Harvard Law School
Emmett Environmental
Law & Policy Clinic

6 Everett Street, Suite 4119
Cambridge, MA 02138
617.496.2058 (tel.)
617.384.7633 (fax)

August 15, 2018

By Electronic Submission to www.regulations.gov

Acting Administrator Andrew Wheeler
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington D.C. 20460

Docket ID No. EPA-HQ-OA-2018-0259

Re: COMMENTS ON PROPOSED RULE: STRENGTHENING TRANSPARENCY IN REGULATORY SCIENCE, 83 FED. REG. 18,768 (APR. 30, 2018)

Dear Acting Administrator Wheeler:

On behalf of itself and other environmental law clinics across the country,[1] the Emmett Environmental Law & Policy Clinic at Harvard Law School (the "Clinic") respectfully submits these comments on the Proposed Rule Strengthening Transparency in Regulatory Science, 83 Fed. Reg. 18,768 (Apr. 30, 2018) (the "Proposal"). For the reasons discussed herein, we urge the Environmental Protection Agency ("EPA") to withdraw the proposed regulation, both because it is procedurally deficient and beyond the scope of EPA's authority and because, if adopted, it will undermine science-based health and environmental safeguards that are critical to the protection of public health and a strong economy.

The Proposal raises a plethora of issues. We will focus our comments on aspects of the Proposal that are directly inconsistent with the administrative and environmental laws we teach our students and undermine the protections these laws afford. In brief, our comments address EPA's:

[1] Other signatories to these comments are the Abrams Environmental Law Clinic at University of Chicago Law School, the Getches-Green Natural Resources and Environmental Law Clinic at University of Colorado Law School, the Environmental Law Clinic at Columbia University School of Law, the Environmental Law Clinic at University of Denver Sturm College of Law, the Environmental Law and Policy Clinic at Duke University School of Law, the Turner Environmental Law Clinic at Emory University School of Law, LeRoy C. Paddock, Associate Dean for Environmental Studies at George Washington University Law School, the Environmental Law and Land Use Clinic at Gonzaga University School of Law, the Environmental Law Clinic at University of Maryland Carey School of Law, the Environmental Advocacy Center at Northwestern University School of Law, the Environmental Litigation Clinic at Pace University School of Law, and the Interdisciplinary Environmental Clinic at Washington University School of Law.

- failure to follow required and customary procedures for issuing draft regulations;
- failure to demonstrate a need to change the agency's consistent interpretation over several decades of multiple statutes; and
- failure to identify any source of statutory authority for the Proposal.

Moreover, the Proposal is inconsistent with EPA's statutory obligations, would impair the ability of other federal agencies to implement their own statutory obligations to protect public health, and includes significant ambiguities that require clarification. The Proposal is not only redundant of existing laws, regulations, and policies, but is also inconsistent with and based on a misunderstanding or mischaracterization of cited authority and existing standards and practices. As discussed further herein, Congress made a deliberate decision not to establish subcategories of regulations or science tied to the availability of underlying data; this is not an oversight that EPA can write into the statutes.[2]

I. EPA Has Not Followed Required and Customary Procedures for Issuing Draft Regulations

The statutory requirements that Congress established for the process by which agencies develop regulations—while often described as "procedural" in nature—assure that agencies reach substantively valid and informed outcomes. These statutory and other rulemaking procedures were put in place for a reason; failing to follow them suggests a lack of informed analysis and, without an authorized basis for foregoing the process, an agency decision cannot be upheld. Thus, while lack of compliance with required procedures is itself a fatal flaw in the Proposal, it also undermines the basis of and credibility for the substance of the Proposal.[3] Here, the proposal violates multiple procedural requirements, including but not necessarily limited to: compliance with the Administrative Procedure Act and Paperwork Reduction Act; consultation with the Office of Management and Budget, other federal agencies, and EPA's own Science Advisory Board; and application of Executive Orders regarding the Protection of Children from

[2] *See e.g., FCC v. NextWave Personal Communications, Inc.*, 537 U.S. 293, 302 (2003) (stating that when Congress has intended to create exceptions to bankruptcy law requirements, "it has done so clearly and expressly"); *Griffith v. United States (In re Griffith)*, 206 F.3d 1389, 1394 (11th Cir. 2000) ("Applying the canons of interpretation that Congress is presumed to know the content of existing, relevant law, and that, 'where Congress knows how to say something but chooses not to, its silence is controlling,' we held that Congress must have consciously chosen not to include the language.") (internal citations omitted); *see also* ANTONIN SCALIA & BRYAN A. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 93 (2012) ("Nothing is to be added to what the text states or reasonably implies . . . . That is, a matter not covered is to be treated as not covered.").

[3] *See e.g., Horsehead Res. Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1268 (D.C. Cir. 1994) (describing the purpose of the Administrative Procedure Act notice and comment requirements as "better-informed agency decision-making" because "'[n]otice improves the quality of agency rulemaking by ensuring that agency regulations will be tested by exposure to diverse public comment'") (internal citations omitted).

Environmental Health Risks and Safety Risks, and Environmental Justice in Minority Populations and Low-Income Populations.[4]

A. Failure to Comply with the Administrative Procedure Act

Under the Administrative Procedure Act ("APA"), notices of proposed rulemakings must reference the legal authority under which the rule is proposed. 5 U.S.C. § 553(b)(2). The Federal Register notice of the Proposal fails to meet this requirement. The Proposal cites provisions from several statutes, but does not explain how any of those provisions provide authority for the Proposal. Even if relevant authority could be found somewhere in the statutes, the APA does not countenance placing the burden on the public to search for it.[5]

Notices of proposed rulemakings must also include "the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C. § 553(b)(3). The purpose of this requirement is to "provide sufficient factual detail and rationale for the rule to permit interested parties to comment meaningfully." *Honeywell International, Inc. v. EPA*, 372 F.3d 441, 445 (D.C. Cir. 2004). The Federal Register notice of the Proposal fails to meet this requirement. It is too vague to allow for fully meaningful and targeted comments. For example, the purported need and objective of the Proposal is couched in references to "transparency" and "validation" but these terms are not defined in the Proposal, nor do they have a single definition amongst professionals in the fields impacted by the Proposal.[6] The Proposal also improperly uses distinct concepts, such as "reproducibility" and "replicability," as though they are interchangeable.

The notice similarly presents key issues beyond definitions at only broad stroke levels, raising issues in such a general manner that it fails to provide the public with adequate notice of what EPA intends. For instance:

- The Proposal requires that certain data and models be made "publicly available in a manner sufficient for independent validation," and indicates that information will satisfy this standard when "it includes the information necessary for the public to understand, assess, and replicate findings." 83 Fed. Reg. at 18,773-74. But it is not clear what degree of availability or explanation would satisfy the Proposal. For example, the "public"

[4] But for many requests from members of the public and organizations, EPA would have also violated statutory requirements for a public hearing and federal norms for reasonable public comment periods.

[5] *See* U.S. Dep't of Justice, *Attorney General's Manual on the Administrative Procedure Act* 29 (1947) ("[T]he reference [to legal authority] must be sufficiently precise to apprise interested persons of the agency's legal authority to issue the proposed rule.").

[6] For a detailed explanation of this point, see the separate comment letter submitted by the Emmett Environmental Law & Policy Clinic on August 7, 2018 on behalf of the President of Harvard University, the Presidents and a number of Department Chairs and Chiefs of four of the world's foremost research and teaching hospitals (Beth Israel Deaconess Medical Center, Brigham and Women's Hospital, Massachusetts Eye and Ear, and Massachusetts General Hospital), the Deans of Harvard's T.H. Chan School of Public Health and Harvard Medical School, preeminent faculty at the Harvard T.H. Chan School of Public Health, the Harvard Medical School, and the Harvard School of Engineering and Applied Sciences, and numerous esteemed research and clinical doctors affiliated with Harvard and its research hospitals [hereinafter "the Harvard Letter"].

referenced in the Proposal could be scientists trained in the relevant field or members of the general public.

- The Proposal provides that, "where necessary, data would be made available subject to access and use restrictions." *Id.* What this process would look like is not addressed in the Proposal or discussed at all in the preamble. This leaves significant open questions, such as who will pay for and implement these restrictions and who will decide which people are allowed to access the data and under what standards.

- The Proposal appears to require EPA to conduct independent peer review of all "pivotal regulatory science," but provides no detail as to what this means or how it will be implemented. *Id.* For example, it is unclear who within the agency would perform this peer review, when it would occur, and whether (and when) prior peer review in the journal publication process would serve as a substitute for EPA peer review.

- The Proposal includes an exemption mechanism but does not provide information about the process or conditions under which exemptions shall or can be sought and granted.

Given these and other ambiguities, the public cannot adequately assess what EPA thinks the Proposal means or how it will implement it. Nevertheless, for purposes of these comments, we assume EPA intends a broad interpretation that would preclude a swath of scientific studies and information from use and consideration in regulatory proceedings.

Moreover, many of the sources cited in the Proposal either do not support the text of the proposed regulation, do not support the proposition for which they are cited, or are so broad that the public does not have fair notice of, and therefore cannot evaluate, EPA's rationale for the Proposal. For example, EPA asserts that it considered policies or recommendations of third party organizations that advocate for open science. The Proposal, however, does not cite specific policies or recommendations, instead merely listing the names of institutions. 83 Fed. Reg. at 18,770 & n.9. Even when a specific report is referenced, such as the National Academies' reports on *Improving Access to and Confidentiality of Research Data*, *Expanding Access to Research Data*, and *Access to Research Data in the 21st Century*, the Proposal fails to cite the specific sections EPA purportedly considered or relied upon or the specific policies embodied in these reports that are allegedly advanced by the Proposal. *Id.* at 18,770 n.10. Other references are similarly vague.

The overall lack of clarity is illustrated by EPA's own solicitation of feedback; it covers so wide a range of issues—posing over two dozen questions—that it makes clear EPA has not identified a proposed path forward on which the public can comment.[7] The Proposal would be more appropriately posited as an Advanced Notice of Proposed Rulemaking; it does not meet the APA's standards for proposed rules.

[7] *See e.g.*, *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 449 (3d Cir. 2011) ("'[A]n agency proposing informal rulemaking has an obligation to make its views known to the public in a concrete and focused form so as to make criticism or formulation of alternatives possible.'") (internal citations omitted).

B. Failure to Provide for Meaningful Review or Seek Input from the Office of Management and Budget, Other Federal Agencies, or EPA's Own Scientific Advisory Boards

Given the complexity and potentially broad-reaching impact of the Proposal, the limited time allotted for review of the Proposal by the Office of Management and Budget's ("OMB") Office of Information and Regulatory Affairs ("OIRA") suggests that the process was intended to be *pro forma* as opposed to meaningful.[8] Yet, despite this truncated review, the Proposal was changed significantly during this period. To the extent that any of those changes were made by OIRA, it would have exceeded the office's authority under Executive Order 12,866, which charges OIRA with conducting cost benefit analyses, not changing the substantive content of agencies' regulations. To the extent the changes were made by EPA, it is unclear on what version of the proposal OIRA conducted a cost benefit analysis and whether the version of the Proposal released to the public was reviewed by OIRA. Furthermore, as reported by Greenwire, former EPA Administrator Pruitt signed the Proposal *before* OIRA even completed its review; raising further doubt about the opportunity for any meaningful review by the OMB.[9] These concerns are addressed in greater detail by the Union of Concerned Scientists in a blog post from May 7, 2018.[10]

EPA is also supposed to provide OIRA, and the public, an "assessment" and the "underlying analysis" of the anticipated benefits and costs of the proposal. E.O. 12,866, § 6(a)(3)(B)-(C), (E)(i). Yet the Proposal contains no serious attempt at assessing either. With respect to benefits, the Proposal contains a single sentence, stating that it will improve "the scientific quality of the Agency's actions and facilitate expanded data sharing and exploration of key data sets." 83 Fed. Reg. at 18,772. This assertion is questionable at best[11] and presented without any underlying analysis. Regarding costs, the Proposal does not attempt an independent assessment, indicating only that "[t]his action should be implemented in a cost-effective way" and referencing an analysis by the Mercatus Center. *Id.* However, a Congressional Budget Office ("CBO") analysis of a similar legislative proposal concluded that it could cost hundreds of millions of dollars a year; the Proposal does not address or distinguish this analysis.[12] EPA did not provide

[8] Pursuant to Executive Order 12,866, agencies must submit proposals for "significant regulatory actions" to OIRA before publication in the Federal Register. OIRA's review can take as long as 90 days; the average review time for the 41 rules that EPA sent to OIRA from the beginning of the current Administration to the submission of the Proposal was 52 days; a significant contrast to the 5 day review period for the Proposal. *See* Genna Reed, *What Happened During the Hasty White House Review of EPA's Science Restriction Rule?*, UNION OF CONCERNED SCIENTISTS (May 7, 2018), https://blog.ucsusa.org/genna-reed/what-happened-during-the-hasty-white-house-review-of-epas-science-restriction-rule.

[9] *See* Sean Reilly, *Pruitt Signed "Secret Science" Plan Before OMB Ended Review*, E&E NEWS/GREENWIRE (Apr. 26, 2018), https://www.eenews.net/stories/1060080209.

[10] Reed, *supra* note 8.

[11] *See* the Harvard Letter, *supra* note 6.

[12] Congressional Budget Office, *Cost Estimate: H.R. 1030, Secret Science Reform Act of 2015*, at 2 (Mar. 11, 2015), https://www.cbo.gov/sites/default/files/114th-congress-2015-2016/costestimate/hr1030.pdf.

OIRA, and has not provided the public, with sufficient information for an analysis of the Proposal's benefits and costs.

Similar questions exist as to whether EPA solicited sufficient, if any, interagency review of the Proposal. For example, the Proposal cites the rulemaking provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") as a source of authority; this provision requires EPA to seek comments from the Secretary of Agriculture and the FIFRA Scientific Advisory Panel on draft regulations. 7 U.S.C. § 136w. EPA did not seek such input prior to publication of the Proposal. Such interagency review would be particularly important with respect to other agencies whose work could be impacted by the Proposal (see discussion in Section V below).

EPA's own Science Advisory Board ("SAB"), which Congress created in 1978 to provide scientific advice to EPA, 42 U.S.C. § 4365(a), challenged EPA's failure to solicit SAB's input on the Proposal—pointing out that it was not even aware of the Proposal until it was published in the *Federal Register* and discussed in news articles.[13] Given that EPA should have provided the Proposal to another federal agency to review, EPA was also required to make the Proposal available to the SAB, along with any relevant scientific and technical information on which the Proposal was based. 42 U.S.C. § 4365(c). A SAB Work Group concluded that the Proposal deals with a "myriad of scientific issues for which the Agency should seek expert advice from the Science Advisory Board," explaining that:

- "There are . . . sensitive situations where public access may infringe on legitimate confidentiality and privacy interests, and where exceptions from complete public access may be appropriate. In addition, there are considerations associated with the cost and effort that would be involved in making large and complex existing datasets available."

- "[T]he precise design of the rule appears to have been developed without a public process for soliciting input from the scientific community. Nor does the preamble to the rule describe precisely how the proposal builds on previous efforts to promote transparency such as the Information Quality Act and EPA's Information Quality Guidelines."

- "The proposed rule does not include any assessment of the impact of data restrictions on existing or future regulatory programs. . . . Furthermore, the rule could have the effect of removing legal, ethical, and peer-reviewed studies of health effects as sources to support the agency's regulatory efforts."[14]

[13] Memorandum from Alison Cullen, Chair, SAB Work Group on EPA Planned Actions for SAB Consideration of the Underlying Science, to Members of the Chartered SAB and SAB Liaisons, regarding Preparations for Chartered Science Advisory Board (SAB) Discussions of Proposed Rule: Strengthening Transparency in Regulatory Science RIN (2080-AA14) (May 12, 2018), https://yosemite.epa.gov/sab/sabproduct.nsf/E21FFAE956B548258525828C00808BB7/$File/WkGrp_memo_2080-AA14_final_05132018.pdf [hereinafter "SAB May 12, 2018 memorandum"].

[14] SAB May 12, 2018 memorandum, *supra* note 13; *see also* Letter from Dr. Michael Honeycutt, Chair, Science Advisory Board, to Scott Pruitt, Administrator, EPA, regarding Science Advisory Board Consideration of EPA Proposed Rule: Strengthening Transparency in Regulatory Science (June 28, 2018) (urging EPA to "request, receive, and review scientific advice from the SAB before revising the proposed rule"),

Even when EPA is not required to seek SAB's opinion,[15] failing to utilize SAB's expertise is inconsistent with the purpose of SAB, which is to "to provide independent advice and peer review to EPA's Administrator on the scientific and technical aspects of environmental issues."[16] The SAB's expertise and input is similarly valuable to the public, and should be available well before the end of the public comment period so as to inform discussion.

C. Failure to Address Impacts under the Paperwork Reduction Act

The Paperwork Reduction Act ("PRA") requires OMB to review federal rules that impose information collection requirements on "persons," including individuals and corporations. 44 U.S.C. § 3502(10). Such collection of information includes "obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or for an agency, regardless of form or format" through the use of "reporting or recordkeeping requirements." 44 U.S.C. § 3502(3)(A)(i). Although EPA asserts that the Proposal is not subject to the PRA, perhaps because it does not include an explicit reference to information collection, the Proposal would create new reporting requirements that would apply to multiple "persons."[17] Specifically, for science to be considered in certain regulatory proceedings, someone (whether the person conducting the science, preparing a report, or utilizing data) would have to "clean" confidential data so that it can be made public. Such reporting and recordkeeping procedures are costly and, in some instances, inconsistent with other federal policies governing information use and dissemination.[18] This aspect of the Proposal must be addressed by OMB as required by the PRA.

D. Failure to Appropriately Interpret and Apply Executive Orders Applicable to Rulemaking Proceedings

Executive Order 13,045: Protection of Children from Environmental Health Risks and Safety Risks, directs agencies to "make it a high priority to identify and assess environmental health risks and safety risks that may disproportionately affect children." Exec. Order No. 13,045, 62 Fed. Reg. 19,885, at § 1-101(a)-(b) (1997). Agencies proposing regulatory actions subject to Executive Order 13,045 must develop, and provide to OIRA, (a) an evaluation of the environmental health or safety effects of the planned regulation on children; and (b) an explanation of why the planned regulation is preferable to other potentially effective and

https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/4ECB44CA28936083852582BB004ADE54/$File/EPA-SAB-18-003+Unsigned.pdf.

[15] When EPA provides any proposed criteria document, standard, limitation, or regulation to any other federal agency for formal review and comment, it must also make such proposal available to the SAB for its review. SAB in turn may provide advice and comments to EPA on the adequacy of the scientific and technical basis of a proposal. Such advice must be provided within a timeframe specified by EPA. 42 U.S.C. § 4365(c).

[16] SAB Charter ¶ 3.

[17] The Proposal would certainly apply to more than the minimum ten persons required by the PRA. *See* 44 U.S.C. § 3502(3)(A)(i).

[18] EPA stated that it would implement the Proposal "in a manner that minimizes costs," but does not discuss fundamental questions such as whose costs should be minimized or techniques for doing so. EPA, *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768, 18,774, 40 C.F.R. § 30.8 (Apr. 30, 2018).

reasonably feasible alternatives considered by the agency. *Id.* at 19,887, § 5-501(a)-(b); *see also* Exec. Order No. 12,866, 58 Fed. Reg. 51,735 (1993) (describing which regulatory actions must be submitted to OIRA). Covered regulatory actions include those that are likely to be "economically significant" under Executive Order 12,866 and concern "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children." 62 Fed. Reg. at 19,885, § 2-202(a)-(b).

The Proposal would affect risk assessment analyses across a variety of environmental statutes. Studies that in the past informed regulations that address public health risks with disproportionate effects on young children, such as asthma from exposure to particulate matter and neurological damage from exposure to lead, could be precluded from consideration today by the Proposal. And, according to EPA, the Proposal is "intended to apply prospectively to final regulations that are determined to be 'significant regulatory actions' pursuant to E.O. 12866."[19] Thus, the Proposal itself should be construed as an action subject to the review requirements of Executive Order 13,045. This would not present a double-bite at the apple in terms of review under Executive Order 13,045; rather it presents the only meaningful opportunity to consider the impact of the Proposal on the protection of children. Once the Proposal is adopted, it would preclude the use of certain science, so any analysis of feasible alternatives under Executive Order 13,045 would already be limited in a way that precludes consideration of the impacts of the Proposal.

EPA's characterization of the Proposal as not establishing any environmental health or safety standards is similarly flawed with respect to determining application of Executive Order 12,898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, which requires agencies to identify and address "disproportionately high and adverse human health or environmental effects" of their programs, policies and activities on minority and low-income populations. Exec. Order No. 12,898, 59 Fed. Reg. 7,629, at § 1-101 (1994). EPA has not addressed how the Proposal would affect the agency's fulfillment of the human health and environmental data collection and analysis obligations imposed by this Executive Order. *Id.* at 7,631, § 3-302.

II. EPA Has Not Demonstrated a Need for the Proposal, which Changes Decades of Agency Interpretation of Numerous Statutes

EPA has been implementing environmental statutes, including via regulatory determinations designed to protect public health, since its inception in 1970. Prior to the Proposal, release of raw data has not been a criterion that EPA used for determining what counted as the "best available" science in reports, studies, analyses, or models. Yet, in this proceeding, EPA has not pointed to a single regulatory action over the thousands it has implemented that was based on faulty science and that this Proposal would remedy. Historically, EPA has stated that a review of raw data would be warranted "[o]nly in extreme cases—for example where there are credible allegations of fraud, abuse or misconduct."[20] As discussed further herein, EPA has advocated

[19] *Id.* at 18,771.

[20] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (Jul. 18, 1997).

this position in court proceedings. This Proposal seems to be a solution in search of a problem that changes existing agency statutory interpretations and policies without an explanation of need.[21]

Transparency is a valuable and important goal, but as used in the Proposal is a guise for excluding large bodies of valid and best available science. When it comes to its own research, EPA "strives to increase access to its research results" but recognizes that, "[w]hether research data are fully available to the public or available to researchers through other means does not affect the validity of the scientific conclusions from peer-reviewed research publications."[22] EPA has not explained why existing federal and professional rules, standards, and policies, many of which promote the objective of transparency, cannot be used to attain the purported objective of the Proposal. A few examples of relevant laws, regulations and guidance at the federal level that advance transparency-related goals, and make the Proposal redundant, include:

- The Information Quality Act: enacted in 2000 to improve the "integrity, quality, and utility" of data released by the Federal Government,[23] directs OMB to provide "policy and procedural guidance" to "ensur[e] and maximiz[e] the quality, objectivity, utility, and integrity of information . . . disseminated by Federal agencies."[24] OMB thus issued such guidelines to be emulated by other agencies.[25] In response, EPA issued its own guidelines to provide public access to information.[26] EPA's guidance directs that "influential scientific, financial, or statistical information" should be held to a higher degree of quality and transparency standards.[27] EPA clarifies that "if access to data and methods cannot occur due to compelling interests such as privacy, trade secrets, intellectual property, and other confidentiality protections, EPA should, to the extent

[21] As described by the Third Circuit, this lack of information is inconsistent with the requirements of the APA. *Prometheus Radio Project v. F.C.C.*, 652 F.3d 431, 449 (3d Cir. 2011) ("[T]he notice required by the APA … must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based.") (internal citations omitted); *see also Lal v. INS*, 255 F.3d 998, 1008-09 (9th Cir. 2001) (invalidating an agency interpretation of a regulation because agency changed course from its settled policies).

[22] EPA, *Plan to Increase Access to Results of EPA-Funded Scientific Research*, at 4-5 (2016), https://www.epa.gov/sites/production/files/2016-12/documents/epascientificresearchtransperancyplan.pdf.

[23] 44 U.S.C. § 3501(9).

[24] *Id.* § 3516 (note); Consolidated Appropriations Act of 2001, 106 P.L. 554, Title V, § 515 (2000).

[25] *See* OMB, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies*, 67 Fed. Reg. 8,452 (Feb. 22, 2002).

[26] EPA, *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency* 3 (Oct. 2002), https://www.epa.gov/sites/production/files/2017-03/documents/epa-info-quality-guidelines.pdf. EPA's guidelines apply to "information" the agency disseminates to the public. *Id.* at 15. The guidelines define "information" as "generally includ[ing] any communication or representation of knowledge such as facts or data, in any medium or form." *Id.* Not all web content is considered "information" under the guidelines. *Id.* For example, "certain information from outside sources that is not adopted, endorsed, or used by EPA to support an Agency decision or position" is not covered under these directives. *Id.*

[27] *Id.* at 20-21.

practicable, apply especially rigorous robustness checks to analytic results and carefully document all checks that were undertaken."[28]

- Under OMB Circular A-110, which has now been incorporated into the Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards, "research data" generated pursuant to federal grants to, or agreements with, institutions of higher education, hospitals, and other nonprofit organization, should be disclosed in response to Freedom of Information Act ("FOIA") requests. The Guidance defines "research data" in part as "recorded factual material commonly accepted in the scientific community as necessary to validate research findings," but exempts from disclosure any "medical information and similar information the disclosure of which would constitute a clearly unwarranted invasion of personal privacy, such as information that could be used to identify a particular person in a research study."[29]

- Memorandum for the Heads of Executive Departments and Agencies on Scientific Integrity (2009): provides that "[e]xcept for information that is properly restricted from disclosure under procedures established in accordance with statute, regulation, Executive Order, or Presidential Memorandum, each agency should make available to the public the scientific or technological findings or conclusions considered or relied on in policy decisions."[30]

Where EPA alleges that the Proposal is consistent with the focus on transparency in these and other laws, regulations, and policies, the agency is really conflating standards of quality with public dissemination of data. For example, the OMB Guidelines Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information provide that "[t]he more important the information, the higher the quality standards to which it should be held," but notes that "confidentiality concerns will sometimes preclude public access as an approach to reproducibility." 67 Fed. Reg. 8452, 8452 & 8456 (Feb. 22, 2002). However, rather than recommend foregoing the use of the information based on confidential information, OMB provides agencies mechanisms for validating information when data are not available. *Id.* at 8456-57.

The Proposal also ignores, or presents no argument for rejecting, scientific practices embodied in the host of nongovernmental methods and best practices established and adhered to by the research community to ensure the transparency, objectivity, and validity of studies, analyses,

[28] *Id.* at 21.

[29] OMB, *Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards*, 78 Fed. Reg. 78,590, at 78,631, 2 C.F.R. § 200.315(e)(3) (Dec. 26, 2013) (guidance incorporated from OMB, *OMB Circular A–110, Uniform Administrative Requirements for Grants and Agreements With Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations* § 36(d) (as amended Sept. 30,1999) [hereinafter "OMB, *OMB Circular A-110*"]) [hereinafter "OMB, *Uniform Administrative Requirements*"].

[30] The White House, Office of the Press Secretary, *Memorandum for the Heads of Executive Departments and Agencies 3-9-09*, at § 1(d) (Mar. 9, 2009), https://obamawhitehouse.archives.gov/the-press-office/memorandum-heads-executive-departments-and-agencies-3-9-09.

models, and reports, including by reproduction and/or replication where appropriate.[31] Nor does EPA explain why the Proposal is preferable to existing recommendations and methods vetted and supported by the scientific community, which endeavor to promote transparency through open science policies and secure data-sharing systems.[32]

EPA has also failed to adequately recognize or explain its change of position, highlighting the arbitrariness of the Proposal. EPA has historically defended the agency's ability to rely on studies for which the raw data had not been publicly available. For example, in the context of setting National Ambient Air Quality Standards ("NAAQS") standards, EPA noted that, except in extreme cases, it "does not generally undertake evaluations of raw, unanalyzed scientific data as part of its public health standard setting process" as it would be "impractical and unnecessary for EPA to review underlying data for every study upon which it relies as support for every proposed rule or standard."[33]

The D.C. Circuit Court agreed with EPA's position in *American Trucking Associations, Inc. v. E.P.A.*, 283 F.3d 355, 372 (D.C. Cir. 2002) and reiterated this holding six years later in a challenge to the 2008 lead NAAQS in which litigants sought access to the raw data underlying a study about lead exposure and children's intellectual function. *Coal. of Battery Recyclers Ass'n v. E.P.A.*, 604 F.3d 613, 623 (D.C. Cir. 2010) (explaining that EPA is entitled to rely on published study results where, as is often the case, "raw data is . . . unavailable due to proprietary interests of a study's scientific investigators or confidentiality agreements with study participants").

While agencies have some leeway in changing existing policies, they must provide or display "a reasoned explanation for the change," "awareness that [they are] changing position," and "good reasons for the new policy;" "an unexplained inconsistency in agency policy is a reason for holding an interpretation to be an arbitrary and capricious change from agency practice." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125–26 (2016) (citations and internal quotation marks omitted).

Importantly, as discussed further herein, EPA has not even considered the impacts of the Proposal on its ability to perform its statutory duties; on the ability of other agencies to perform their statutory duties; on existing regulations and judicial precedent; or on the health of the American public.

Given the lack of demonstrated need, or consideration of consequences, cutting off use of a broad swath of historically accepted science is an outsized and irrational solution to a speculative

[31] Existing tools to ensure the rigor, quality, and validity of research include peer review, detailed public methodologies, and corroboration of results by subsequent studies. These issues are further discussed in the Harvard Letter, *supra* note 6.

[32] *See id.*

[33] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (Jul. 18, 1997).

concern. As written, EPA's approach is akin to using a sledgehammer on a small nail, before even confirming that there is a nail.[34]

III. EPA Does Not Have Authority to Promulgate the Proposal: The Statutes Administered by EPA Do Not Provide for the Creation of a New Category of Regulations or Science

"[I]t is 'axiomatic' that 'administrative agencies may act only pursuant to authority delegated to them by Congress.'" *Clean Air Council v. EPA*, 862 F.3d 1, 9 (D.C. Cir. 2017). Multiple statutes administered by EPA direct the agency to consider and utilize science. While the type of science to be considered, *e.g.*, best science or best available science, and the process for considering science, *e.g.*, as one of multiple, discrete factors or as part of broader balancing analyses, varies across statutes, nowhere do these statutes suggest that "best" science is limited to that for which associated raw data is available to the public.[35] Courts have concurred. *See, e.g.*, *American Trucking Ass'n v. EPA*, 283 F.3d 355, 372 (D.C. Cir. 2002) (finding that the Clean Air Act imposes no requirement for EPA to "obtain and publicize the data underlying published studies on which the Agency relies" and that "requiring agencies to obtain and publicize the data underlying all studies on which they rely 'would be impractical and unnecessary.'") (internal citations omitted). The EPA may not read into a statute a requirement that makes its implementation impractical.[36]

Nor do the statutes administered by EPA have a concept akin to the Proposal's "pivotal regulatory science." EPA is now attempting to re-interpret multiple statutes with virtually no analysis. Such reinterpretation would read new requirements into well-established statutes decades after their passage in a manner inconsistent with EPA's historic positions. If Congress had intended to create additional subcategories of regulations or science as suggested by the Proposal, it would have done so.

The Proposal's creation of a new category of regulation, "regulatory decisions," and new categories of science—"pivotal regulatory science" and "regulatory science"—rely on factors that Congress did not authorize or intend EPA to consider. When Congress wanted to place additional emphasis on certain types of or access to science it did so;[37] not establishing

[34] This is not to suggest that scientists and others should not continue to do everything they can to make studies accessible and transparent, or that EPA should not encourage that behavior. But there are already many mechanisms in place within government, academia, professional organizations, and more, to promote these objectives.

[35] This is not surprising given that, as an initial matter, releasing underlying data will generally not improve the quality of resulting reports, studies, or analyses, and therefore will not do anything to render any individual study "better." *But cf.* note 42.

[36] *See, e.g.*, SCALIA & GARNER, *supra* note 2, at 63 ("A textually permissible interpretation that furthers rather than obstructs the document's purpose should be favored.").

[37] *See, e.g.*, notes 44 & 45.

subcategories of regulations or science tied to the availability of underlying data was a deliberate decision by Congress, not an oversight that EPA can write-in to the statutes.[38]

Hence, the Proposal would change EPA's interpretation of multiple statutes that govern the agency's consideration and use of science by creating new subcategories of science and regulations. None of the statutes referenced by EPA support the Proposal's suggestion to redefine regulations or science, much less require EPA to pursue the course it has proposed.

IV. The Proposal Is Inconsistent with EPA's Statutory Obligations and Conflicts with other Applicable Federal Requirements

The Proposal would prevent EPA from relying on the best available information in discharging its duties. EPA is charged with developing regulations that provide societal benefits by reducing harm to human health and the environment from the presence of chemicals in air, soil, drinking water, food, and consumer products. The Proposal implicates research that is central to making such determinations; creating an obstacle to the consideration of such science is contrary to both primary statutory directives and requirements to conduct cost benefit analyses. Likewise, EPA fails to address how it could implement a regulation that is inconsistent with federal requirements and standards governing the use of science across agencies.[39]

A. Statutory Requirements to Develop Health Based Standards and Conduct Cost-Benefit Analyses

EPA acknowledges that it must use the "best available science" in all of its regulatory actions.[40] This directive is embodied in multiple statutes implemented by EPA and is reflected in other environmental statutes, further illustrating Congress' conceptualization of "best" available science. Broadly speaking, there are three basic types of statutory requirements that the EPA and other agencies consider scientific information. First, there are requirements that the agency consider the "best available science." Second, there are requirements that the agency consider particular factors, including scientific factors. Third, there are requirements that the agency balance economic costs or technological feasibility against public health, environmental, or other benefits that must be scientifically assessed. The precise terminology regarding the required use of science may, as illustrated below, vary across statutes, but what these provisions have in common are requirements for EPA and other agencies to use scientific information that is "best," not simply adequate, and "available."

[38] *See supra* note 2.

[39] Moreover, as discussed herein, the Proposal would flip the existing default by automatically excluding the best scientific research, rather than admitting science and then deciding if circumstances exist that warrant excluding a study. The status quo makes more sense than creating a blanket preclusion of valid studies and then allowing their use only by going through a timely and expensive exemption process.

[40] EPA, *Strengthening Transparency in Regulatory Science*, 83 Fed. Reg. 18,768, 18,769 (Apr. 30, 2018) (citing Exec. Order No. 13,563, 76 Fed. Reg. 8,321 (Jan. 21, 2011)).

Table 1: Examples of Statutory Directives regarding Use of Science by EPA and other Agencies

Statute	Provision	Scientific and Technical Requirements
Safe Drinking Water Act	42 U.S.C § 300g-1(b)(3)(A)	EPA must use "[t]he **best available, peer-reviewed science and supporting studies** conducted in accordance with sound and objective scientific practices," and "[d]ata collected by accepted methods or best available methods (if the reliability of the method and the nature of the excision justifies use of the data)."
	42 U.S.C. § 300g-1(b)(1)(b)(ii)	EPA must use "**best available public health information**" in determining whether to regulate contaminants.
Clean Water Act	33 U.S.C. § 1321(a)(27)	Some provisions dealing with oil and hazardous substances on the Gulf Coast require "**best available science**."
Toxic Substances Control Act	15 U.S.C. § 2625(h)	"In carrying out sections 2603, 2604, and 2605 of this title, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the **best available science**".
Magnuson–Stevens Fishery Conservation and Management Act	16 U.S.C. § 1851(a)(2)	"Conservation and management measures shall be based upon the **best scientific information available**."
Endangered Species Act	16 U.S.C. § 1536(a)(2)	In consultation to ensure no jeopardy to endangered or threatened species, "each agency shall use the **best scientific and commercial data available**."
	16 U.S.C. § 1536(c)(1)	Advice that an endangered or threatened species may be present in a location should be "based on the **best scientific and commercial data available**."
	16 U.S.C. § 1536(h)(2)(b)(i)16 U.S.C. § 1533(b)(1)(A)	Permanent exceptions shall be given to prevent extinction of species "based on the **best scientific and commercial data available**." The Secretary must determine whether a species is a threatened or endangered based upon "the

		best scientific and commercial data available."
Marine Mammal Protection Act	16 U.S.C. § 1371(a)(4)(C)	"If the Secretary determines, using the **best scientific information available**, that certain forms of deterrence have a significant adverse effect on marine mammals, the Secretary may prohibit such deterrent methods, after notice and opportunity for public comment, through regulation under this chapter."
	16 U.S.C. § 1371(a)(3)(A)	The decision to waive the ban on taking must be based on the "**best scientific evidence available** and in consultation with the Marine Mammal Commission."

None of these statutory provisions link the concept of the "best available science" to the availability of underlying raw data, nor can such a limitation be read into the statutes. Where Congress wanted to direct EPA's decision regarding what science to consider or how—it did so.[41] When Congress wanted to link "best available science" to data being publicly available—it did so.[42] Thus, if Congress had wanted to put a blanket limitation on EPA's consideration of science for which underlying data is not publicly available, it clearly knew how to do so—and it chose not to.

As EPA has previously explained, the agency would be unable to fulfill statutory mandates if it could not consider studies that follow federal laws and ethical standards regarding the privacy of patient and individual data:

[41] *See, e.g.*, Toxic Substances Control Act, 15 U.S.C. § 2625(h) (directing EPA to consider, as applicable, the following factors: "(1) the extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) the extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) the extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models"); *see also* Comprehensive Environmental Response, Compensation, and Liability Act, 42 U.S.C. § 9604(i)(10) and (13) (providing that the Agency for Toxic Substances and Disease Registry give EPA specified data and information for review biennially and requiring that "[a]ll studies and results of research conducted under this subsection (other than health assessments) shall be reported or adopted only after appropriate peer review").

[42] *See, e.g.*, Clean Water Act, 33 U.S.C. § 1321(a)(27) (defining "best available science" in the context of natural resource protection and restoration projects on the Gulf Coast as science that:

> "(A) maximizes the quality, objectivity, and integrity of information, including statistical information;
> (B) uses peer-reviewed and publicly available data; and
> (C) clearly documents and communicates risks and uncertainties in the scientific basis for such projects")

> If EPA and other governmental agencies could not rely on published studies without conducting an independent analysis of the enormous volume of raw data underlying them, then much plainly relevant scientific information would become unavailable to EPA for use in setting standards to protect public health and the environment. . . . [S]uch data are often the property of scientific investigators and are often not readily available because of the proprietary interests of the investigators or because of arrangements made to maintain confidentiality regarding personal health status and lifestyle information of individuals included in such data. Without provisions of confidentiality, the possibility of conducting such studies could be severely compromised.[43]

Examples of EPA statutory mandates that could be impeded by the Proposal include (i) the development of standards to control emissions from burning hazardous waste fuels under the Resource Conservation and Recovery Act ("RCRA") "as may be necessary to protect human health and the environment," 42 U.S.C. § 6924(q)(1); and (ii) determinations of whether hazardous sites need to be placed on the Comprehensive Environmental Response, Compensation, and Liability Act's ("CERCLA") National Priorities List. With respect to the latter, CERCLA provides that, if a health assessment indicates that a release or threatened release may pose a serious threat to human health, the Administrator of the Agency for Toxic Substances and Disease Registry ("ATSDR") shall "notify the Administrator of EPA who shall promptly evaluate such release or threatened release in accordance with the hazard ranking system . . . to determine whether the site shall be placed on the National Priorities List." 42 U.S.C. § 9604 (i)(6)(H). As referenced in footnote 41, health assessments provided by ATSDR to EPA on a scheduled basis are exempt from peer review as a prerequisite to submission.

The Proposal would also cut EPA off from information needed to complete the cost-benefit analysis of regulations required under certain statutes and government-wide requirements.[44]

Not only would the Proposal impede EPA's fulfillment of its statutory duties, it would also be contrary to judicial precedent, which holds that "best available science" includes "all existing scientific evidence relevant to the [agency] decision [in question]." *Ecology Ctr., Inc. v. U.S. Forest Serv.*, 451 F.3d 1183, 1194 n.4 (10th Cir. 2006) (*quoting Heartwood, Inc. v. U.S. Forest*

[43] National Ambient Air Quality Standards for Particulate Matter, 62 Fed. Reg. 38,652, 38,689 (Jul. 18, 1997).

[44] *See, e.g.*, Exec. Order No. 13,783, 82. Fed. Reg. 16,093 (Mar. 31, 2017) ("It is also the policy of the United States that necessary and appropriate environmental regulations . . . are of greater benefit than cost, when permissible, . . . and are developed through transparent processes that employ the best available peer-reviewed science and economics."); *see also* 42 U.S.C. § 7411(a)(1) (CAA provision requiring EPA to consider costs when establishing performance standards for new stationary sources of pollution); 42 U.S.C. § 7412(n)(1)(A) (CAA provision directing EPA to regulate power plants if such regulation is "appropriate and necessary," which includes consideration of costs); 42 U.S.C. § 300g–1(b)(3)(C) (SDWA provision establishing requirements for health risk reduction and cost analysis under which quantifiable and non-quantifiable benefits of a proposed rule must be measured against its cost); 15 U.S.C. § 2605(c)(2)(A)(iv) (TSCA provision requiring EPA to consider "the reasonably ascertainable economic consequences" of a proposed rule).

Serv., 380 F.3d 428, 436 (8th Cir. 2004)). While agencies need not produce new evidence,[45] they must seek out information and "'***cannot ignore existing data***.'" *Id.* (emphasis added). Even if an agency is anticipating the arrival of better evidence, it must act on the basis of the evidence it currently has.[46]

Many of the fundamental public health studies on which EPA has based key rules and standards under the statutes are studies for which the raw data was not or could not have been released. Nonetheless these studies have been examined and validated,[47] as will future studies. Arbitrarily cutting off consideration of a category of science is inconsistent with EPA's statutory obligations.[48]

B. Conflict with Other Federal Standards

EPA has not demonstrated authority to adopt regulations that conflict with federal statutes and standards that apply across federal agencies. For example: OMB Circular A-110, and its superseding guidance, are applicable to all Federal agencies unless a *statute* "specifically prescribes policies or specific requirements that differ from the standards provided herein, the provisions of the statute shall govern."[49] As discussed above, OMB Guidance defines "research data" subject to public disclosure differently than the Proposal, in such a way that the Proposal would constrain use of science endorsed by the policy. There is no provision for a single agency to change applicability of OMB Guidance, or redefine its terms, via regulations.[50]

V. The Proposal Would Impair the Ability of Other Federal Agencies to Implement Their Statutory Requirements

The Proposal would also impair the ability of other federal agencies to discharge their own statutory obligations and report data and findings to EPA. For example, in order for the

---

[45] *See Friends of Blackwater v. Salazar*, 691 F.3d 428, 435 (D.C. Cir. 2012) (quoting *Sw. Ctr. for Biological Diversity v. Babbitt*, 215 F.3d 58, 60 (D.C. Cir. 2000)) ("[U]nder the 'best ... data available' standard, 'the Secretary has no obligation to conduct independent studies.'").

[46] *See, e.g., San Luis & Delta-Mendota Water Auth. v. Jewell*, 747 F.3d 581, 630 (9th Cir. 2014) ("[T]he fact that science must advance further before the complicated ecosystem interactions in the Bay–Delta are fully understood does not necessarily mean that the Fish and Wildlife Service failed to rely on the best available science.")

[47] *See* the Harvard Letter, *supra* note 6.

[48] The Proposal is also arbitrary in suggesting that science that cannot be used in setting regulations could still be used in individual permitting decisions.

[49] *OMB Circular A-110*, *supra* note 29, at 3; *see also Uniform Administrative Requirements*, *supra* note 29, at 78,595, § 200.101 ("The guidance maintains existing language stating that this guidance does not supersede any existing or future authority under law or by executive order or the Federal Acquisition Regulation.").

[50] OMB's sign-off should not be construed as approval of a change in Circular A-110 or the guidance because that change would affect ***all*** federal agencies; EPA lacks the authority to carry out such a change. Worse, the change will create havoc for other agencies and impede their ability to implement the statutes that require them to protect public health. Examples of such agencies that could be so affected are the Food and Drug Administration, the National Institutes of Health, the Department of Agriculture, and the Occupational Safety and Health Administration.

Occupational Safety and Health Administration ("OSHA") to promulgate standards under the Occupational Safety and Health Act ("OSHA Act"), 29 U.S.C. 651 *et seq.*, the agency is required to demonstrate the existence of significant risks to employees using "best available evidence." *See* 29 U.S.C. § 655(b)(5). Currently, OSHA fulfills this obligation, in part, with information provided by EPA's TSCA Section 9(a) reports.[51] If the Proposal results in the exclusion of confidential data, then OSHA will likely be forced to either gather supplementary evidence or ignore the reports altogether. Such an outcome will not only impede OSHA in its regulatory functions, but could also burden EPA with additional responsibilities.[52]

The Proposal would similarly compromise coordination requirements and data sharing agreements between the EPA and the U.S. Department of Agriculture, the U.S. Food & Drug Administration within the U.S. Department of Health and Human Services, and ATSDR.[53] Such a blow to inter-agency information sharing would be devastating to regulatory progress throughout the federal government.

* * *

In summary, EPA has not demonstrated a need for the Proposal, which is procedurally flawed, beyond EPA's authority, and inconsistent with EPA's statutory obligations. Moreover, the Proposal would impair the ability of other federal agencies to implement their statutory

[51] EPA is required under TSCA section 9(a), 15 U.S.C. § 2608(a)(1), to report any determinations of risk from "the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture" to relevant agencies, such as OSHA, with a detailed statement of information supporting such findings. *See also Memorandum of Understanding between the Environmental Protection Agency and the Department of Labor* (Feb. 6, 1986), https://www.osha.gov/laws-regs/mou/1986-02-06.

[52] If the agency receiving a TSCA Section 9(a) report fails to issue a response within the time period specified by the report, or fails to respond to the report in the specified time period ***and*** initiate an action within 90 days of the report's publication in the Federal Register, then EPA must regulate the suspected substance under section 6(a), 15 U.S.C. § 2605(a), or take any action under section 7, 15 U.S.C. § 2606. *See* 15 U.S.C. § 2608(a)(3)-(4). Accordingly, even if OSHA makes an effort to supplement the record, it may fail to meet either the deadline mandated by the TSCA Section 9(a) report or the 90-day action deadline due to temporal, financial, and/or workforce restraints. The resulting regulatory obligations could overwhelm EPA.

[53] Multiple statutes require information sharing and coordination between EPA and other federal agencies. For example, under the Federal Insecticide, Fungicide, and Rodenticide Act, the Department of Agriculture ("USDA") is required to coordinate with EPA in the design of surveys for the collection of statistical data on the use of pesticides and related crop diseases and make available to the EPA Administrator the aggregate results of those surveys. *See* 7 U.S.C. § 136i-2. Under the Federal Food, Drug, and Cosmetic Act, the Department of Health and Human Services and USDA, in consultation with EPA, must conduct surveys to document dietary exposure to pesticides among infants and children in order to aid EPA in "establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue." 21 U.S.C. § 346a(b)(2)(C). The Proposal would also negatively impact information sharing agreements such as that between EPA and the Federal Drug Administration to share non-public information related to the "agencies' respective programs regulating substances that may be present in human food, animal food and feed, animal drugs, and cosmetics." *See Memorandum of Understanding On Information Sharing Between U.S. Environmental Protection Agency Office of Chemical Safety and Pollution Prevention and Department of Health and Human Services Food and Drug Administration Foods and Veterinary Medicine Program* (Sept. 1, 2015), https://www.fda.gov/AboutFDA/PartnershipsCollaborations/MemorandaofUnderstandingMOUs/DomesticMOUs/ucm457193.htm.

requirements and undermine the use of the best available information and science, which is critical to the protection of public health. For these and all of the reasons discussed above, the Proposal should be withdrawn.

Thank you for your attention to these comments.

BY:

Wendy B. Jacobs
Emmett Clinical Professor of Environmental Law and Director
Emmett Environmental Law & Policy Clinic
Harvard Law School
wjacobs@law.harvard.edu

Aladdine D. Joroff
Lecturer and Staff Attorney
Emmett Environmental Law & Policy Clinic
Harvard Law School
ajoroff@law.harvard.edu

On behalf of the Emmett Environmental Law & Policy Clinic and the following signatories:

Rick Eichstaedt
Adjunct Professor and Director
Environmental Law and Land Use Clinic
Gonzaga University School of Law

Mindy Goldstein
Clinical Professor of Law
Director, Turner Environmental Law Clinic
Director, Environmental and Natural Resources Law Program
Emory University School of Law

Sean M. Helle
Director and Associate Clinical Professor
Getches-Green Natural Resources and Environmental Law Clinic
University of Colorado Law School

Seema Kakade
Assistant Professor of Law and Director
Environmental Law Clinic
University of Maryland Carey School of Law

Maxine I. Lipeles
Director, Interdisciplinary Environmental Clinic
Senior Lecturer in Law
Washington University School of Law

Edward Lloyd
Evan M. Frankel Clinical Professor of Environmental Law
Director, Environmental Law Clinic
Columbia University School of Law

Nancy C. Loeb
Clinical Associate Professor of Law and Director
Environmental Advocacy Center
Northwestern University Pritzker School of Law

Kevin Lynch
Associate Professor of Law
Environmental Law Clinic
University of Denver Sturm College of Law

Michelle B. Nowlin
Clinical Professor of Law and Supervising Attorney
Environmental Law and Policy Clinic
Duke University School of Law

Todd D. Ommen
Adjunct Professor of Law and Managing Attorney
Environmental Litigation Clinic
Pace University Elisabeth Haub School of Law

LeRoy C. Paddock
Associate Dean for Environmental Studies
George Washington University Law School

Mark N. Templeton
Clinical Professor of Law and Director
Abrams Environmental Law Clinic
University of Chicago Law School