraw the proposal from further consideration.

Sincerely,

Paul J. Miller
Executive Director

cc: NESCAUM Directors
NESCAUM Air Toxics and Public Health Committee
Lynne Hamjian, Cynthia Greene, Bob Judge, EPA R1
Rick Ruvo, EPA R2