May 18, 2020

Submitted via regulations.gov

Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue NW
Washington, D.C. 20460
Attn: Docket No. EPA-HQ-OA-2018-0259

Re: *Comment on Supplemental Notice of Proposed Rulemaking ("SNPRM")—Strengthening Transparency in Regulatory Science*, 85 Fed. Reg. 15396 (Mar. 18, 2020) ("Proposed Rule")

Dear Administrator Wheeler:

This comment letter is submitted on behalf of a group of 100 professors of law whose names appear below. We are affiliated with 70 universities in 33 states and the District of Columbia, and all have substantial professional experience in the areas of administrative and environmental law. We write to express our serious concerns with the above-referenced Proposed Rule, as revised in the Supplemental Notice of Proposed Rulemaking ("SNPRM"). Many of us previously commented on the Proposed Rule in this docket, concluding that "[t]he rule's ill-considered, inadequately noticed, and overwhelmingly vague proposal would make sweeping changes to the way EPA makes those choices with barely any thought given to the incredibly complex regulatory, scientific, and privacy issues implicated."[1] In our view, the modifications to the Proposed Rule serve only to further overstep EPA's authority, curtailing the use of valid, relevant, and rigorously reviewed science in an extraordinarily broad range of EPA's future decisionmaking processes.

Given the breadth and vagueness of the revised proposal, it is hard to imagine EPA could take, or contemplate taking, any significant regulatory or policy action without being constrained in its ability to consider important scientific research under this rule. The Proposed Rule, if adopted, will impose serious costs to public health and safety. Not only does EPA lack

[1] 68 Legal Scholars, Comment on Proposed Rule—Strengthening Transparency in Regulatory Science (August 14, 2018), *available at* https://www.law.ucla.edu/~/media/Files/UCLA/Law/Pages/Publications/CEN_EMM_PUB-FINAL-EPA-HQ-OA-2018-0259-Comment-Letter.ashx.

authority to issue the Proposed Rule, but the revisions in the SNPRM strike at the very heart of EPA's mission, in clear contravention of EPA's authorizing statutes.

Even as EPA expands the Proposed Rule to capture nearly all science the agency considers—while still exempting without explanation agency adjudications and enforcement activities[2]—it presents among these revisions an "alternative" approach that would, if adopted, allow EPA to consider studies based on non-publicly available data under certain circumstances. In reality, the revised Proposed Rule further hamstrings EPA's ability to use the best science when it regulates. And EPA's proposed alternative implementation—weighing studies based on non-public data less heavily than those based on public data—bears no relationship to widely-accepted principles and procedures of scientific review.

Simply put: The public availability of data is not necessarily related to the scientific rigor and validity of a study. Forcing EPA to treat the criterion of public data availability as paramount, above the robustness of a study's actual analysis, means EPA cannot fulfill its statutory mandates to consider the best available science when regulating to protect public health and the environment. While we support efforts by the scientific community to address data accessibility, the Proposed Rule would ignore the complexities of that issue and scientists' ongoing work to tackle it; the proposal would limit regulatory activity before any consensus has been reached among scientists on approaches to data availability. Staggering costs to public health and safety will result.

We object to the revisions discussed in the SNPRM for the following reasons, which are more fully set forth below: (1) the Proposed Rule continues to fall outside the scope of EPA's rulemaking authority, and (2) the proposed revisions represent an expansion of the Proposed Rule wholly at odds with EPA's core mission.

We believe that the Proposed Rule is not only unnecessary and antithetical to the goal of achieving regulatory transparency, but would also severely constrain EPA's ability to use the best quality science to make critical decisions. Eliminating the consideration of relevant science from the decisionmaking process based solely on the availability of underlying data would

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[2] The SNPRM exempts these activities from the Proposed Rule's reach in section 30.3, without further elaboration. Ostensibly, this would preserve the right of private parties, including regulated entities, to rely on any science they wish in the context of agency enforcement actions, even as the agency declines to consider the same science as part of regulatory decisionmaking processes. Beyond resulting in confusion and an uneven application of the purported rationale for the Proposed Rule, this carve out highlights how the agency's selective approach to "scientific transparency" is likely to undercut, rather than support, the agency's mission to protect public health and the environment using the best science.

compromise EPA's ability to effectively carry out its mission to protect public health and the environment. We strongly urge that the Proposed Rule be withdrawn.

I. The Proposed Rule Falls Outside EPA's Rulemaking Authority

Despite EPA's assertion that the amended Proposed Rule governs "internal agency procedures" and "does not regulate any entity outside the Federal government," the Proposed Rule is, in fact, a substantive regulation. It will profoundly impact how EPA interacts with regulated parties by changing how the agency performs its core functions.

"It is axiomatic that an administrative agency's power to promulgate legislative regulations is limited to the authority delegated by Congress." *Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988). EPA steps far beyond that authority in the SNPRM, proposing a regulation that would change the way the agency engages in virtually any decisionmaking or scientific process—outside of agency adjudications and enforcement activities—whether or not that process ultimately leads to the adoption of regulations. EPA has revised the Proposed Rule to cite the agency's housekeeping authority as its basis to regulate. But EPA has no statutory authority to issue the Proposed Rule, either through the Housekeeping Statute or via other environmental statutes EPA has previously cited.

A. The Housekeeping Statute Confers No Authority To Issue A Rule Of This Scope

EPA now asserts "housekeeping" authority to issue the Proposed Rule, maintaining that these sweeping changes to agency practice and policy are nothing more than "procedural" rules or "internal agency procedures" that "do[] not regulate any entity outside the Federal Government," akin to how EPA manages its filing system. This is a serious mischaracterization of the Proposed Rule's import and effect.

The so-called Housekeeping Statute, 5 U.S.C. § 301—which does not, on its face, even apply to EPA[3]— was "originally adopted in 1789 to provide for the day-to-day office housekeeping in the Government departments," and courts at every level have consistently found that it does not authorize substantive rules. See, e.g., *Chrysler Corp. v. Brown*, 441 U.S. 281, 310 (1979); *U.S. ex rel. O'Keefe v. McDonnell Douglas Corp.*, 132 F. 3d 1252, 1255-56 (8th Cir. 1998); *City and County of San Francisco v. Azar*, 411 F. Supp. 3d 1001, 1023 (N.D. Cal. 2019). While the Housekeeping Statute might appropriately authorize "a regulation that governs...the filing of government documents pertaining to the day-to-day business of government," it does not confer an

[3] The SNPRM acknowledges that EPA is not among the "Executive department[s]" to which the statute's terms apply. 85 Fed. Reg. 15397. While the SNPRM claims that the subsequent Reorganization Plan No. 3 conferred housekeeping authority upon EPA, that plan nowhere mentions the Housekeeping Statute or provides such authority.

"unrestricted grant of authority" allowing the agency to make broad policy changes that drastically alter the way it discharges its fundamental duties. See *Respect Inc. v. Committee on Status of Women*, 815 F. Supp. 1112, 1123 (N.D. Ill. 1993). Indeed, Housekeeping Statute authority is generally limited to actions that are exempt from the very notice and comment rulemaking procedures EPA has undertaken for the Proposed Rule (and that EPA has tacitly acknowledged[4] are required by doing so). See *Chrysler Corp*., 441 U.S. at 310 (the Housekeeping Statute "authoriz[es] what the APA terms 'rules of agency organization procedure or practice' as opposed to 'substantive rules.'"); 5 U.S.C. § 553(b)(3)(A) (exempting rules of agency procedure, organization, and practice from notice and comment rulemaking).

EPA's characterization of the Proposed Rule as merely "procedural" or "internal" is erroneous and misleading. In reality, the Proposed Rule would have the effect of amending substantive and well-settled standards for decisionmaking under a number of the environmental statutes EPA administers, including the Clean Air Act, the Toxic Substances Control Act, the Safe Drinking Water Act, and others. For example, Clean Air Act § 109 mandates that EPA set air quality standards based on "air quality criteria," which must "accurately reflect the latest scientific knowledge useful in indicating the kind and extent of all identifiable effects on public health or welfare." 42 U.S.C. §§ 7409, 7408(a)(2). The Toxic Substances Control Act requires EPA to use the "best available science" when evaluating the testing and regulation of chemicals. 15 U.S.C. § 2625(h). Decisions are to be made using the "weight of the scientific evidence," and EPA is required to consider all information related to a chemical substance, including hazard and exposure information, "that is reasonably available to the Administrator." 15 U.S.C. §§ 2625(i), (k). Similarly, the Safe Drinking Water Act mandates use of the "best available public health information" when EPA determines whether to regulate a contaminant, and reliance on the "best available, peer-reviewed science and supporting studies" when making regulatory decisions. 42 U.S.C. §§ 300g-1(b)(1)(B)(ii), 300g-1(b)(3). While EPA claims that "in the event the procedures outlined in this proposed rulemaking conflict with the statute that EPA administers, or their implementing regulations, the statutes and regulations will control," the Proposed Rule so directly conflicts with multiple statutory requirements as to render this assertion meaningless. In sum, the Proposed Rule cannot be implemented without upending statutory standards for the use of science.

Such fundamental change to agency policy is the very type of action courts have consistently characterized as substantive. See, e.g., *Mendoza v. Perez*, 754 F.3d 1002, 1021 (D.C. Cir. 2014) (a

[4] The SNPRM also characterizes the Proposed Rule as a "significant regulatory action" as defined in Executive Order 12866; that Executive Order excludes "[r]egulations or rules that are limited to agency organization, management, or personnel matters"—the very types of actions authorized by the Housekeeping Statute. In other words, the Proposed Rule cannot *both* be authorized the Housekeeping Statute and subject to the requirements of E.O. 12866.

substantive regulation "supplements a statute, adopts a new position inconsistent with existing regulations, or otherwise effects a substantive change in existing law or policy."); *Rocky Mountain Helicopters, Inc. v. F.A.A.*, 971 F.2d 544, 546 (10th Cir. 1992) (a rule that "changes existing law, policy, or practice" is substantive). "Misuse" of the Housekeeping Statute as purported authorization for these rules has repeatedly been rejected as an "attempt to twist this simple administrative statute into an authorization for the promulgation of substantive rules." See *U.S. ex rel. O'Keefe*, 132 F. 3d at 1255; see also E*xxon Shipping Co. v. U.S. Dep't of Interior*, 34 F. 3d 774, 776-78 (9th Cir. 1994); *In re Cincinnati Radiation Litigation*, 874 F. Supp. 796, 821 (S.D. Ohio 1995) (Housekeeping Statute did not authorize a Department of Defense directive mandating that the Department's experimentation on human subjects could only be conducted where the subject provided full and voluntary consent).

EPA's Proposed Rule would singlehandedly alter the way EPA discharges its core statutory responsibilities under the key environmental statutes it is tasked with administering, at significant cost to public health and safety. Far from a mere procedural dictate or internal standard, the Proposed Rule dramatically changes the nature of EPA's activities—both regulatory and non-regulatory—in ways that are inconsistent with existing law and a major departure from past agency policy. The Housekeeping Statute does not authorize such game-changing rulemaking.

B. The Cited Environmental Laws Provide No Authority For This Rulemaking

EPA also continues to cite to numerous provisions in environmental statutes to support this rulemaking,[5] but none provides authority for the agency to promulgate the Proposed Rule. Generally, these provisions fall into one of two categories: (1) provisions authorizing EPA to conduct research in furtherance of statutory objectives and (2) general provisions authorizing the EPA Administrator to promulgate regulations as necessary to achieve the purposes of a given statute. None of these statutory references provides the requisite authority for adoption and implementation of the Proposed Rule.

EPA points to provisions authorizing the establishment of research and development programs pursuant to each of the federal environmental laws EPA administers. But these statutory references are unavailing. Each statute directs EPA to set up research programs and to undertake specific activities attendant to the administration of those programs, but none governs—or even references—the extent to which research should be used in regulatory

[5] EPA incorporated into the SNPRM its citations from the original Proposed Rule: 42 U.S.C. § 7403, 42 U.S.C. § 7601(a), 33 U.S.C. § 1254, 33 U.S.C. § 1361, 42 U.S.C. § 300j-1, 42 U.S.C. § 300j-9(a)(1), 42 U.S.C. § 6912(a)(1), 42 U.S.C. § 6979, , 42 U.S.C. § 9660, 42 U.S.C. § 11048, 7 U.S.C. § 136r(a), 7 U.S.C. § 136w, and 15 U.S.C. § 2609. It also clarified that prior citations to 42 U.S.C. § 6979 and 42 U.S.C. § 9616 should be to 42 U.S.C. § 6981 and 42 U.S.C. § 9615 respectively.

decisionmaking by EPA. Further, any regulatory authority EPA may have under the referenced provisions is limited to the individual research and development programs in question, and does not extend to unrelated research by outside parties. In other words, the cited provisions allow EPA to set up its own research programs, but do not create authority to place limitations on how research, whether conducted or financed by EPA or produced by an outside party, is used to set regulatory standards.

For example, EPA purports to derive authority for the Proposed Rule from Clean Air Act § 103. That provision simply authorizes EPA to establish a national research and development program for the prevention and control of air pollution and, as part of that program, to conduct and promote the coordination of research and studies relating to the causes, effects, extent, prevention, and control of air pollution. 42 U.S.C. § 7403(a)(1). The section authorizes specific activities of the Administrator in establishing such a program, none of which includes limiting the scope of reviewable data, research, or studies when undertaking regulatory action. The section has no bearing on how or to what extent EPA utilizes research in regulatory decisionmaking processes.

The rulemaking authority provided by provisions authorizing the EPA Administrator to promulgate regulations "as necessary to carry out his functions" under various environmental statutes does not extend to actions that would undermine, rather than further, the relevant acts' directives. *See* 42 U.S.C. § 7601(a) (Clean Air Act); 33 U.S.C. § 1361 (Clean Water Act); 42 U.S.C. § 300j-9(a)(1) (Safe Drinking Water Act); 42 U.S.C. § 6912(a)(1) (Resource Conservation and Recovery Act); 42 U.S.C. § 9615 (Comprehensive Environmental Response, Compensation, and Liability Act); 42 U.S.C. 11048 (Emergency Planning and Community Right-To-Know Act); 7 U.S.C. § 136w (Federal Insecticide, Fungicide, and Rodenticide Act). As discussed in greater detail below, both the intent and the language of the Proposed Rule are in direct opposition to the statutory requirements of these environmental statutes, which seek to protect public health and the environment.

In sum, EPA offers no legal authority upon which it may lawfully base a rulemaking of this significance.

II. The Significant Expansion Of The Proposed Rule Directly Contravenes EPA's Core Mission

EPA is charged not only with conducting research on pollution's adverse effects and how they can best be controlled, but also with "strengthening environmental protection programs and recommending policy changes." President Richard M. Nixon, *Special Message from the President to Congress About Reorganization Plans to Establish the Environmental Protection Agency and the National Oceanic and Atmospheric Administration* (July 9, 1970). EPA cannot properly fulfill this

role unless it makes use of the best available scientific information, regardless of data availability to the public. But the SNPRM broadens the Proposed Rule's impairment of EPA's ability to consider the best science to cover even more actions of significance, particularly those likely to protect public health and the environment. It expands the Proposed Rule both to cover more types of data and models, and also to cover more types of agency activities that those data and models underlie. The enormity of this revision cannot be overstated.

EPA purports to be promulgating the Proposed Rule to enhance transparency in regulatory decisionmaking processes, but its effect would be to paralyze those processes while offering no guidance for scientists working to provide relevant and high caliber information to the agency. The Proposed Rule disregards settled scientific standards and drums up a transparency problem that does not exist, focusing on data availability instead of study reliability. It adds nothing to—and in fact completely ignores—the complex discussions within the scientific community about how best to achieve additional transparency and enhance replicability while maintaining commitments to patient confidentiality and production of high quality science. And its vague language suggests unpredictable implementation that will only further interfere with EPA's mission to protect public health and the environment.

First, the SNPRM greatly expands the application of the Proposed Rule, to cover all data and models underlying the activities covered by the proposal. While the Proposed Rule initially applied only to dose-response data and models utilized to support EPA's regulatory decisions ("pivotal regulatory science"), the SNPRM now extends the Proposed Rule's application to *all* data and models—not just dose-response data. The SNPRM makes the breadth of the Proposed Rule, as amended, clear: "…the proposed requirements of this rule would apply broadly to data and models underlying pivotal regulatory science and pivotal science which support significant regulatory decisions and influential scientific information, respectively, rather than simply to dose-response data and models." 85 Fed. Reg. at 15400. This expansion of the rule's scope would hamper the agency's ability to use science in contexts from climate modeling to bench chemistry.

Second, the SNPRM greatly expands the types of agency activities to which the Proposed Rule would apply, to include data and models used in non-regulatory contexts. The SNPRM states that "EPA is proposing to expand the scope of this rulemaking to apply to influential scientific information as well as significant regulatory actions." 85 Fed. Reg. at 15398. The SNPRM devises a new category of information, "influential scientific information," a category of "pivotal science" that underlies such information, and applies the Proposed Rule's provisions to all of it. These new definitions are so expansive and vague as to render the Proposed Rule applicable to any scientific study that EPA considers for nearly any meaningful purpose, outside of the proposal's exceptions for adjudications and enforcement activities.

EPA defines "influential scientific information" 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." Nowhere in the SNPRM does EPA explain how it will determine particular science has such a "clear and substantial impact"; there are no factors for the agency to consider when making such a determination, nor examples of scientific information that would be encapsulated within the definition. The defined terms are so broad they ostensibly could apply even to science that never actually impacts any agency policy or regulation: If EPA finds science reasonably "will have" an impact in the future, that is enough to bar the agency from considering key data in the present, whether or not such an impact ultimately occurs. Moreover, a wide range of EPA activities might be found to impact "private sector decisions" outside the scope of the agency's own regulatory authority, making the potential reach of this provision virtually limitless. Beyond that, as discussed above, the SNPRM clarifies that the data and models impacted by the Proposed Rule are not limited to dose-response data and models, but cover a wide range of scientific data and models, ranging from environmental fate studies to engineering models to environmental release data to climate models and beyond. Given these parameters, it is hard to imagine a scientific study, dataset, or model that would not be subject to the Proposed Rule.

The SNPRM also clarifies that, in order to be considered by EPA, a study's data must be available for "reanalysis," rather than "reproducibility," the term used in the original Proposed Rule. This change further interferes with the agency's ability to comply with statutory requirements to utilize the best science. Reanalysis requires that a study's results be capable of verification utilizing the same data set originally studied. This would discount from the agency's consideration studies that can be replicated--in other words, where the study's results are observed across multiple data sets—but that cannot be reanalyzed because they are based on non-public data, even though such studies may be considered more scientifically robust. The result of this process overhaul would be to restrict EPA's use of critical research in key decisions that impact public health and the environment, even when that research is peer-reviewed. The SNPRM's revisions rob EPA of the ability to consider an ever-growing body of scientific research in an ever-growing number of circumstances. While EPA's revised proposal contemplates that "tiered access," such as restricted access to confidential data for independent validation by "authorized researchers," can resolve this issue, that access would require the research institutions and researchers to authorize restricted access. But this requirement is not consistent with many contractual agreements with research subjects, and will be infeasible or impossible to implement both retroactively and prospectively in a way that allows the agency to rely on high-quality science.

The SNPRM provides an alternative proposal that fares no better. This alternative—weighting studies based on publicly available data more heavily than those based on non-publicly

available data, rather than forbidding the use of the latter entirely—seems designed to create the appearance of flexibility but flouts EPA's mission and settled scientific principles just as egregiously. Not only is there no scientific basis for employing such a weighting system, but the SNPRM offers no meaningful explanation for how and when EPA would apply such weighting. The SNPRM suggests that "other things being equal," a "high-quality" study based on publicly available data would receive more weight than a study supported by non-publicly available data, but that explanation leaves much undefined. For example, EPA does not explain what it would consider to be a "high-quality" study, or how it would determine whether "other things" are equal in any given circumstance. In the likely event that the agency is presented with multiple studies that could be considered "high-quality" but that are based on varying amounts of data and whose conclusions are supported with varying robustness, there are no criteria for the agency to apply in determining which studies to consider, or how heavily to weigh them.

At best, the lack of clear guidance on how studies should be weighted would lead to inconsistent and unclear application of the Proposed Rule. But more importantly, weighting, discounting, or excluding relevant studies from consideration based *not* on the quality of the science but on the public availability of underlying data directly contradicts EPA's statutory mandates, including those discussed above in Section I above,[6] and core mission. EPA itself has defined "best available science" and similar statutory standards without reference to the public availability of data; for example, EPA has explained that:

> Use of best available science involves the use of supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data).[7]

The "best available science" and similar standards set out in environmental statutes require the use of scientific information and analysis that follow standards accepted by the scientific

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[6] In addition to the examples discussed above, there are many other statutory requirements for EPA to employ science that this Proposed Rule directly contravenes. For example, Clean Water Act § 104 requires EPA to undertake continuing comprehensive studies of the effects of pollution on estuaries and estuarine zones, considering "all pertinent information"—a mandate at odds with the Proposed Rule's push to exclude relevant peer-reviewed research from the regulatory process. 33 U.S.C. § 1254(a)(1).

[7] Environmental Protection Agency Office of Chemical Safety and Pollution Prevention, *Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluations Under the Toxic Substances Control Act*, EPA 740-R17-001 (June 2017).

community, not information and analysis that EPA arbitrarily selects based upon the public availability of data—a criterion often irrelevant to scientists' standards for determining whether research represents the best science. *American Trucking Ass'ns, Inc. v. EPA*, 283 F. 3d 355, 372 (D.C. Cir. 2002) (explaining that curtailing EPA's ability to rely on published studies would exclude "plainly relevant scientific information" from regulatory decisionmaking processes). Forcing EPA to ignore high quality science controverts EPA's statutory obligations and will impair EPA's ability to protect public health and the environment.

The SNPRM's approach would, in an extraordinarily wide range of meaningful circumstances, replace EPA's existing, successful protocols—already in step with established scientific procedures—with a process driven by arbitrary, non-scientific gatekeeping. The proposed requirements, while ostensibly driven by concerns about transparency and accountability, in fact ignore well-established indicia of reliable scientific research, such as peer review. This emphasis contradicts EPA's own statutory mandates and is inappropriate, given the courts' agreement that publicizing the data underlying studies upon which EPA relies "would be impractical and unnecessary." *American Trucking Ass'ns*, 283 F.3d at 372; see also *Coalition of Battery Recyclers Ass'n v. EPA*, 604 F. 3d 613, 623 (D.C. Cir. 2010). The expansive revisions to the Proposed Rule would reduce, not enhance, the quality of data available to EPA as it makes critical decisions and engages in its own efforts to study a wide variety of environmental impacts.

III. Conclusion

As legal scholars, we found the initial Proposed Rule to be both unlawful and unsound; the revisions proposed by the SNPRM concern us even more deeply. Far from promoting transparent regulatory decisionmaking, the rule would institute an arbitrary process to stymie EPA's use of the most relevant science in key regulatory decisionmaking processes, at great cost to the public.

EPA is charged with making critical choices that impact human health and safety and the preservation of our environment. This unlawful, unauthorized, ill-conceived, and overwhelmingly vague rule would make sweeping changes to the way EPA makes those choices with barely any thought to the incredibly complex regulatory, scientific, and privacy issues implicated.

Congress has articulated, in various ways and in various statutes, its intention for EPA to use the highest-quality scientific information to inform the agency's work. The Proposed Rule, both in its original form and with the SNPRM's revisions, would purport to require the agency to disregard Congress's text and intent by imposing requirements at odds with scientific decisionmaking principles. Moreover, these decisions are simply too important to be made

without the benefit of the best information science has to offer. EPA's proposed justifications cannot, as a matter or law or policy, support this effort to undermine its mission. We therefore urge EPA to withdraw the Proposed Rule.

Sincerely,[8]

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