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EPN Comments on EPA's Supplemental Proposal
"Strengthening Transparency in Regulatory Science"
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I. Introduction and Summary

Two years ago, EPA Administrator Scott Pruitt issued a proposal that directed EPA, whenever it promulgates rules that impose costs on industry, to ignore all scientific studies for which supporting data were not made fully available to the public. 83 Fed. Reg. 18768 (April 30, 2018).

This proposal does not reflect longstanding, accepted scientific practice of using the best available science in the development of policy. The scientific community and EPA itself have worked out many different satisfactory approaches to assuring the reliability of scientific studies with or without such data disclosure. Moreover, concerns based on history, practicality, and confidentiality often make such disclosures infeasible for otherwise valid and useful studies. EPA's proposal did not discuss in any way how barring studies would further the policies of the regulatory statutes that it would affect, nor what was wrong with the current approaches to assuring study reliability.

EPA has now issued a supplement to that proposal purportedly designed to strengthen the essentially non-existent legal justification it first offered, and to suggest ways in which excluded studies might still be considered if the Administrator in his sole discretion decided to allow that. Most consequentially, EPA additionally proposes to vastly extend the scope of the original proposal. That proposal had only covered studies and dose-response models used to support "significant regulatory actions."

Now EPA plans to expand coverage in two ways. First, it would extend model coverage to all models, defining "model" about as broadly as is conceptually possible as "a simplification of reality that is constructed to gain insights into select attributes of a physical, biological, economic or social system." 85 Fed. Reg. 15405, proposed §30.2. Second, EPA would apply its new rules not just to data and models supporting significant regulatory actions, but to assessments of multiple studies, data and models it labels as "influential scientific information," -- thus not even limiting the rule's scope to regulatory actions. This would include assessments such as EPA Integrated Science Assessments and National Academy of Sciences reports.

At the same time the agency reaffirms its choice not to apply this new approach to any action that benefits industry, such as permit grants or product approvals. By extending its proposal to all models, and all studies including those cited in EPA or other assessments, the agency has made this exclusion even more arbitrary and indefensible.

This document sets out the comments of the Environmental Protection Network (EPN) on this proposal. EPN is an organization of former EPA employees and others concerned about the integrity of the agency and its credibility, most notably in the use of relevant and defensible science in its decisions. The authors of these comments had significant science, policy and legal responsibilities for many decades within EPA involving the very statutes and policies under question. EPN members would be directly affected by this proposal, both because they often comment on EPA assessments of studies and models, and because, like all Americans, they will be affected by the substantive decisions made under the new regulatory approach that EPA proposes to establish. EPN filed extensive comments on the initial proposal, as did numerous organizations and individuals; this submission does not repeat what our previous submission presented about EPA's previous, poorly presented, poorly articulated and unjustified proposal.

As these comments explain, EPA's supplement does nothing to cure the fundamental legal defects of Administrator Pruitt's original position. It compounds them. The agency continues to ignore both the

truly applicable legal authorities and the policies they articulate. The agency was recently rebuked severely by the D.C. Circuit for exactly this type of dereliction. *Physicians for Social Responsibility v. Wheeler, F. 3d (*Slip Opinion No. 19-5104, D. C. Cir. April 21, 2020). The new authorities that EPA cites do not remotely support its position.

The agency also continues its complete omission of any reference to or discussion of specific rules that were adopted based on studies lacking public data which rules, in retrospect, turned out to be unwarranted or inappropriate for any reason. See *National Ass'n of Fed Employees v. Vilsac*k, 681 F. 3d 483, 485-86 (D.C. Cir. 2012) (merely asserting that a legitimate governmental interest justifies an action without establishing that the problem exists is "a solution in search of a problem" and, therefore, arbitrary.)

EPA suggests that any problems can be fixed by a grant it gives itself of future flexibility. Unfortunately, the language does not actually commit the agency to anything. In essence, EPA proposes to grant itself power to do what it wants in any individual case unconstrained by any articulated decision-making principles, a position that is unbecoming to this previously proud agency. A blank check of this nature cannot solve the proposal's fundamental problems. The Science Advisory Board (SAB) recently reiterated its criticism of EPA's promissory note for future case-by-case exceptions:

> "The SAB finds that exclusion of segments of the scientific literature, with the possibility of inclusion of other selected information without pre-defined criteria, could allow systematic bias to be introduced with no easy remedy. The proposed exception process applies no constraints on how this mechanism could be used or that it be restricted to the issue of confidential data. Such a proposal is inconsistent with the scientific method that requires all credible data be used to understand an issue and to allow systematic review to evaluate past research." [1]

EPA's suggestion to extend its exclusionary authority to the broadest conceivable set of models and to any model or study underlying 'influential scientific information" raises fundamentally different issues from its initial proposal to restrict the use of specifically defined studies for regulatory decisions - issues the

[1] 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).*

proposal does not even explicitly state, much less acknowledge and discuss. In addition, the implementing language is incoherently drafted and does not tell the reader what studies it would cover or how it would work. See United Parcel Serv., Inc. v. Postal Regulatory Comm'n, No. 19-1026, F. 3d , 2020 WL 1856495, at *8 (D.C. Cir. Apr. 14, 2020) (remanding where agency explanation was "incoherent, and thus, unreasonable").

This dramatic expansion of the scope of the rule, as well as its major policy implications, clearly qualifies this supplemental proposal itself as a "major regulatory action" requiring the preparation of a regulatory impact analysis (RIA). The fact that EPA has not prepared an RIA compounds the already-fundamental error of not assessing the proposal's impacts, and is yet one more instance of its fundamental arbitrariness. EPA itself in effect admits this substantive failing when it defines "highly influential scientific information" (a subset of "influential scientific information), to which the proposal would extend the bar on use of undisclosed studies, as documents whose dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.
85 Fed. Reg. 15398 n. 5

You can't have it both ways. These are almost precisely the conditions under which the preparation of an RIA is required for regulations. If this rule will extend to and shape the message of studies that have an impact big enough to trigger an RIA for regulations, by what logic can EPA avoid preparing an RIA for the rule that drives these results? EPA's actions to-date make clear that no such analysis has been, or will be, prepared, which we believe runs afoul of the principles set out in *Physicians for Social Responsibility v. Wheeler,* F. 3d , Slip Opinion No. 19-5104, D. C. Cir. April 21, 2020 (EPA's failure to adhere to Office of Government Ethics regulations that provide "overall direction of executive branch policies" is actionable under the Administrative Procedure Act.)

In addition to these glaring substantive deficiencies, the supplemental proposal exhibits equally glaring procedural deficiencies. These include failure to provide adequate notice (including any assessment of impacts as just noted), violation of the agency's own peer review guidance, and violations of outside-scientific body pre-proposal review requirements of the Environmental Research, Development and Demonstration Act (ERDDA) and the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA). These errors are consequential and prejudicial.We will first summarize EPA's proposal and then develop these points more fully.

II. EPA's Proposal

A. Legal Justification

EPA now claims authority to base its data restriction proposal not just on the provisions of specific EPA laws that we addressed in our opening comments, but also on the general federal Housekeeping Statute, 5 U.S.C. § 301. This provision, enacted by the first Congress, provides that the head of an executive department or military department may prescribe regulations for the government of his department, the conduct of his employees, the distribution and performance of its business, and the use and preservation of its records, papers, and property. As the Supreme Court has recognized, this language only authorizes rules that govern internal agency operations, and cannot be used to justify a legislative rule. In an attempt to bring the proposed science restrictions within that purpose, EPA's proposal states that it does not regulate any entity outside the federal government. Rather, they claim that the proposed requirements would modify the EPA's internal procedures regarding the transparency of science underlying regulatory decisions and that this rule would not regulate the conduct or determine the rights of any entity outside the federal government. Their position is that it exclusively pertains to the internal practices of the EPA. 85 Fed. Reg. 15398.

EPA specifically states that its proposal does ***not*** interpret or rely on the specific regulatory provisions of the various EPA statutes, despite the flood of comments it received demonstrating that these

were indisputably the governing statutory authorities. But in a backhanded acknowledgment of a possible problem, the proposal states that this internal agency procedure is intended to be consistent with the statutes that EPA administers and EPA plans to implement this procedural rulemaking in accordance with all applicable statutory and regulatory requirements. Nonetheless, it says that in the event the procedures outlined in the proposed rulemaking conflict with the statutes that EPA administers, or their implementing regulations, the statutes and regulations will control. Id.

B. Provisions for Relief in Certain Cases

EPA's original proposal would have required the agency to bar the use as regulatory support of any study that rested on undisclosed data. However, it would also have given the EPA Administrator the power to waive that bar in any particular case if data disclosure was infeasible. The new proposal rewrites this approach without changing its essence.

First, it revises and reaffirms the bar on use of studies (and models) that rest on undisclosed data. It adds new language specifying that the disclosure requirement can be met by "tiered access," a term it does not define.

Second, it puts forward an alternative regulatory section that would provide for considering such studies, but in highly ambiguous language. In one place, it states that EPA "may" consider studies for which the underlying data are not available, while in another, it states that the agency will "give greater consideration" to studies for which the underlying data are available, which suggests that other studies will still be somewhat considered. See 85 Fed. Reg. 15405 (proposed §30.5). The first reference is the more direct of the two and would generally govern.

The alternative section also says a study can qualify for consideration if it grants "restricted access [to underlying data] in a manner sufficient for independent validation." The difference between "restricted access" and "tiered access" is not explained even though the two concepts seem very similar. The agency makes no commitment to adopt this provision.

Finally, EPA revises and narrows its proposal to grant the Administrator waiver authority. While the original version would have allowed a waiver when disclosure was "not feasible," presumably for any reason, the new version would allow waivers only if disclosure was "not feasible" for technical reasons, or if disclosure would "conflict with laws governing privacy, confidentiality, confidential business information, or national and homeland security."

C. Extending the Data Requirement to Influential Scientific Information

EPA's original proposal would only have applied to the use of studies to support the issuance of regulations that impose costs on industry. This supplemental proposal would extend that bar to the use of studies with undisclosed data as part of ***other*** studies as long as they qualify as "influential scientific information" - that is, as "scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions." 85 Fed. Reg. 15405.

The proposal does not in any way address either the legal support for this proposal or the policy need for it. Nor does it delineate its scope or how it would work.

III. Discussion

A. Legal Support - The Housekeeping Statute

The Housekeeping Statute, 5 U.S.C Section 5 provides as follows:

> The head of an Executive department or military department may prescribe regulations for the government of his department, the conduct of its employees, the distribution and performance of its business, and the custody, use, and preservation of its records, papers, and property. This section does not authorize withholding information from the public or limiting the availability of records to the public.

All courts considering the issue, starting with the Supreme Court, have held that the Housekeeping Statute cannot be used as a basis for a legislative rule. Chrysler Corp. v. Brown, 441 U.S. at 310; see also, e.g. United States ex rel. O'Keefe v. McDonnell Douglas Corp., 132 F.3d 1252, 1255 (8th Cir. 1998) (applying Chrysler Corp. and finding that the Housekeeping Statute did not provide authority for substantive regulations); Exxon Shipping Co. v. United States Dept. of Interior, 34 F.3d 774, 776-78 (9th Cir. 1994)

(Housekeeping Statute did not authorize regulations allowing that agency to withhold deposition testimony of federal employees).

EPA's proposals (both the original and supplemental proposals) have every indicia of a substantive, legislative rule: codification in the Code of Federal regulations, adoption through notice and comment proceedings, and mandatory language of command (e.g., "the agency will only use" in proposed section 30.5), See Long Island Care at Home, Ltd. v. Coke, 551 U.S. 158, 172–73 (2007) (adoption through notice and comment procedures); American Mining Congress v. Mine Safety and Health Admin., 995 F. 2d 1106, 1112 (D.C. Cir. 1993) (codification in Federal register); General Electric Co. v. EPA, 290 F. 3d 377, 383 (D.C. Cir. 2002) (binding language).

Rules that bind an agency itself are legislative rules. In CropLife Am. v. EPA, 329 F. 3d 876 (D.C. Cir. 2003), the D.C. Circuit held that an EPA press release which stated that the agency would not consider third-party-controlled human exposure studies for purposes of pesticide registration was a legislative rule. Like the supplemental proposal, the press release in CropLife purported to establish exceptions to its binding language to accommodate situations in which use of a study might be legally compelled. 329 F. 3d at 881-82. The court held that the press release bound both EPA and registrants during pesticide registrations and so was a binding "substantive rule;" it "binds private parties or the agency itself with the 'force of law." 329 F. 3d at 883 (emphasis supplied).

The current "housekeeping" proposal, like the press release in Croplife, would set binding rules governing how EPA uses science in its decision processes. Its hollow assurances of later action to consider studies when legally compelled to do so does not alter its status as a legislative rule any more than the similar assurances in CropLife. Since the Housekeeping Statute provides no authority for issuing legislative rules, it cannot provide a basis for either the supplemental or initial proposal. Both would bind EPA, under the conditions set out by EPA, namely that underlying data and models be publicly available (with some proposed exemptions and a grant to the Administrator of discretion) to not consider a scientific study it

could have previously considered. The proposed rules would also bind the public. Furthermore, EPA's rule would require researchers interested in contributing to regulatory protections and influential scientific information to alter their conduct or risk having their efforts deemed unusable. Ultimately, the rule would diminish the public's statutorily protected interests in regulations informed by the best available science, an outcome that EPA itself has recently contended results from substantive choices about the scientific evidence it will consider.

The Housekeeping Statute's "antecedents go back to the beginning of the Republic, when statutes were enacted to give heads of early Government departments authority to govern internal department affairs." *Chrysler Corp. v. Brown*, 441 U.S. 281, 309 (1979). It authorizes what the Administrative Procedure Act "terms 'rules of agency organization, procedure or practice' as opposed to substantive rules," *Id.* at 310, and enables "department heads to make regulations governing day-to-day operation of the department," *id.* n 41. [2] A typical housekeeping rule would govern purely internal agency procedures and practices such as storage and transport of records. The bottom line is that the Housekeeping Statute authorizes only rules of agency organization, procedure, or practice -- not "legislative" or "substantive" rules. That is not what EPA is doing with this regulation. Courts have found nothing in the legislative history to support a different reading. No case law offers support for an alternative reading.

Congress took explicit action in 1958 to amend Section 301 to "correct" agencies from abusing the Housekeeping Statute by attempting to use its authority as a substantive basis to withhold information from the public. As the Supreme Court noted in Chrysler Corp., Congress had looked carefully at the statute in 1958. The Special Subcommittee on Government Information had "unanimously agreed that [§ 301] originally was adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments," and attempts to construe it as something more was "misuse," which "twisted" the statute. The

[2] Under the APA, "rules of agency organization, procedure, or practice." are exempt from notice and comment requirements. 5 USC 553(a)2). Thus a corollary of EPA's proposal to use the Housekeeping Statute to issue this rule is that it could have issued the rule without even providing public notice or an opportunity to comment.

courts have repeatedly checked subsequent agency attempts to "twist" the statute to a range of substantive purposes and found those efforts illegal. The supplemental proposal now attempts, similarly and illegally, to twist the statute to withhold science from consideration in rulemakings that broadly affect the public interest.

There is no merit to EPA's claim that this fits into the Housekeeping authority because it addresses how the agency "handles" information. Every EPA activity during the rulemaking process, as the agency receives, evaluates, and responds to information submitted to the record, and considers it in regulatory decisions, could be said to involve "handling" information in the sense EPA is using it. Under EPA's reasoning, those would all be "housekeeping" actions, and could be governed by housekeeping rules, rather than rules promulgated under the rulemaking provisions of the APA. EPA also argues that the proposal neither regulates nor affects "any entity outside the federal government."[4] But EPA goes on to concede that the rule governs information that may have "a substantial impact" on important "private sector decisions" and a potential impact on the public or private sector impact of more than $500 million. 85 FR at 5398. And the regulation will, as also noted, impose substantive limits on the use of science in rulemaking under the eight environmental laws[3] identified in the proposal.[4]

The proposal, if finalized, would make major changes in how EPA conducts rulemakings that affect major segments of the economy -- compelling EPA to ignore information regardless of its relevance and probity, based only on the public availability of the underlying data, and nullifying procedural rights under

[3] EPA states that it is proposing a rule "specifically addressing the agency's conducting of, and reliance on scientific activity" under the Clean Air Act; the Clean Water Act; the Safe Drinking Water Act; the Resource Conservation and Recovery Act; the Comprehensive Environmental Response, Compensation, and Liability Act; the Federal Insecticide, Fungicide, and Rodenticide Act; the Emergency Planning and Community Right-To-Know Act and the Toxic Substances Control Act. EPA is proposing to issue a rule that would govern the use of science under each of these statutes.

[4] Under a strained reading, one might take the language of EPA's proposal as saying that while the data on which EPA relies for its ***own*** support of regulations will be restricted, that bar will not apply to studies submitted by the public. This would make little sense and we are confident it is not EPA's position. But how can a restriction on the comment rights of the public be termed an internal housekeeping matter?

the Administrative Procedure Act, which ensures "interested persons an opportunity to participate in [a] rule making through submission of written data, or arguments" and directs that the agency consider "relevant matter presented." 5 USC § Section 553(c). To then claim that authority to do this is predicated on a law intended to make sure that federal agencies make their internal trains run on time would be laughable, if it were not tragic -- and part of the tragedy is that the proposed rule would effectively deprive commenters of the right to have their information given due consideration, and would deprive agency decision-makers of research and data -- of science -- essential to good decision-making.

The COVID-19 crisis, underway at this very moment as we write and file comments, has put into stark relief what happens when science is minimized, excluded or ignored. But the rule is not about procedural rights. The decision to preclude full consideration of relevant and reliable information in developing regulations affects important "private sector decisions" and the level of environmental protection provided to the public alike. Thus, it is sad to read EPA's earnest assurances that the proposed rule "would not regulate the conduct or determine the rights of any entity outside the federal government," an assertion that is palpably wrong. One might as well say that a restriction on the evidence that a prisoner can use to prove his or her innocence does not affect his rights.[4] The only sense in which the rule will have no effect outside the federal government is the narrow, hyper-literal sense in which firing a gun has no non-auditory effects because it is the fired bullets that cause such effects. [5]

EPA's supplemental proposal posits that the agency could use its housekeeping authority without "exercising substantive rulemaking authority delegated to it by a particular statute or statutes that it administers" to issue these rules. 85 FR at 15398. That begs the question of where the authority for the rule comes from because, as already explained, the Housekeeping Statute provides no legal basis for the proposed rule. Moreover, the supplemental proposal completely ignores the question of how a regulation

[5] We also do not believe such a rule can even be lawful under the APA, a subject the proposal nowhere addresses. The Housekeeping Statute provides no authority for rules that circumvent statutory requirements.

not issued under the rulemaking authority of a statute can govern agency regulatory actions under the statute. What is plain and beyond refute is that the Housekeeping Statute, even as EPA rationalizes it, provides no authority for anything more than purely internal actions, certainly not for measures that have profound impacts beyond the agency and into society, much less for rules that authorize or mandate EPA to disregard relevant and reliable information in formulating rules or in responding to public comments on those rules.

It is sad to watch magical thinking replace logical, rigorous legal analysis when EPA considers its authorities for this far reaching and radical proposal, particularly in decision processes that have sweeping impacts on public health. As proud former career staff at EPA, we are pained to have to point this out. If EPA wants to issue a binding rule to govern rulemaking under eight different statutes, it cannot cut corners and rely on the Housekeeping authority to do that.

B. The Proposal's Lack of Factual Foundation

The supplemental proposal also lacks any factual foundation. As our original comments pointed out, the agency's original proposal cited 17 sources in support, each of which turned out to be either inapplicable, irrelevant, or counterfactual. This supplemental proposal continues this unfortunate and shoddy history by citing OMB Issuance M-19-15. That memorandum says nothing about precluding use of, or downgrading consideration given to, scientific information for which raw data are not publicly accessible. The memorandum in fact continues to recognize (at p. 5) that agencies must "ensure that privacy and confidentiality are fully protected and that data are properly secure so that open data do not disclose personally identifiable information." It does discuss circumstances under which tiered access to data is appropriate (p. 9), a discussion that does nothing to support the sweeping scope of this supplemental proposal.

The supplemental proposal also cites an NAS report entitled "Principles and obstacles for sharing data from environmental health research." See 85 Fed. Reg. 15404 (reference 6). That assertion rests on a

generic reference to an unspecified portion of a 148 page document. The agency is apparently unaware (or, worse, failed to disclose) that the NAS document in question is merely a workshop report even though its own citation clearly states just that**.** Workshop reports are assembled to represent all divergent points of view, and have no other purpose. These are ***not*** NAS consensus recommendations and contain a very strong disclaimer to this effect:

> "The statements, recommendations, and opinions expressed are those of individual presenters and participants, and are not necessarily endorsed or verified by the [NAS] and they should not be construed as reflecting any group consensus." (Footnote on Page 1 of the workshop report).

Simply put, this document, taken as a whole, supports nothing and should never have been cited.

C. EPA's Attempts to Save its Proposal by Allowing Exceptions

1. *Exceptions to Avoid Conflict With Substantive Legal Provisions*

As noted earlier, EPA's proposal does not discuss any substantive provisions of regulatory statutes. However, it attempts to insulate itself against conflict with them by providing that:

> [I]n 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.

EPA provides neither substantive legal standards nor procedures for making this shell game of a determination. Rather, it is an entirely lawless and cynical ploy. It calls on EPA to "balance" between an approach to data evaluation that is illegal because it rests neither on statutory authority nor on responsible analysis and the approach the law prescribes. The next step will be to argue that because EPA has given itself authority to sometimes not do the illegal thing, its authority to do the illegal thing should be sustained.

All this shows that EPA is well aware of the probability that the authorities on which it rests its proposal do not support it, and that any rule remotely like its proposal could only rest on the substantive provisions of the various regulatory statutes describing the types of data that can be used as rulemaking support.

It also makes clear how EPA will try to defuse this issue without ever actually confronting it. If such an "in case of conflict" provision were to take effect, EPA quite predictably would use it to uphold its data bar in most cases, hoping to prevail not on the merits, but because of the presumption of regularity given to government action and lack of opposition due to the expense and uncertainty of differing with the government. In extreme cases, EPA could back down. And if it should lose in an individual case, that could always be blamed on misapplication of the "in case of conflict" provision, not on any defect in its structure. This gambit does nothing to preserve the rule's legality, failing for the same reason that the initially proposed case-by-exception fails: a subsequent promise to cure an arbitrary result does nothing to cure that illegality. See *Ameren Services v FERC* 880 F. 3d 571, 584 (DC Cir 2018):

> We once described an agency's effort to offer future rulemaking as a response to a claim of agency illegality as an "administrative law shell game," *Am. Tel. & Tel. Co. v. FCC*, 978 F.2d 727, 732 (D.C. Cir. 1992), a phrase the Supreme Court thought apt. *See MCI Telecomm. v. Am. Tel. & Tel. Co.*, 512 U.S. 218, 222, 114 S.Ct. 2223, 129 L.Ed.2d 182 (1994).

Compounding this illegality is the absence of any discussion of either the substantive criteria or the procedural mechanisms by which EPA would determine whether this censored-science rule would be inconsistent with its actual statutory authorities. An agency's empty reference to adherence to statutory factors is not reasoned decision-making. See *Philadelphia Gas Works v. FERC, 989 F. 2d 1246, 1251 (D.C. Cir. 1993) (*for FERC to utter the words 'unique facts and circumstances' and 'equity,' … as a wand waved over an undifferentiated porridge of facts, leaves regulated parties and a reviewing court completely in the dark as to the core of FERC's reasoning and its relationship to past precedent"); *Verizon Cos. v. FCC* , 570 F. 3d 294, 304 (D.C. Cir. 2009) ("These conclusory statements that such factors are being considered cannot substitute for the reasoned explanation that is wanting in this decision"); *American Gas Ass'n, v. FERC*, 593 F. 3d 14, 19 (D.C. Cir. 2010) ("A passing reference to relevant factors, however, is not sufficient to satisfy the Commission's obligation to carry out reasoned and principled decision-making. The Commission must fully articulate the basis for its decision.")

2. *Provisions for Case by Case Relief*

EPA's supplemental proposal contains additional discussion, as described above, of the ambiguous and limited circumstances in which the agency might relax its ban on studies and models that rest on undisclosed data.

But whatever changes in detail EPA might put forward, all these provisions suffer from one fundamental fatal defect. As pointed out in our initial comments, and as noted above, a provision for specific relief does not cure an underlying substantive legal defect. Put another way, a promise to correct an otherwise illegal action in some individual case does not cure the substantive illegality.

Since EPA has totally failed to justify any *per se, a priori* restrictions based on data availability, any proposals for relief from those restrictions are proposals for relief from something that should not exist in the first place. As such, they are both unnecessary, and unable to increase in any way the legal defensibility of those restrictions, since they still allow the agency, to the exact extent that the relief provisions do ***not*** apply, to unjustifiably refuse to consider certain studies.

Beyond that, even EPA's alternative proposal on study and model acceptability does not set out any truly binding standards for making decisions. The factors it mentions are so numerous and poorly articulated that the agency would remain free to do whatever it wants.

But a review of the factors that ***are*** mentioned shows that even on its own terms, the agency's approach to regulatory data is partial, incomplete, and free from attention to the most important issues. The agency suggests that it might consider studies for which the underlying data were unavailable due to concerns about privacy, confidentiality, confidential business information, or national security. You will search the proposal in vain for any reference to considering studies because they had repeatedly been confirmed by other studies, or because their quality had been assured by other means, or because analysis could adjust for any likely flaws, or because they were the only data available to address an pressing regulatory issue.

The net result is to focus entirely on the characteristics of the individual studies, while totally ignoring the overall body of knowledge of which they form a part, or of the consequences of ignoring them for the regulatory decisions they might potentially support. As our initial comments pointed out in detail, this is exactly the opposite of generally accepted and widely endorsed scientific practice.

In short, adopting this proposal would do even more than adoption of the initial proposal to bar the agency from basing its decisions on the best available science as the law requires. We explore this subject in more detail in Appendices A and B, although one example here conveys the egregious magnitude of the supplemental proposal. As detailed in Appendix B, the supplemental proposal would either bar a majority of the key long-term cohort studies in the 2018 PM ISA from consideration, or perhaps merely downgrade them (the proposal is to too opaque to allow any certainty as to its intended result) -- all without reference to the studies' methodological quality, consistency with prior studies, or any other individual consideration.

D. Extending the Proposal from Rules to Influential Scientific Information and to Non- Dose Response Models

1. *General Defects in the Proposed Extension*

As noted above, EPA's supplemental proposal would extend its exclusion of studies with undisclosed underlying data from regulatory actions to the preparation of "influential scientific information" even if it had no regulatory effect. The supplemental proposal would also extend to non-dose response models. See proposed section 30.5.

EPA's proposal does not in any way explain the legal justification for these expansions, the scientific or policy need for it, or even delineate its scope or how it would work. As detailed in Appendix B of these comments, the scope of these proposed expansions is vast and pernicious. There is no indication that EPA has considered the impacts of its proposal, what it actually encompasses and why, or indeed any sign that EPA has actually thought carefully about any of these points. In addition to being the most basic types of substantive legal errors, there is a near-total absence of notice. Commenters are left to guess what the

agency has in mind and its rationale.As such, it cannot be regarded as a valid rulemaking proposal on which final action could be based, since it fails to give the public notice of the agency's thinking in a detailed or focused enough way to allow intelligent comment.

It is EPA's job, not the job of public commenters, to provide this justification. But to illustrate why agencies are required to explain their reasoning and the support for what they propose, and to show how badly EPA has failed, we will outline some of the key questions that EPA has not addressed.

a) What are the legal authorities under which EPA prepares the studies that would be affected, and how do they support this step? All government actions must be authorized by law. Yet this proposal does not even mention that topic, much less discuss how the statutory language (whatever it might be) supports such restrictions on studies prepared under its authority.

b) What possible sense does it make to exclude, arbitrarily and without justification, categories of studies that can contribute to understanding of particular problems that EPA is directed by statute to manage? Of course, EPA should be sure that regulatory decisions with binding legal effect rest on information whose quality has been tested. But the studies themselves have no binding effect; they are building blocks and evidence that the agency uses to reach a conclusion. That process is debased when science is excluded for reasons that have nothing to do with its quality and probity. To do so violates well-developed understandings of how science works. The cure is not arbitrary exclusion, but, as John Milton said in a different context, to "Let [Truth] and Falsehood grapple; who ever knew Truth put to the worse, in a free and open encounter?" We ask what EPA is so afraid of that it proposes to exclude these studies from the decision process as EPA manages major, consequential public health issues?

c) What agency activities would be covered? The proposal is thoroughly ambiguous on this point. On the one hand, it states that the new provisions would "not apply to any type of agency action" other than "significant" rules. 85 Fed. Reg. 15405. However, it does not define the term

"agency action." "Action" could mean literally everything an agency does in the course of its work. It could mean "agency action" as defined in the Administrative Procedure Act, see 5 U.S.C. § 551(13), but it does not say that. In any event even that term is notably ambiguous and regularly generates difficult administrative law questions.[6] On the other hand, the rule's requirements would extend to all "influential scientific information," which is defined as:

> scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. 85 Fed. Reg. 15405

Given the scope of the expressed concerns, it would seem unreasonable to exempt the majority of EPA activity from its scope by a broad definition of "agency action." Moreover, a broad definition of "agency action" would make the new restrictions applicable to studies in their less important uses, and inapplicable to studies used for the more consequential task of supporting agency decisions. This seems inconsistent with the policy behind the supplemental proposal. These concerns, clearly valid even when expressed as here in summary form, take on far more weight when viewed in the context of individual EPA regulatory programs as we discuss below.

d) How would this even work? EPA sponsors some studies through grants, some through contracts for various purposes, and conducts some studies itself. Other studies are submitted to the agency in response to regulatory requirements. All these activities take place on a decentralized basis in many different offices. At what point in the process would studies be selected for the data bar? At what stage in their preparation would the bar apply? Who would enforce it, and under what standards? What rights of appeal would exist? And what would happen to disapproved studies? Would they be withdrawn from the public and burned? If not,

[6] Under that definition, "'agency action' includes the whole or a part of an agency rule, order, license,sanction, relief, or the equivalent or denial thereof, or failure to act."

what would be their fate?

The proposal's only approach to addressing these questions states that the data bar would apply before "finalizing"of affected studies by EPA, an undefined term that is really too general to be any answer at all.

e) What studies would be covered? Studies that are "models" or support "models" are clearly covered, and the proposal defines "model" in part as a simplified representation of an"economic" or "social" system. The preamble adds a reference to "engineering models." EPA's entire discussion of the need for its initial proposal, such as it is, focuses overwhelmingly on health effects data and models and specifically on epidemiology. The supplemental proposal proceeds to take a giant leap, without any explanation, moving from its initial concerns to a much wider range of studies, without discussion or investigation that the "problems" they asserted for the initially covered studies also exist across the many times greater range of ***other*** studies that this proposal would also cover, or that the solution to any problems would be the same. This is a head-spinning jump, made without discussion. When a federal agency proposes to make such far ranging changes, it is obligated to explain why and to support that with data and information.

2. *The Defects of the Extension in Specific Regulatory Context*

As with EPA's initial proposal, EPA did not provide ***any*** analysis explaining how a bar on influential studies would work in the context of specific EPA programs. This is a fatal legal defect just as it was before. It is the agency's job, not the job of citizen commenters, to supply the missing analysis; it is doubly discouraging that having been put on notice on this point in our and other previous comments, the agency chose to repeat this reversible error.

Nevertheless, within the limits of time and resources and to the extent that the ambiguity and lack of clarity of EPA's proposal permits, EPN has briefly examined the impact of this proposal on nine EPA programs. These are:

- Review under the Toxic Substances Control Act (TSCA) of the safety of chemicals now on the market.
- Issuing TSCA rules that require existing chemicals to be tested
- TSCA approval of "premanufacture notices" (PMNs) for chemicals not yet on the market.
- Registering pesticides under Federal Insecticide, Fungicide and Rodenticide Act
- Issuing cleanup standards under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)
- Issuing drinking water advisories under the Safe Drinking Water Act (SDWA)
- Issuing water quality criteria under the Clean Water Act (CWA)
- Approving Total Minimum Daily [pollution] Loads (TMDLs)for individual water bodies under the Clean Water Act
- Developing criteria and reviewing National Ambient Air Quality Standards under the Clean Air Act (CAA)

Our discussion reveals a complete lack of agency attention to how its proposal might actually work in practice. EPA has not examined the extent of any additional resource needs or the impact on statutory deadlines. Nor has EPA examined even the most obvious of the conceptual problems that would arise. For example, if an exempt agency action relied on a scientific study that, in any other context, would be classified - or perhaps had already been classified - as "influential scientific information," how would that data be handled? Similarly, EPA often relies on states to take regulatory actions that would be exempt from coverage if EPA undertook them itself. How would the rule treat any guidance that EPA might issue to advise states on how to take these actions?

We include further supporting detail in Appendices A and B.

a) TSCA Review of Existing Chemical Safety

TSCA requires the EPA to review the safety of all chemicals deemed "High Priority" now on the market and to do so by set deadlines. This is a formidable task, as the current number is approximately 45,000. To accomplish this, EPA has established a three-stage process designed to review and evaluate ***all***

the scientific information relevant to a chemical, and then gradually narrow the number to those that might warrant regulatory action.

The comprehensive surveys that EPA is undertaking would inevitably rely in part on studies and models that will not meet EPA's proposed new requirements. Accordingly, whether, and to what extent, EPA's proposals would apply to this program is of obvious critical relevance to its successful operation. But that question cannot be answered from the proposal, which does not discuss that impact in any way. In all those cases where the review does not result in formal regulatory action, the new rules would presumably apply unless EPA adopted a very broad definition of "agency action." Such a broad definition would have to be broad enough to cover studies performed for completely non-regulatory purposes - perhaps as part an independent university research program or studies done in other countries - that became part of EPA's review. Under that approach, such a study would be covered by the new rules in some circumstances, but not in others. Does EPA intend this? Is it even workable?

If the new rules would apply, EPA has a legal obligation to evaluate the new burdens it would place on the program, the resources that would be available to bear them, and the impact on EPA's ability to meet the statutory deadlines. To do this, EPA would have to define exactly how the new requirements would work in practice. At what point in this multi-stage process of evaluation would the restrictions on the studies and models that can be considered be applied? What would be the specific reason for that application point? How could that application point be defended given the clear desire of Congress for a comprehensive survey of all data relevant to a chemical?

If EPA plans to comply simply by ignoring studies that do not meet the new requirements, an assessment of the legal validity of that approach would also be required. EPA has done exactly ***none*** of this and apparently, as with many other issues, throws the burden on commenters to figure out what it meant and why.

b) TSCA Test Rules

TSCA §4 gives EPA authority to require chemical manufacturers to test their product for several reasons, one of which is that "there is insufficient information or experience to determine or predict the effects of these activities." EPA now proposes to make data disclosure a key element in judging the acceptability of a study. This would logically imply that in assessing the "sufficiency" of effects information on a chemical, EPA will have to avoid reliance on studies without data disclosure, and instead order manufacturers to conduct new and conforming studies to replace the studies that do not meet the disclosure standards. After all, isn't EPA legally obliged to apply its own view of high standards of data quality to the implementation of a statute for which Congress expressly made data quality a central implementation concern? If not, why not? As before, the proposal does not address any aspect of these issues.

c) PMN Approval

TSCA §5 requires EPA to review the likelihood that a new chemical will present an unreasonable risk to human health or the environment before it can be marketed. At present, much of the information that EPA reviews rests on confidential business information or otherwise would not meet the requirements of the proposal. To fill some of these gaps, EPA relies on models that likewise would often not meet those requirements.

Once again, EPA has failed to address how it can refuse to apply these new requirements to data and models used to support PMNs given express direction from Congress to the agency to consider data quality. Indeed, yet again, EPA has not addressed the issue of applicability to this program at all, or addressed the impacts on the public health or the environment if it did. Nor, once again, has EPA explored the resources that would be needed to respond.

d) Pesticides Registration under FIFRA

Despite the ambiguity of the definition of "agency action," it seems clear that EPA would regard pesticide registration as one of the "agency actions" to which its new rules would not apply.
But it is questionable whether this would be legal.

First, under FIFRA, an applicant has the burden of showing that a pesticide meets the standard for registration. The stakes in that decision are great, since approval of a pesticide is approval for the release into the environment of a chemical specifically designed to kill living things. EPA never explains how it can justify letting an applicant support licensing of such a chemical by submitting data that the agency could not rely on for its own regulatory decisions often aimed at much smaller potential hazards. Second, given the scope of the information that must often be reviewed to grant or sustain a registration, it may well be that applicants will rely - directly or indirectly - on studies or models that EPA has already found do not meet the new disclosure requirements, or that would clearly fail to meet them.

We are provided no indication of how EPA would react. Would a study that EPA has barred from use in other contexts still qualify to support a pesticide registration? Would any special waiver proceedings be required? Would that affect its acceptability in other contexts?

These are important questions of general significance to ***all*** EPA regulatory decisions that rest in part on studies with broad social impact, some of which may be impacts on regulation, but most of which are not. Such studies are relevant to EPA decisions far beyond pesticides. But once again, EPA's proposal does not refer to them in any way and leaves to commenters the responsibility to point that out.

e) CERCLA Cleanup Standards

EPA, for many years, has issued recommendations on the soil and groundwater purity levels to be attained in CERCLA cleanups. These rest on detailed and constantly updated literature reviews. In themselves, they have no direct legal effect, and they are very rarely absolutely legally binding. However, they undeniably shape regulatory decisions. Once again, EPA has not given any indication whether or not the issuance of these standards would be "agency action" exempt from the new requirements. Nor - once again - has EPA evaluated in any way the impact on the program or the resources needed to mitigate that impact.

f) Drinking Water Advisories and Benchmarks

EPA has issued more than 500 guidance values ("advisories" and "benchmarks") to state and local water supply systems detailing the potential hazards of pesticides and other chemicals in drinking water. This information has no binding legal effect, but state agencies rely on it to shape their efforts to protect public health. EPA's proposal, however, does not discuss whether the issuance of these advisories and benchmarks would be regarded as "agency action," exempt from the new requirements, or the impact on the program and how EPA would address that impact, if they are not exempt.

g) Issuing Water Quality Criteria under the Clean Water Act

EPA has issued about 170 separate documents to establish scientific guidance for water quality. These do not have regulatory effect but provide background for regulatory decisions that set actual water quality standards. These criteria are, therefore, an essential part of the water quality standards program which is, in turn, an essential part of the Clean Water Act. Taken by themselves, they would clearly qualify as "influential scientific information." They would often rely on studies and models that would not meet the new requirements. Would these be "agency actions" exempt from the new requirements despite their lack of legal effect? If they would not, what would be the impact of the new requirements on human and environmental health, program functioning, and resource needs? Once again, the proposal is completely silent on these vital issues.

h) Setting or Approving Total Minimum Daily Loads for Individual Water Bodies under the Clean Water Act

The Clean Water Act requires states, or, if they default, EPA, to establish"total maximum daily [pollution] loads" for individual water bodies to specify the pollution levels that they can tolerate. About 65,000 such TMDLs have been established, mostly by states, but some by EPA. TMDLs rest on extensive bodies of scientific information and modeling in several different technical fields. Once again, EPA has completely failed to even specify whether or not its new requirements would apply to this program.

The question whether these new requirements would apply to TMDLs raises a fundamental issue that goes far beyond the TMDL program itself. Perhaps the new requirements would not apply to EPA-issued TMDLs because of the specific regulatory language exempting EPA actions. But would they apply to the extensive technical guidance that EPA issues to states on how to write TMDLs? And if they did, how could EPA exempt its own requirements from the same standards?

These questions are relevant, not just to the TMDL program, but to the entire structure of "cooperative federalism" under several EPA statutes. They would apply, for example, in almost exactly the same form, to permit decisions under the Clean Water Act or to permit and state implementation plan decisions under the Clean Air Act. Typically, under each of these statutes, EPA issues extensive technical guidance to state programs even though they retain the power to make regulatory decisions. Yet EPA's proposal does not mention this issue in any way. Nor does it discuss the impact of these new requirements on the TMDL program or how the agency might address them.

i) The Clean Air Act

Quite clearly, EPA's national ambient air quality standards [NAAQS] established under the Clean Air Act were the primary target of EPA's original proposal. We discussed them in detail in our initial comments. EPA's new proposal would further increase that impact in at least two ways. First, as noted it would extend the bar on the use of undisclosed data from dose-response models to all models. That would affect the many other models - for example, economic models, energy use models, and atmospheric models - on which NAAQS analysis relies. Second, many of the documents prepared in the course of setting a NAAQS are themselves "influential scientific information" or rely on other studies that would or could qualify as "influential scientific information."

Application of the bar on the use of undisclosed studies to these documents would further increase the cost and complexity of establishing NAAQS and diminish the quality of the decision-making record. This would be particularly clear in the case of the Regulatory Impact Analysis that is prepared for every

NAAQS. By law, these documents play no part in EPA's decision, so the original proposal would not have covered them. However, they would unquestionably qualify as "influential scientific information."

EPA's proposal does not analyze any of these issues. It is ironic then, that developments since EPA's original proposal have further underlined the complete lack of justification for anything like EPA's proposal where NAAQS establishment is concerned.

We discuss these matters in detail in Appendix B.

E. Procedural Deficiencies

EPA's supplemental proposal is replete with basic, and insurmountable, procedural deficiencies. Among them:

1. *Failure to provide Adequate Notice and Opportunity for Comment*

EPA fails to provide any information on such basic matters as potential impacts of the expanded proposal under each of EPA's substantive statutes; the potential social costs in the form of decreased protection to public health; the economic costs (the tiered access option could be very costly); and any benefits of the supplemental proposal. Nor does EPA discuss the need for and implications of fundamental changes in position from such things as EPA's own peer review guidance. Commenters can only guess as to each of these matters; it is not their responsibility to have to guess. EPA thus has failed to provide any notice of issues of fundamental import, and failed to provide adequate notice and opportunity for comment. The agency has also completely failed to meet the rulemaking standards required under *FCC v. Fox Television,* 556 U.S. 502 (2009). See *Physicians for Social Responsibility v. Wheeler,* F. 3d, (slip op. at pp. 13-17) (D.C. Cir. April 21, 2020) (rebuking EPA for announcing a changed policy while failing to acknowledge and explain why it was differing from long-standing past EPA policies, including its peer review guidance). And see Clean Air Act §§307 (d) (3) (A) and (B) detailing specific requirements for proposals, including factual data and methodologies underlying a proposal). These errors deprive commenters of the most basic information needed to formulate reasoned comments and so are prejudicial.

2. *Failure to Extend the Public Comment Period*

Even without the advent of the coronavirus pandemic, 60 days is insufficient for public comment on a supplemental proposal that dramatically expands the reach of the initial proposal. With the pandemic bringing the nation to a standstill (and the uncertainty that any one of the volunteer experts who prepare our comments might at any time come down with the virus and be unavailable to research or write comments), the insistence on a 60-day period borders on abusive. And the problem is compounded by the insufficiency of EPA's initial and supplemental proposals in providing basic information and support for what the agency is proposing. It bespeaks a zeal to cripple the agency's use of good science.

3. *Failure to Comply with ERDDA*

42 U.S.C. § 4365(b) requires EPA to submit this supplemental proposal to EPA's SAB for review at the time it is sent to OMB for inter-agency review. EPA ignored this requirement twice over: for both the initial proposal and the supplemental proposal. The error is especially troubling given the agency's pledge to provide the SAB with ample notice, an evidently hollow pledge made after the agency signally failed to comply with these statutory requirements with respect to the initial proposal. Deprived of proper notice, the SAB never met publicly regarding the supplemental proposal, and necessarily excluded the public from its undocumented deliberations. In spite of these limitations, the agency should take heed of the SAB's warning:

> "There appears to be consistency among analyses of how to address transparency that are orthogonal to the Proposed Rule. 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. [7]

[7] SAB report of April 24, 2020 at 18.

4. *Failure to Comply with FIFRA*

This supplemental notice of proposed rulemaking, like the initial proposal, is procedurally deficient because it failed to comply with the rulemaking requirements in FIFRA §25. EPA states that its supplemental proposal pertains to regulatory actions taken under the authority of FIFRA and cites FIFRA as one authority for the overall rulemaking that its supplemental proposal modifies. Thus, both the initial and supplemental proposals are subject to the procedural requirements for rulemaking imposed by FIFRA §25. FIFRA §25 requires the agency to transmit a copy of proposed rules to the Departments of Agriculture (USDA) and Health and Human Services (HHS) and to the FIFRA Scientific Advisory Panel (SAP) prior to publication of the proposal for public comment. The statute gives the SAP, USDA, and HHS 30 days within which to comment, and, if any does so, EPA must publish their comments and the agency's responses in the *Federal Register* that announces the opportunity for public comment. FIFRA also requires that EPA provide a copy of the proposed rulemaking to the Senate and House Agriculture Committees prior to publication of the proposed rule.

The preamble of EPA's supplemental proposal contains no information concerning the agency's compliance with these essential procedural requirements for rulemaking under FIFRA; we can only conclude that EPA has flagrantly disregarded its legal responsibilities. In these congressionally imposed requirements, Congress has deemed the input of USDA, HHS, and the SAP essential to ensuring that, in issuing regulations affecting the operation of EPA's regulatory programs affecting pesticides, EPA fully considers the impacts of all proposed rules on agriculture (USDA) and human health (HHS), and that the rules are grounded in sound science (SAP). Without such input, there is a high likelihood that the rules will produce unsound outcomes from essential scientific and public policy perspectives.

5. *Failure to conduct an adequate assessment under the Paperwork Reduction Act*

EPA has also failed to comply with the Paperwork Reduction Act [PRA], 44 USC §§ 3501 et seq.[8] Consequently, OMB should direct EPA to prepare and submit to it an Information Collection Request [ICR] that estimates the burden expected to result from the proposed rulemaking. Further, OMB should direct EPA to make its ICR available for public comment and should direct EPA to extend (or reopen) the period for submission of public comments on the supplemental notice until the end of the comment period on the ICR.

The PRA imposes obligations on every federal agency whenever the agency proposes measures that will lead to the submission to the agency of information from 10 or more individuals (or entities). The PRA requirements apply even when the submission of information by the public is voluntary. The PRA applies not only to the institution of new measures for collecting information but also to any measures that would expand the amount or types of information that OMB has previously approved.

It is clear and indisputable that the PRA applies to the measures announced in EPA's supplemental proposal. While styled as a regulation somehow affecting only the internal operations of the agency, in reality the proposed rule would plainly impact the practices and actions of scientists, economists, and a wide range of others with respect to the amount of information submitted to EPA. The supplemental notice proposes that EPA would not consider, or would give less weight to a study unless all underlying data were publicly available. It is reasonable to expect that researchers, who want the agency to rely on their studies, and to the extent they are able, would choose to submit not only the summary data related to their studies' conclusions, but also all of the underlying raw data that supported those conclusions. Moreover, the supplemental proposal would broaden dramatically the scope of the studies to which its provisions on data utilization would apply. Thus, the impact of the proposal would be to expand the amount of information

[8] EPA's supplemental proposal states that "This action does not contain any information collection activities and therefore does not impose an information collection burden under the PRA." This is simply wrong; the rule would cause scientific researchers to change their behavior with respect both to recordkeeping and submission of underlying raw data. While the submissions might be characterized as "voluntary," such submissions are nonetheless subject to the PRA.

submitted far beyond limits set under any existing approvals for collection of information under every statute noticed in the proposal.

Whenever a proposed rulemaking or other action by an agency would make a change as substantial as would result from the supplemental proposal, the PRA requires the agency to follow specific procedures; EPA has failed to do so. 44 USC §3507. The PRA requires EPA to draft and submit to OMB an ICR containing an estimate of the burden imposed by the supplemental proposal, as well as an explanation of why the collection of information is necessary and the steps that EPA has taken to minimize the burden on the public.

The PRA also requires EPA to publish a notice in the *Federal Register* announcing a public comment opportunity of at least 60 days. This action is to occur at the same time as the agency opens the comment period on the proposal. In the words of the PRA, the purpose of such a *Federal Register* notice is:

> to solicit comment to:
> (i) evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;
> (ii) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information;
> (iii) enhance the quality, utility, and clarity of the information to be collected; and
> (iv) minimize the burden of the collection of information on those who are to respond, including through the use of automated collection techniques or other forms of information technology; [44 USC sec. 3506 (c)(2)(A), (B)]

EPA neither submitted an ICR to OMB nor sought public comment on its ICR. As a result, EPA has deprived the public of the chance to provide meaningful comments on these aspects of the rule. But, more important, EPA has withheld valuable details about how the agency anticipates its proposal would affect the development and submission of scientific studies for EPA's consideration. These details are essential in helping the public evaluate the proposal and develop comments on its merits.

Among other responsibilities, the PRA also requires agencies to certify that each collection of information:

> (A) is necessary for the proper performance of the functions of the agency . . .

> (C) reduces to the extent practicable and appropriate the burden on persons who shall provide information to and for the agency, including with respect to small entities, . . . [and]
> (E) is to be implemented in ways consistent and compatible, to the maximum extent practicable, with existing reporting and recordkeeping practices of those who are to respond. [44 USC 3506(c)(3)(A), (C), (E)]

Publication of a notice of an opportunity to comment on the ICR would afford the public an opportunity to comment on whether the proposed collection would meet these goals. Based on the limited information about how EPA would implement its proposal, EPN asserts none of these goals could be met.

First, the proposed rulemaking hardly appears "necessary" for the "proper performance of the functions of the agency." For nearly 50 years, EPA has operated without the draconian constraints on its consideration of data that the proposal would impose. There is neither a new statute, a new court decision, nor even any widespread scientific or public expression of a need for this rulemaking. It is therefore impossible to see how this proposal is necessary for any agency function.

Second, there is no demonstration that this proposal reduces burdens on small entities, particularly academic researchers. Quite the contrary. To ensure that EPA would consider their studies, scientists, academic or otherwise, will have to keep indefinitely, and potentially provide to EPA or members of the public, much more extensive records documenting their work, in a format dictated by the agency. Such behavior would be a sea-change in the world of academic research and would impose significant new costs on researchers who often work individually or in small groups. EPA's proposed rulemaking makes no effort to adjust the burdens on these small entities according to the source of the scientific information.

Finally, the proposed rule totally ignores how it would impact existing reporting and recordkeeping practices. If the current practices for reporting and recordkeeping of scientific research important for environmental regulation were deemed adequate, this proposed rule would be unnecessary; if they are not, EPA must intend the proposal to change those practices. The PRA requires agencies to address how its proposal would modify those practices and to show why the proposal makes as little change as considered absolutely necessary. EPA's proposal does not even begin to address this requirement.

Because of the many ways in which EPA and OMB have ignored the requirements of the PRA, EPA and OMB should start over. The EPA should prepare an informative ICR, submit it to OMB, make it publicly available, and take comment on it for the statutorily required 60 days. We note the stark contrast between the determination by Congress that 60 days should be the minimum time allowed for comment on an ICR and the scant 30 days EPA initially allowed for comment on the supplemental proposal, which presents a myriad of complicated issues to unravel and analyze. In the course of preparing the "specific, objectively supported estimate of burden" [44 USC sec. 3506(c)(1)(A)(iv)], EPA would undoubtedly realize that its proposal would substantially increase the burden, especially on small entities.

More important, the exercise would force EPA to articulate how its proposal had now become "necessary for the proper performance" of its functions, in the face of successful operation for nearly 50 years without such a rule. EPN expects any objective consideration of this proposal under the PRA would lead either to its withdrawal or to very extensive revisions and a reproposal. Just to note, another stark contrast is the explicit congressional directive in the PRA to agencies to "protect respondents' privacy and honor pledges of confidentiality." 44 USC sec. 3506(e)(3) [emphasis added] compared with EPA's apparent disregard for the privacy and pledges of confidentiality provided subjects of epidemiological studies of the kind it would exclude from use in certain agency decision-making unless that data were made public.

These violations are indicia of arbitrary and unreasoned decision-making, and are actionable under the Administrative Procedure Act. *Physicians for Social Responsibility v. Wheeler, F. 3d , 2020 WL 1921539 at *4-11; Union of Concerned Scientists v. Wheeler*, 954 F. 3d 11, 17-20 (1st Cir. 2020).

Respectfully submitted on behalf of the Environmental Protection Network,

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APPENDIX A

The Defects of EPA'S Proposed Extension of its Study and Model Bar in Specific Regulatory Contexts

TSCA Review of Existing Chemical Safety

The Toxic Substances Control Act, as amended in 2016, requires EPA to evaluate the safety of existing chemicals via a three-stage process (prioritization, risk evaluation, risk management). There are statutory deadlines associated with each of the stages, and proscriptions on the numbers of chemicals that need to be in the pipeline (high priority), or excluded from it (low priority) during each cycle of evaluation.

Since the agency had already begun a prioritization process and scheduled a set of 10 chemicals for risk evaluation before the law was amended, these 10 became the first batch to move through the process. Twenty (20) is actually the mandated magic number for each cycle of review.

In Stage 1, the prioritization process, EPA must consider certain criteria such as hazard, exposure, persistence and bioaccumulation as they judge the impact of a chemical on human health and the environment. These criteria are data-driven and may require the application of models as a screening tool to determine whether a chemical should be considered high or low priority.

The process has been designed to ensure that the agency can focus on chemicals with the greatest potential for *risk*. Chemicals with low hazard and/or exposure potential that meet the definition of Low-priority substances are taken out of consideration for further assessment for the time being. Stage 2 is Risk Evaluation. Chemicals deemed high-priority substances move immediately into risk evaluation.

There also is a separate mechanism available whereby manufacturers can request that the agency conduct a risk evaluation. Under this scenario, the manufacturers are required to provide EPA with the information necessary to conduct a risk evaluation on those conditions of use that are of interest to them.

Documents are prepared that describe a chemical's exposure potential (e.g., fate and transport, environmental releases, occupational, consumer and general population exposure), its hazard potential to environmental species and human subpopulations and, finally, a risk characterization in which exposure and hazard data are integrated to determine whether a specific exposure scenario poses an unreasonable risk to the environmental species and/or human (sub) population of interest.

It is imperative to understand that empirical data do not exist for every element of a risk evaluation and that models, many of which have already been peer-reviewed and validated, are employed to fill the data gaps and allow the agency to reach conclusions about risk.

Because EPA did not analyze the potential impacts of its proposal on this process, EPN developed a case study, presented below, that illustrates the typical numbers of studies and models that are employed in a risk evaluation for a single chemical.

Stage 3 is Risk Management. If, at the end of the risk evaluation process, EPA determines that a chemical presents an unreasonable risk to human health or the environment, the chemical must immediately move to risk management. During this stage, cost-benefit analyses are conducted to determine the impacts of the regulatory options under consideration. Models are employed to facilitate these cost-benefit analyses.

Current status of the Existing Chemical Risk Evaluation program: At the present time, only 32 high-priority chemicals are in Stage 2-Risk Evaluation (two represent acceptance by the agency of a manufacturer request for review). Twenty additional chemicals were recently declared low-priority and set aside for now. To date, only a very small number of Existing Chemicals have been subjected to partial, albeit inadequate, risk management actions.

This time-sensitive and resource-intensive three-step process is to continue until all active substances on the TSCA Inventory have been prioritized for evaluation (or, not). There are currently about

45,000 active substances in the TSCA Inventory, so there are 52 in the system and at least 44,948 to go! With 20 chemicals in and 20 chemicals out each prioritization cycle, that means, eventually, we can expect to see at least 22,474 risk evaluations and some number of risk management actions in the future. And, by extension, this means that there are potentially 10's to 100's of thousands of studies that exist now or could exist in the future that may or may not be allowed to be used in the assessment process. Furthermore, this means that there are potentially dozens of models that may or may not be allowed to be used in the assessment process.

The supplemental proposal defines a model as "A simplification of reality that is constructed to gain insights into select attributes of a particular physical, biological, economic, or social system." This definition can be found in EPA's *Guidance on the Development, Evaluation, and Application of Environmental Models.* EPA/100/K-09/003 March 2009 (Available at https://www.epa.gov/sites/production/files/2015-04/documents/cred_guidance_0309.pdf) and is the same as presented in the 2007 NRC report *Models in Environmental Regulatory Decision Making* (available at https://www.nap.edu/catalog/11972/models-in-environmental-regulatory-decision-making).

It should be noted that the aforementioned guidance document focuses on the subset of all models termed "computational models" by the National Research Council. These are models that use measurable variables, numerical inputs, and mathematical relationships to produce quantitative outputs. Does the agency envision the same scope of applicability in the promulgation of the proposed rule? This point needs clarification.

It is rather puzzling that the original proposal and the supplemental proposal obsess so much about transparency as related to the models that the agency employs in the risk assessment and risk management process. EPA supports an easily-accessible, publicly-available webpage (Registry of EPA Applications,

Models and Data Warehouses (READ) (available at https://ofmpub.epa.gov/sor_internet/registry/systmreg/searchandretrieve/basic/search.do), which catalogs publicly-available models that the agency uses. There are currently 2,197 entries in this library of tools, a subset of which are models. And, specific to EPA's Existing and New Chemicals programs, Office of Chemical Safety and Pollution Prevention (OCSPP) hosts a web page (Predictive Models and Tools for Assessing Chemicals under the Toxic Substances Control Act (TSCA), available at https://www.epa.gov/tsca-screening-tools). Using these two sources and others available by searching the internet, one can access the publicly-available, agency-developed models that it employs. If the agency has to resort to the use of a proprietary model to conduct some aspect of its work, it is not within its purview to release the code to it. One must arrange that with the owner of the model. This, however, has become an increasingly rare circumstance.

We can further appreciate the scope and complexity of this review process by seeing how it worked in the case of one specific chemical, namely trichloroethylene (TCE). OPPT employs a systematic review process (neither peer- reviewed nor deemed to be adequate by most knowledgeable experts) that identifies and sorts published and other literature for use in the development of risk evaluations. For TCE, these studies cover the domains of physical-chemical properties, environmental fate and transport, environmental releases, occupational exposure, consumer exposure, environmental exposure, environmental monitoring, biomonitoring, environmental hazard, human health hazard, and human epidemiology. The information in these studies serves more than one purpose. The studies may provide the empirical evidence for directly reaching conclusions about elements within the domain. Or, they may provide data that are used to populate models that seek to clarify relationships in the absence of adequate empirical evidence.

The sorting process begins with the identification of potentially useful literature by searching for keywords in study titles. This step may yield many thousands of possibilities (data screening) . Additional

scrutiny of abstracts and other details in the studies results in the culling of those that will be of little or no value in the risk evaluation. It is possible, often likely, that the culled list may still constitute hundreds of citations. Another level of detailed scrutiny yields the studies deemed useful for inclusion and discussion in the risk evaluation (data extraction/data evaluation), with an even smaller set that are considered to be key to the qualitative and quantitative assessment of the area of focus (data integration).

Let's see how this plays out for TCE for some representative domains (the numbers = number of studies):

1. Engineering Releases and Occupational Exposure
Data screening = 10,132
Data extraction/data evaluation = 152
Data Integration = 36

2. Consumer and Environmental Exposure Data Sources
Data screening = 1140
Data extraction/data evaluation = 151
Data Integration = 19

3. Environmental Hazard
Data screening set = 8563
Data extraction/data evaluation = 71
Data Integration = 25

4. Human Health Hazard
Data screening = 5954
Data extraction/data evaluation = 180
Data Integration = 170

The pattern is similar for the remaining domains: thousands of studies identified in the screening set, hundreds in the data extraction/data evaluation set and tens to hundreds in the data integration set.
In the TCE assessment, at least one, perhaps several models were employed and populated with data from the many studies in each domain cited above along with other information sources. Given the opaque and confusing discussion of models in the original and supplemental *Federal Register* notices, we will assume that every time the term "model" comes up in the draft risk evaluation, it fits into EPA's definitional universe.

So, how many models (and which ones) are employed in the TCE draft Risk Evaluation? They will not be described in detail, just annotated.

1. Three Conceptual Models:
    a. Industrial and Commercial Activities and Uses: Potential Exposures and Hazards
    b. Consumer Activities and Uses: Potential Exposures and Hazards
    c. Environmental Releases and Wastes: Potential Exposures and Hazards
2. EPI (Estimation Programs Interface) Suite™- a validated and peer-reviewed predictive tool composed of several modules for evaluating physical/chemical and environmental fate properties
3. E-FAST (Exposure and Fate Assessment Screening Tool) version 2014 - also composed of several modules and used in the aquatic exposure assessment
4. EPA Water Saturation Loss Model
5. Inhalation exposure models (e.g., the Near-Field/Far-Field mass balance model) used to estimate occupational exposures to workers and ONUs
6. Dermal Exposure to Volatile Liquids (DEVL) model used to estimate occupational dermal exposures for workers
7. Monte Carlo modeling to estimate exposure concentrations in occupational settings
8. Modeling approaches for occupational settings
    a. Surrogate monitoring data
    b. Fundamental modeling approaches
    c. Statistical regression modeling approaches
9. Consumer Exposure Model (CEM) Version 2.1 containing several modules, used to model consumer inhalation and dermal exposure, and bystander inhalation exposure
10. Species Sensitivity Distributions (SSDs) for Acute Hazard Data, based upon model averaging of the Gumbel, triangular, normal, and logistic distributions
11. Physiologically-Based Pharmacokinetic (PBPK) model, a peer-reviewed and validated model, used to support route-to-route extrapolation(oral-to-dermal), to determine the relationship between the external dose/concentration (i.e., exposure) and internal dose at the target organ of interest, and to facilitate conversion of animal kinetic data to human equivalents.
12. Benchmark dose (BMD) model - the tool to refine and extend the shape of the dose response curve for a variety of non-cancer hazard endpoints constituting TCE's human health toxicity profile and to calculate the Point-of-Departure (POD).
13. Mathematical modeling, using a linear non-threshold model to calculate the Individual Unit Risk (IUR) for cancer based upon the increased incidence of kidney cancer and modified by data on liver and NHL cancer incidences in humans.

So, let's summarize the magnitude of the process of assessment in the Existing Chemicals program, as illustrated by the TCE case study:

- TCE is but one of roughly 45,000 chemicals to be subjected to prioritization, risk evaluation and risk management.
- TCE's risk evaluation covers 12 domains of information. For other chemicals, an additional domain (general population exposure) is included.
- Study selection for each domain begins with the identification of perhaps many thousands of potential "hits," reduced to hundreds during data extraction/data evaluation and tens to hundreds for data integration. Multiply this by >22,000 and the result is staggering.
- It is not clear whether or to what extent one should conclude that the data in the studies identified during data extraction/evaluation and data integration constitute "pivotal regulatory science," because they all contribute to the weight of evidence in the qualitative and quantitative assessment exercise. No studies used were claimed to be confidential business information (CBI). Apparently, raw data were available only for the 2019 Charles River study. Indeed, in general under EPA practice, if a study is funded via any kind of assistance agreement, the recipient of the funding owns the data. EPA lacks access to part or all of the data and models in many cases and does not have the authority to provide public access to part or all of the data and models. If EPA chooses to constrain its ability to the use of data and models only to those which are publicly available, the system will essentially shut down.
- Approximately 15 models were used in the TCE assessment. This is likely to be the norm with the same ones being used repeatedly. Most of the models EPA employs in the TSCA program have been developed by the agency, and are publicly-available. Access can be gained through a number of EPA webpages and/or searches on the internet. Others are described in the peer-reviewed literature, access to which is controlled by the authors.

TSCA Existing Chemical Test Rules

TSCA section 4 gives the Administrator of EPA authority to require manufacturers and processors of chemicals to test the chemicals that they manufacture and process. If the Administrator finds that: (1) the manufacture, distribution in commerce, processing, use or disposal of a chemical substance or mixture may present an unreasonable risk to human health or the environment, or is produced in substantial quantities and may result in substantial or significant human exposure or substantial release to the environment; (2) there is insufficient information and experience to determine or predict the effects of these activities; and (3) testing is necessary to develop such information, the Administrator shall by rule, order, or consent agreement require such testing to be conducted.

The TSCA amendments of 2016 gave EPA additional authority to require testing when the data were needed for discharging EPA's responsibilities under sections 5 and 6 of TSCA or any of EPA's other authorities (e.g., the Clean Water Act) or at the request of other federal agencies to discharge their regulatory obligations.

The transparency policy could affect section 4 in several ways: If it were applied in the broadest case, it might preclude EPA from using studies in the toxicological literature (for which underlying data are seldom available) from being used to make the "may present finding" to require testing. This would undercut one of EPA's mechanisms for obtaining test data; however, EPA could still require testing of high production volume, high release/exposure chemicals, and chemicals for which a specific regulatory need was identified.

A more likely and significant impact would be on EPA's ability to discharge its responsibilities under the second (data inadequacy) finding. To make this finding, EPA conducts a thorough literature search and retrieves relevant studies from the literature and usually issues a rule to require studies that have not been published to be submitted to the agency. Typically, the bulk of the information considered are studies

published in peer-reviewed scientific journals. Despite being accepted by the scientific community and generally comporting with EPA's test guidelines, these studies do not meet the transparency requirements of the proposed rule, since it requires that all raw underlying data and the models used to analyze data supporting the study are available for public review. No matter how the applicability of the transparency rule is defined, the fact that section 4 data could be "pivotal or influential science" to support one of EPA's significant regulatory decisions means that the transparency rule would apply to EPA's decision making under TSCA section 4. Thus, if the transparency rule were in effect, EPA would have to judge studies from peer reviewed journals and any other studies for which underlying data and models were not available as inadequate under Section 4. Ignoring this large category of information would cost industry hundreds of millions of dollars to repeat perfectly good, scientifically acceptable studies, which the public would ultimately pay for through higher prices for products containing or made from those chemicals. And it would significantly delay or, in some cases, preclude assessment and regulation of risks to human health and the environment.

TSCA PMN Approval

Section 5 of TSCA requires manufacturers of new chemicals to submit a "premanufacture notice" (PMN) to EPA at least 90 days prior to the commencement of manufacture of the chemical. The PMN must contain readily available information including: the name and chemical structure; anticipated categories of use; amount of the chemical to be manufactured, processed, and used; identification of byproducts; environmental and human health effects; number of individuals anticipated to be exposed during each activity; and the manner and method of disposal. EPA can stop a chemical from entering production or impose limits on production, processing, distribution in commerce, use and disposal due to a finding that the chemical may present an unreasonable risk to human health or the environment. It can also stop production if it lacks adequate information regarding the chemical's safety and order the PMN submitter to

conduct testing to generate the needed data. One new feature of the 2016 TSCA amendments is that EPA must make an affirmative finding on the safety of a new chemical or significant new use of an existing chemical before it is allowed into the marketplace. This finding that a chemical is safe increases the need for more and higher confidence information.

Claims of CBI cover much of the information in PMNs, including the identity of the chemical, production volume and intended use. Information regarding the human health and effects on the environment of the substance is usually quite limited in PMN submissions and may only include acute toxicity.

To compensate for these limitations, EPA groups PMN chemicals with shared chemical and toxicological properties into categories in order to streamline the process for agency review of new chemical substances. They include chemicals for which sufficient history has been accumulated so that hazard concerns and testing recommendations vary little from chemical to chemical within the category. The hierarchy of data used to evaluate a chemical is as follows:

- Experimental data on the chemical itself
- Data on an analogue using SAR
- Predictions from a suitable model

EPA has devised a number of predictive models. These models make use of comparisons of the new substance with the properties of existing chemicals of similar structure, and chemical and physical properties -- an analysis known as structure activity relationship (SAR). EPA uses seven hazard models covering ecotoxicity, cancer and non-cancer endpoints, and eight exposure models to predict consumer exposure, environmental release and chemical fate. These models are all publicly available.

As noted above, much, if not most, of the information used to determine if a chemical may present an unreasonable risk to human health or the environment or would result in substantial human exposure or release to the environment is claimed as CBI. Thus, it could not comply with the transparency rule. How EPA will deal with this remains to be seen. The proposed rule merely states that it is an issue to be worked out.

CERCLA Cleanup Standards

EPA has listed 1335 hazardous waste sites for cleanup on the Superfund National Priorities List (NPL). Since 2003, EPA has used a three-tier hierarchy to select human health toxicity values for use in risk assessments to guide those cleanups. Superfund risk assessments are performed to evaluate whether action is warranted under the statute; to establish protective cleanup levels for air, water, and soil; and to determine the residual risk posed by cleanup actions. They do not set absolute legally binding standards but rather presumptive levels. The methodology under which the assessments are conducted expressly recognize that EPA should take action to reduce public health risks using the best available science without waiting for further study to improve the certainty of the toxicity values. Insisting on certainty leads to delay, which has its own costs.

The first priority, Tier 1, is to use Integrated Risk Information System (IRIS) values since these values have undergone rigorous peer review and reflect EPA's consensus toxicity values (except for currently-registered pesticides).

Tier 2 consists of Provisional Peer Reviewed Toxicity Values (PPRTVs) that are developed by the Superfund Technical Support Center in EPA's Office of Research and Development. PPRTVs are developed when a contaminant without an IRIS value poses a health risk at a Superfund site.

Tier 3 includes other EPA and non-EPA sources of toxicity information with priority given to those sources of information that are most current, are based on methods and processes that are publicly available, and are peer reviewed. Tier 3 sources are used when neither IRIS values nor PPRTVs are available, and cleanup action must proceed. Tier 3 sources include CalEPA toxicity values and Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels.

If the final science transparency rule applies retroactively to influential scientific information, every one of these toxicity values will have to be re-examined. If the human toxicity studies underlying these values fail to meet the new tests of transparency and reproducibility, the cleanup levels for air, water and soil based on these toxicity values will be discredited. As a result, the cleanup actions underway at all 1335 Superfund sites will be undermined, as well as the cleanups completed at 424 sites that have been deleted from the Superfund NPL. If the final science transparency rule applies only prospectively to new toxicity values, EPA will still need to revise the hierarchy of human health toxicity values to incorporate the new transparency and reproducibility requirements. EPA will incur significant costs and time replacing the hierarchy, the toxicity values, and the cleanup levels at many sites. Despite this major impact, the supplemental notice provides no estimation of the costs and benefits.

Safe Drinking Water Act Drinking Water Advisories and Benchmarks

EPA's proposal will affect two major elements of EPA's Safe Drinking Water Act program. The first SDWA element impacted will be EPA's drinking water health advisories. To date, EPA has published 154 drinking water health advisories that identify the concentration of an unregulated drinking water contaminant not expected to cause noncarcinogenic effects from human exposures of one day, 10 days, or a lifetime. The second SDWA element impacted will be EPA's human health benchmarks for pesticides in drinking water. To date, EPA has published 394 benchmarks that identify the concentration of a registered pesticide in drinking water not expected to cause adverse health effects. All of these advisories and

benchmarks were subjected to external peer review. Neither the advisories nor the benchmarks are enforceable, but water utilities often use them when their source water is contaminated with a pollutant for which there is no federal drinking water standard. If the final science transparency rule applies retroactively to influential scientific information, every one of these advisories and benchmarks will have to be re-examined. If the human and/or animal toxicity studies underlying these advisories and benchmarks fail to meet the new tests of transparency and reproducibility, the treatment provided by utilities for these pollutants will be discredited. If the final science transparency rule applies only prospectively to new advisories and benchmarks, EPA will still need to replace the current methodologies for these recommended values in order to incorporate the new transparency and reproducibility requirements. EPA will incur significant costs and time replacing these methodologies and recommendations. Despite this major impact, the supplemental notice provides no estimation of the costs and benefits.

Clean Water Act Water Quality Criteria

These criteria are EPA's recommendations regarding the safe level of pollutants in surface waters that states can use as the basis of their enforceable water quality standards if they do not choose to develop their own scientifically defensible standards. EPA uses the world's best available science to develop aquatic life and human health criteria based on methodologies that have been peer reviewed and used effectively for years. To date, aquatic life criteria have been published for 47 toxic chemicals. These criteria are designed to protect plant and animal life in surface water bodies from both short and long term exposures to pollutants. They are based on analyses of aquatic life toxicity studies and use of bioaccumulation models. To date, human health criteria have been published for 120 toxic chemicals, two pathogen indicators, and two harmful algal bloom toxins. These criteria are designed to protect people who drink the water and eat the seafood from surface water bodies. They are based on analysis of human and animal toxicity studies and use of bioaccumulation models. All of these criteria were subjected to external peer review and public notice

and comment before they were finalized. If the final science transparency rule applies retroactively to influential scientific information, every one of these criteria will have to be re-examined. If the studies and bioaccumulation models underlying any of these criteria fail to meet the new tests of transparency and reproducibility, the enforceability of state water quality standards will be undermined since most such standards are based on the EPA criteria. If the final science transparency rule applies only prospectively to new criteria, EPA will still need to replace the current methodologies for both aquatic life and human health criteria in order to incorporate the new transparency and reproducibility requirements. EPA will incur significant costs and time replacing these methodologies and water quality criteria. Despite this major impact, the supplemental notice provides no estimation of the costs and benefits.

Clean Water Act TMDL Approval

The CWA requires each state to develop TMDLs for every waterbody the state identifies as having uses impaired because of pollution. The objective of the TMDL is to determine the pollutant loading capacity of the waterbody and to allocate that load among the pollutant sources so that the appropriate control actions can be taken to achieve the state's water quality standards. States are responsible for developing TMDLs and submitting them to EPA for approval. Even if a third party develops the TMDL with a proprietary model, the state is responsible for submitting that TMDL to EPA. If EPA disapproves a state TMDL, EPA must develop a replacement TMDL. TMDLs are developed using a range of techniques from simple mass balance calculations to complex fate and transport mathematical models. To date, over 65,000 TMDLs have been developed and approved for use in regulating point sources of pollution and controlling pollutant discharges from nonpoint sources. If the final science transparency rule applies retroactively to influential scientific information, every one of these TMDLs will have to be re-examined. If the model underlying a TMDL fails to meet the new tests of transparency and reproducibility, the enforceability of the state's point source permit limits and nonpoint source controls based on that TMDL

will be undermined. If the science transparency rule applies only prospectively to new TMDLs, EPA will need to disapprove any new TMDL based on a proprietary model since such a model would not meet the new transparency and reproducibility requirements. Whether the science transparency rule applies retroactively or prospectively, EPA will incur significant costs and time replacing TMDLs. Despite this major impact, the supplemental notice provides no estimation of the costs and benefits.

APPENDIX B

Review of the Ill effects EPA's Supplemental Proposal in Reviewing and Establishing Standards and Regulations under the Clean Air Act

Introduction

Given the massive rejection of the original proposal by thousands of scientists and other commenters, EPA had to recognize that the limitations in public availability of CBI and/or PII issues noted above were not sustainable. The original proposal, quite plainly, would have precluded the use of studies "employing data and models that include CBI data, proprietary data, PII data that cannot be sufficiently de-identified to protect the data subjects, as well as many older studies." The supplemental proposal attempts to address these comments, with a primary and an alternative scheme that fail to come to grips with the inherent limitations identified by commenters.

EPA now proposes two approaches for modifying the section addressing this central issue. The first version of the revised Section 30.5 states:

> When promulgating significant regulatory decisions or finalizing influential scientific information, the Agency will only use pivotal regulatory science and/or pivotal science that includes studies with restricted data and models (i.e., those that include confidential business information (CBI), proprietary data, or Personally Identifiable Information (PII) that cannot be sufficiently de-identified to protect the data subjects) 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 and models if the data and models are publicly available in a manner sufficient for independent validation.

EPA also proposes an alternative version that would allow all studies to be considered, but would "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 alternative gives greater consideration to studies if (1) the data and models are publicly available, or if not, (2) are available through "**restricted**

access, such as through a secure data enclave" that would permit independent validation. For other studies, EPA may still consider them "depending on the other attributes of these studies." EPA assessments must identify and explain why greater consideration was given to some studies.

The preamble does not explain the essential difference between use of "tiered access" in the first alternative and "restricted access" in the second. Presumably the ultimate level in tiered access might include PII that would permit re-analysis, which in many cases would have to be restricted to protect privacy. Both alternatives also appear to commit EPA to working with third parties to ensure that studies can comply with the rule -- although the proposal is too vague to allow commenters to do more than guess at its intent.

Either version of this provision would extend the restrictions on the use of certain studies and models for supporting regulations to the assessments contained in the development of influential scientific information. EPA defines these as assessments that might affect public policy or even private sector decisions. The inclusion/exclusion of studies and models, or greater/lesser consideration thereof, would not be based on the actual quality of the studies or models in question, but on a non-scientific metric -- whether data and models are publicly available or available through some undefined tiered or restricted access process.

As noted above, neither of the proposed conditions is consistent with the Clean Air Act: each arbitrarily excludes or downgrades studies, a priori, without consideration of the studies' merits. But as now discussed in this Appendix, in attempting to expand the conditions under which some studies and models might qualify for inclusion or "greater consideration," this new proposal still would exclude a large number of important and valid scientific studies and models from being used and evaluated on their own scientific merit. Moreover, EPA has still not done any analyses of the potential costs and disruptions caused by this provision for EPA itself and for external scientists. It has not completed the study it promised to use in evaluating the potential for model and data repositories in the final rule. Nor has the agency provided any

specifications on what would be an acceptable approach for restricted access. Most important, EPN strongly agrees with the following statement in the SAB's draft report that the agency is proffering 'solutions' to a non-problem: "…the EPA has not fully identified the problem to be addressed by the Proposed Rule. The EPA must comply with federal transparency and data integrity laws and, as discussed in this report, some additional requirements of the Proposed Rule may not add transparency, and even may make some kinds of research more difficult."

It is EPA's job, and legal obligation, to assess the impacts of its actions. But even a cursory look -- all that is possible in this inadequate period for public comment -- indicates that many studies and some assessments that EPA has judged to be influential in the last year alone would be excluded or downgraded, or in the case of assessments, need to be redone based on the new proposal.

Review of the Scientific Criteria and Standards for "Criteria" Air Pollutants

EPN does not have the time or the capacity to do what EPA should have done (and has the legal obligation to do) -- that is, to conduct a full analysis of the effect of the new proposal on all studies and models that might be excluded or given improper weight in the many criteria, risk assessments, or other examples of influential science assessments produced by EPA in recent years. Instead, we focus on the potential impact on a class of studies that have been important in reviewing the scientific criteria for particulate matter air pollution.

This example is particularly appropriate, because it is clear that the original motivation for proposed 'secret science' legislation in recent years, and the 2018 transparency proposal that was modelled on that legislation, stemmed from continuing objections raised by some about two "cohort" epidemiology studies of air pollution and health effects based on the Harvard Six City (1993) and American Cancer Society (ACS) data. The objections ignore the important point that a subsequent re-analysis of these studies sponsored by

the Health Effects Institute confirmed their major conclusions, and there are now many replications of them using different cohorts and locations.[9]

Most, but not all, of the most recent of these cohort studies were included in EPA's 2018 draft and final Integrated Science Assessment (ISA) for Particulate Matter (December 2019),[10] which were prepared by the Office of Research and Development (ORD). EPA listed the draft ISA as "influential scientific information" in FY 2019. Cohort studies of airborne particulate matter (PM) continue to play a major role in the most recent ISA weight of evidence conclusions on causal relationships between fine particles and multiple effects such as total mortality, cardiovascular and respiratory effects and cancer. See, e.g., PM ISA section 11.2.2, Figures 11-17 and 11-18; see also PM Policy Assessment at 3-19 ("Recent cohort studies, which have become available since the 2009 ISA, continue to provide consistent evidence of positive associations between long-term PM2.5 exposures and mortality. Many of these recent studies have extended the followup periods originally evaluated in the ACS and Harvard Six Cities cohorts and continue to observe positive associations between long-term PM2.5 exposures and mortality").

As noted in the comments submitted by the ISEE and Schwartz,[11] it is generally not possible to provide full public access to all information needed to reanalyze such cohort studies, in order to protect privacy.[12] Tables 11-5 and 11-6 of the ISA list over 40 North American and European cohort studies that provided information on PM and total mortality. Five of the more recent North American cohort studies

[9] See Appendix B, EPN Comments August 2018.
[10] PM ISA Ref.
[11] Schwartz, J. 2018. "Transparency" as Mask? The EPA's Proposed Rule on Scientific Data. NEJM. DOI: 10.1056/NEJMp1807751
[12] The issue is not limited to air pollution studies. EPA and some SAB members are too sanguine about the ease of protecting PII in an era of big data. Recent work by Boronow et al (2020) examined 12 prominent Environmental Health Studies to assess privacy risks. All 12 had at least 2 of 5 data types that overlap with public data bases. Participants' region of residence could be inferred with 80-98% accuracy using environmental measurements. The linkages between study data voter lists, tax and real estate data, and more "potentially raises substantial privacy risks." Privacy Risks of Sharing Data from Environmental Health Studies Katherine E.Boronow,1 Laura J.Perovich,1,2 Latanya Sweeney,3 Ji Soo Yoo,3 Ruthann A.Rudel,1 Phil Brown,4 and Julia GreenBrody1 EHP January 2020.

have used Medicare data, which is an example of a restricted database that can only be assessed by qualified researchers who must agree to particular conditions. Given the distinction EPA makes between "tiered access" and "restricted access," it is reasonable to conclude that, under the first approach, none of these important restricted access studies could be considered under the first option. Possibly, these Medicare-based studies might qualify for "greater consideration," under the alternative, but again, one can only guess given the supplemental proposal's pervasive vagueness.

Yet, at least eight of the U.S. studies in these tables are based on followup analyses that include the most recent health effects data from the Harvard Six City and the ACS programs. As discussed elsewhere, the original study participants were given assurances that their personal data and identities would not be shared with others, and access is highly limited.

In addition, seven of the recent North American studies were done using Canadian cohorts, for which access is extremely limited. Access is also highly limited for all ten of the European studies under the EU General Data Protection Regulation.[13] The EU requires that all PII data must be controlled by a data controller, who must show that any use of the data has been consented to by the individuals involved. Therefore, our analysis suggests 30 of the 40 plus cohort studies of PM and mortality listed in the ISA could not be considered at all in the first version of 30.5. Under the alternative, 25 of them could not be given full consideration. Not only does this illustrate how arbitrary the supplemental proposal is, but the proposal violates CAA section 108 (a)(2), which defines air quality criteria, among other things, as "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 air pollutant in the ambient air." EPN does not believe it is possible to say with a straight face that the Medicare studies, which have a statistical power orders of magnitude greater than any previous PM epidemiologic study, are not "useful" in identifying the effects of

[13] Council Directive 2016/679 2016 O.J. (L119) 1, 88 (EC).

PM2.5 in the ambient air. Yet the supplemental proposal would either bar them from consideration or a priori downgrade their worth.

EPA's proposal would also ensure that any current or future meta-analysis of any collection of studies (e.g., for multimedia lead or other pollutants) would be downgraded if they included any individual studies or models that did not meet the rule's requirements. A 2018 meta-analysis of fine particle/mortality studies included 53 cohorts. The listing of studies included reveals that the results have been replicated many times by many groups in many countries.[14] As EPN and thousands of public commenters wrote on the 2018 initial proposal, replication, not re-analysis, is the "gold standard" of science. In this regard, it is of note that comparing the results of the ACS, Six City, and Canadian PM mortality studies with those using the restricted Medicare other data (Figure 11-8 of the ISA), the hazard ratios for long term PM2.5 exposure and total mortality all fall in the same range, suggesting no scientifically-based rationale for eliminating or downgrading the overall weight given to the studies EPA would censor.

In addition to the final PM ISA, EPA recently published a final PM Policy Assessment (2020) prepared by the Office of Air and Radiation (OAR). In the past, EPA has listed other OAR NAAQS Policy Assessments as Influential Scientific Assessments. The policy assessment draws from the scientific assessment in the ISA, but goes further to determine what studies and information are most relevant to decisions on whether the NAAQS remain adequate to protect public health or should be revised, and if so how.

The final PM Policy Assessment (PA) concluded: "When taken together, we reach the conclusion that the available scientific evidence, air quality analyses, and the risk assessment, as summarized above, can reasonably be viewed as calling into question the adequacy of the public health protection afforded by the

[14] Vodonos A, Awad YA, Schwartz J. The concentration-response between long-term PM exposure and mortality: a meta-regression approach. Environ Res 2018;166:677-689.

combination of the current annual and 24-hour primary $PM_{2.5}$ standards." The EPA assessment went on to recommend consideration of a more stringent health-based standard for $PM_{2.5}$ (fine particles), from below the current 12 ug/m^3 standard to as low as 8 to 10 ug/m^3 based primarily on their assessment of the evidence, and supported by the risk assessment.

The outright elimination or downgrading of many cohort studies in the ISA that would occur under the proposed Section 30.5 alternatives would also remove them from use or from full consideration in the PA, where today a number would be considered as "pivotal regulatory science." Several of these studies, some based on ACS data, provided important evidence linking long-term reductions of fine particles to increased life expectancy (Table 3-3). Others, notably the Canadian Cohort studies, provided a major basis for considering levels as low as 8 ug/$m^3$for an annual standard. Some studies based on restricted Medicare data (e.g. Di et al 2017) provide ample evidence that the current standards are not sufficiently protective of public health, but could not be considered under the tiered access alternative. Maybe the second alternative would allow their consideration, maybe not. The two Canadian studies, which drive the lower bound of consideration, would be eliminated from consideration or downgraded.

As noted above, the fact that these downgraded studies produced relative risk estimates similar to studies using restricted Medicare or available data removes any scientific basis for suggesting their use or relative weight in these assessments has anything to do with the prior commitment to study subjects with respect to privacy.

<u>General Issues raised by the Supplemental Proposal Use of "tiered access" and "restricted access"</u>

Again as noted earlier, EPA efforts, such as they are, to provide any clear indication of what it intends in this supplemental proposal are abortive. What is the real difference between tiered and restricted access? The rule gives an example of restricted access that might simply be the ultimate level of a tier. Does

EPA mean to exclude restricted access in the first version and that tiered access is another term for publicly available? Who knows? Commenters are left to guess. It is also of note that EPA's use of "other things equal" and "depending on their other attributes," (85 FR 15405, Section 30.5(a)) are singularly unhelpful. Moreover, does giving less "consideration" in assessments really devolve into giving no weight?

EPA has still not done any serious assessment of the costs and benefits of tiered access or restricted access criteria, nor has it completed its promised assessment of how the agency might set up a data system.

The new proposal is opaque on the role EPA intends to play in implementing a rule requiring studies and models to have public or restricted access to all data or code. The SAB conducted a consultation on mechanisms for applying a tiered access approach for securing PII and confidential information in August 2019. No consensus was attempted but a number of SAB members responded to EPA's questions regarding the use of a tiered access approach for access to PII data. Several were skeptical because EPA had not provided any specifics of how to adapt such an approach for the rule. Language from the SAB summary letter is instructive of the challenges the public and the science community face in making sense of this proposal:[15]

> "A member again commented that it was difficult to understand how a tiered approach to implementing the proposed rule would work. He suggested that the EPA provide information about studies used in the past that would be subject to concerns about protection of PII and CBI under the requirements of the proposed rule."
>
> A member commented that using NIH experience as a model for the tiered approach may not be very useful because much of the data EPA needed to support regulations had a spatial/temporal component not present in NIH data. He also noted that it was not clear that the owners of non-federal data would want to provide the data to EPA and, in fact, may not be able to provide data without permission from study participants. The member commented that it would be helpful for the SAB to see an example of the kind of tiered approach that EPA intended to use.

[15] SAB Summary Letter

SAB later provided comments from all SAB members who chose to respond.[16] Some echoed these concerns about whether EPA had done its homework on the issue.

Dr. Barbara Beck noted, "The information provided by U.S. EPA is insufficient for me to provide a complete answer," following it with a list of unanswered questions.

Dr. Steven Hamburg wrote:

> "Analysis of the implications of the proposed Science and Transparency rule with respect to PII and CBI is lacking and beyond the scope of this consultation and as such it is impossible to understand the implications of the proposed rule on both protected information and the expectation of privacy by both individuals as well as with respect to commercially sensitive information. The lack of analysis is greatly compounded by the lack of details about the proposed rule itself."

Mr. Robert W. Merritt wrote:

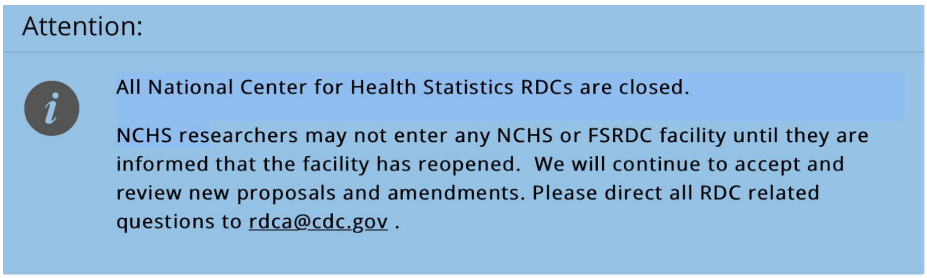
> I would include a comment as to the enormous cost and extended timeline implied by this rule change, an issue I feel has not been fully addressed, and which argues for limiting this rules applicability to future studies. I am an expert in database design and conversion with four decades of experience in working with state and federal databases, during their transition from internal to public-facing, particularly as a result of the Paperwork Reduction Act of 1980 and as amended in 1995. I can attest that estimation of the cost and completion of these efforts were generally off by a factor of five, at a minimum, and some were never entirely completed.

EPA does not even acknowledge these comments, much less respond to them. While the above comments were not made with specific reference to proposed Section 30.5,[17] they remain on point because they address an issue that is directly relevant to both the public and restricted access and tiered access discussed in the supplemental proposal preamble. Moreover, at the August consultation, EPA staff confirmed that EPA was working with the National Center for Health Statistics at the Centers for Disease Control and Prevention (CDC) to conduct a pilot study using a secure data enclave to host EPA data sets in a restricted use environment to examine how PII data could be protected. They also suggested the pilot would be completed in about six months (i.e. end of March) and that "the final rule would build upon the information obtained from the pilot."

[16] SAB individual comments.

[17] EPA compounded its initial violation of ERDDA by not providing the SAB with its Supplemental proposal at any time, much less at the time prescribed by statute.

Apparently, this work, which was to be a foundation for the final rule, was not completed in time to inform the supplemental proposal or EPA chose to move forward without waiting to get its results. The preamble states that "EPA is currently conducting a pilot study using the RDC's secure data enclave" referring to the Research Data Center of the NCHS/CDC. Clearly, this key study that EPA told SAB would be "used to inform the final rule" has not been made available for public comment. Apparently, in its place, the preamble notes that the RDC itself is "a model of tiered access for data involving PII." Has EPA examined that site to see if it actually assists in understanding what EPA suggests is a model for the rule? Ast of April 1, 2020 the RDC site yielded only the following:[18]



Of course, this shutdown is the result of the pandemic (providing a concrete illustration of the reasons EPN and many other commenters asked for a suspension of the comment period, or at least 60 additional days). This farcical game of hide and seek for defining tiered access is emblematic of the utter disregard of both the tradition of sound science/policy principles and the rulemaking process at EPA. The violation of routine norms of adequate notice and opportunity for comment is palpable.

It is appropriate at this point to mention the strong disparity between the "transparency" requirements EPA would demand when data and models are used as influential scientific information that might affect policy or decisions by the private sector and that used by the White House in presenting estimates of the potential number of U.S. deaths from COVID-19. From *The Washington Post* on April 2:

[18] RDC site, accessed April 8, 2020. https://www.cdc.gov/rdc/index.htm

"Almost the entirety of what the public knows about the death projection was presented on a single slide at a briefing Tuesday from the White House coronavirus task force. A White House representative said the task force has not publicly released the models it drew from *out of respect for the confidentiality of the modelers*, many of whom approached the White House unsolicited and simply want to continue their work without publicity." (emphasis added)

The White House not only did not release data and models, but apparently did so to protect the privacy of the modelers. This suffices to illustrate the hypocrisy of the decision processes and attitudes toward science that we are here addressing.

Based on our analysis of the revised Section 30.5 as well as the wholly inadequate analysis of potential impacts and costs of implementing this and other provisions, EPN continues to conclude that the rule proposal as amended by the supplemental proposal remains a solution searching for a problem.

Impacts on non-dose response models and influential scientific information in EPA rulemakings

The supplemental proposal's impacts on non-dose response models and influential scientific information (proposed section 30.5) are not addressed by EPA, but appear to be enormous and perverse. EPN had time to examine just a single section of a single rule to try and assess that impact -- EPA and NHTSA's September 15, 2011 final rule adopting greenhouse gas emission standards and fuel efficiency standards for heavy duty vehicles and engines. 76 FR 57106. That section of the Heavy Duty Rule preamble discusses:

- Emissions of greenhouse gases and resulting impacts on the climate (76 FR at 57294-300 nn. 324-353
- Non-GHG pollutant emissions, health effects of those pollutants, and potential impacts of the rule theron. 76 FR at 57300-309 nn. 354-438 and 76 FR at 57312-314 nn. 467-471
- Exposure and health effects associated with traffic; 76 FR at 57309-310 nn. 439-449

- Environmental effects of non-GHG pollutants; 76 FR at 57310-312 nn. 450-466

The total number of references in this single preamble section of a single rule numbers in the hundreds to thousands. Each reference contains multiple sub-references. Each reference and sub-reference appears to be "influential scientific information" -- i.e. has "a clear and substantial impact on ... important public policies" (proposed section 30.2 definition). That is why EPA cited it as support for the positive health and environmental effects resulting from its action for first-time control of GHG emissions from heavy duty vehicles and engines.

In its comment responses, EPN expects the agency to explain whether or not these references are or would be covered by the rule, why, what the effects on EPA's authority to control emissions of pollutants under CAA sections 202 (a)(1) (2) and (3) are or would be, and EPA's reasoning for these findings. For example, just picking two of these references at random, would Goldstein, B.D. (1988) Benzene toxicity, Occupational Medicine, State of the Art Reviews 3:541-554 be covered? Would EPA's Health Assessment Document for Diesel Engine Exhaust, EPA/600/8-90-576 (Office of Research and Development) be impacted and how? This reference is a source EPA has used in all of its rules regarding emissions from heavy duty engines. EPA should do this same analysis and provide a comparable explanation for references in other of its significant rules.

Of course, EPA was already required to do this type of analysis. Reasoned decision-making requires, at the barest of minimums, that an agency be aware of the effects of its actions. *State Farm*, 463 U.S. at 43. Moreover, since none of EPA's thinking on the actual effects of its proposal is presently available to commenters, EPA must afford the public notice and opportunity to comment on its responses and findings.

The supplemental proposal's extension to all models also has drastic ramifications to which the proposal is mute. What are the proposal's implications for such transportation sector fate and transport

models as GREET[19] and MOVES[20]? The standard air quality model CMAQ used by EPA to assess air quality impacts in most stationary source regulations ?[21] What are the implications of exposure and monetization models such as BEN-Map CE?[22] Are econometric models, including the Integrated Planning Model (IPM)[23] used to evaluate impacts on electricity generating units, implicated and if so why and how?

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[19] GREET - Greenhouse gases, regulated emissions, and energy use in transportation — is a full life-cycle model sponsored by the Argonne National Laboratory (U.S. Department of Energy's Office of Energy Efficiency and Renewable Energy). It fully evaluates energy and emission impacts of advanced and new transportation fuels, the fuel cycle from well to wheel and the vehicle cycle through material recovery and vehicle disposal need to be considered. It allows researchers and analysts to evaluate various vehicle and fuel combinations on a full fuel-cycle/vehicle-cycle basis. It provides estimates for total energy consumption, emissions of the six major GHGs, and emissions of criteria pollutants.

[20] MOVES — **Motor Vehicle Emission Simulator —**is a state-of-the-science emission modeling system that estimates emissions for mobile sources at the national, county, and project level for criteria air pollutants, greenhouse gases, and air toxics.

[21] CMAQ -- the **Community Multiscale Air Quality Modelling System** -- is an active open-source development project of. EPA that consists of a suite of programs for conducting air quality model simulations. CMAQ combines current knowledge in atmospheric science and air quality modeling, multi-processor computing techniques, and an open-source framework to deliver fast, technically sound estimates of ozone, particulates, toxics and acid deposition.

[22] **BenMAP-CE** is an open-source computer program that calculates the number and economic value of air pollution-related deaths and illnesses. The software incorporates a database that includes many of the concentration-response relationships, population files, and health and economic data needed to quantify these impacts.BenMAP-CE enables users to load their own data or use pre-loaded datasets for the U.S. and China

[23] The **Integrated Planning Model (IPM)** is a multi-regional, dynamic, deterministic linear programming model of the U.S. electric power sector. It provides forecasts of least-cost capacity expansion, electricity dispatch, and emission control strategies for meeting energy demand and environmental, transmission, dispatch, and reliability constraints. IPM can be used to evaluate the cost and emissions impacts of proposed policies to limit emissions of sulfur dioxide (SO2), nitrogen oxides (NOx), carbon dioxide (CO2), hydrogen chloride (HCl), and mercury (Hg) from the electric power sector. Sub-models contained within the IPM (each of which appears implicated by the proposal) are:

- NEEDS v6
- Documentation for EPA's Power Sector Modeling Platform v6 - January 2020 Reference Case
    - IPM v6 Regions (shapefiles)
- Results using EPA's Power Sector Modeling Platform v6
- IPM Peer Review
- Retail Price Model - Documentation describing how EPA estimates the difference in average retail electricity prices between projection scenarios.
- Power Sector Labor Analysis Methodology

What of models EPA uses for assessing effects of climate change, including MAGICC[24] and GCAM?[25] Again, it is incumbent on EPA to evaluate potential impacts of the proposal on all of its standard modeling tools and its reasoning therefore, and then to provide the public with notice and opportunity for comment on these findings.

[24] Model for the Assessment of Greenhouse Gas Induced Climate Change, often used by the IPCC and cited repeatedly by EPA.

[25] Global Change Assessment Model (GCAM) is an integrated assessment model that links the world's energy, agriculture and land use systems with a climate model. The model is designed to assess various climate change policies and technology strategies for the globe over long time scales. GCAM runs in 5-year time steps from 1990 to 2100 and includes 14 geographic regions in the energy/economy module and 151 regions in the agriculture and land use module. The model tracks emissions and atmospheric concentrations of greenhouse gases (CO2 and non-CO2), carbonaceous aerosols, sulfur dioxide, and reactive gases and provides estimates of the associated climate impacts, such as global mean temperature rise and sea level rise.

APPENDIX C

The Supplemental Proposal has Multiple Positions on Older Studies

EPA's supplemental proposal raises the issue of whether this rule should apply to all studies, regardless of when they were published. This issue is itself pivotal in terms of the total costs, reach, and practicality of the rule. The underlying data, models and computer code for some studies, particularly older studies, may not be readily publicly available, whether due to technological barriers to data and model sharing (e.g., differences in data storage devices) or how long such data are retained. The draft SAB review of the 2018 proposal noted that "retrospective application of the requirement would be difficult to implement, could be expensive with no clear responsibility regarding who would cover the added costs and could impact the conclusions drawn arbitrarily." It recommended against it. The final report, which includes comments on the rule as supplemented states: "....the retrospective application of modern transparency standards is a challenge. A large amount of work would be required to locate, curate and retrospectively make datasets available for public access. This requirement could adversely affect the ability to move this program forward in a meaningful capacity."

The supplemental proposal tries to have it both ways, and offers several possible positions in two sections of the rule. EPA maintains its original position in 30.5 that the rule would apply to studies, data, and models regardless of when they were published, but requests comments on whether this should apply only to data and models that are generated after the effective date of the rule making.

The revised section 30.9 amends the criteria for case-by-case exemptions by the Administrator. EPA now proposes that the Administrator *may* [l]grant an exemption if "compliance is impracticable because technological barriers render sharing of the data infeasible, the development of the data or model was completed or updated before" *the effective date of the rule*, "or making the data and models publicly available

would conflict with certain laws governing privacy, confidentiality, confidential business information, or national or homeland security" (emphasis added). The proposal also asks for comments on these criteria.

The agency is again asking for commenters to weigh these options for addressing older studies without providing any analysis of the relative costs, benefits and disruption not only to the agency and the processes it manages, but for those scientists who produced the studies in question. In fact, because EPA has yet to provide any clear basis that this rule is necessary, or would indeed produce net benefits without substantial disruptions and costs, we suggest none of the above.

We note that even some SAB members who actually support a rule warn against the unassessed costs and chaos that would result from making it retroactive. With respect to the ad hoc exemption criteria, the SAB draft report on the 2018 proposal noted that: "Given the lack of clarity, the proposed rule could be viewed as a license to politicize the scientific evaluation required under the statute based on administratively determined criteria for what is practicable." The final report states: "Reference to a vague 'feasibility' standard suggests that such waiver decisions are to be made solely by the Administrator. In the absence of clear guidance, such waivers might appear to be inconsistent or lacking objectivity."

These threats are nowhere more blatant than in the supplemental notice at section 30.9, which leaves the decision of whether an older scientific study should be included in supporting regulation up to a case-by-case determination by the EPA Administrator. EPN believes that it should not be up to the Administrator or any political appointee to make a constrained judgment as to whether scientific information should or should not be included in assessments that form the basis for any kind of regulatory decision -- significant or not.